Confidentially submitted to the Securities and Exchange Commission on May 19, 2021. This revised draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM F-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Genenta Science S.r.l.[1]

(Exact name of registrant as specified in its charter)

Republic of Italy	**2836**	**Not Applicable**
(*State or other jurisdiction of incorporation or organization)*	*(Primary Standard Industrial Classification Code Number*	*(I.R.S. Employer Identification Number)*

Pierluigi Paracchi **Chief Executive Officer** **Via Olgettina No. 58** **20132 Milan, Italy** **Tel: +39-02-2643-4681**	**Cogency Global Inc.** **122 East 42nd Street, 18th Floor** **New York, New York 10168** **Tel: +1.800.221.0102**
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)	*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

Copies to:

Mitchell S. Nussbaum, Esq. **Norwood P. Beveridge, Esq.** **Loeb & Loeb LLP** **345 Park Avenue** **New York, NY 10154** **Tel: +1.212.407.4000**	**Thomas S. Levato, Esq.** **Ettore A. Santucci, Esq.** **Goodwin Procter LLP** **620 Eighth Avenue** **New York, New York 10018** **Tel: +1.212.813.8800**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date hereof.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. [ ]

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.
Emerging growth company [X]

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act. [ ]

†The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price [(1)(2)(3)]**	**Amount of registration fee [(3)]**

Ordinary shares, par value € per share, as represented by American Depositary Shares	$	$

(1) The ordinary shares will be represented by American Depositary Shares, or ADSs, each of which represents one ordinary share. A separate Registration Statement on Form F-6 (Registration No. 333-) has been filed for the registration of ADSs issuable upon deposit of the ordinary shares.
(2) Pursuant to Rule 416 under the Securities Act of 1933, as amended, or the Securities Act, the ordinary shares registered hereby also include an indeterminate number of additional ordinary shares as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.
(3) Estimated solely for purposes of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act. Includes the offering price of ordinary shares that the underwriters have the option to purchase to cover over-allotments, if any.
(4) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

[1] We intend to change the legal form of our company under Italian law from a limited liability company (società a responsabilità limitata, or S.r.l.) to a joint stock company (società per azioni, or S.p.A.) prior to the completion of this offering.

EXPLANATORY NOTE

Genenta Science S.r.l., the registrant whose name appears on the cover of this registration statement, is an Italian limited liability company (società a responsabilità limitata, or S.r.L.). Prior to the effectiveness of this registration statement, Genenta Science S.r.l. will convert into an Italian joint stock company (società per azioni, or S.p.A.) pursuant to Italian law and change its name to Genenta Science S.p.A. as described in the section "Corporate Conversion" of the prospectus. In the prospectus, we refer to our conversion to a corporation as the "Corporate Conversion." As a result of the Corporate Conversion, the holders of the different classes of equity, or quotas, of Genenta Science S.r.l. will become holders of ordinary shares of Genenta Science S.p.A. Except as disclosed in the prospectus, the financial statements and selected historical financial data and other financial information included in this registration statement are those of Genenta Science S.r.l. and do not give effect to the Corporate Conversion. Upon the Corporate Conversion, the financial statements and selected historical financial data and other financial information of Genenta Science S.r.l. included in this registration statement will become the financial statements and selected historical financial data and other financial information of Genenta Science S.p.A. Ordinary shares of Genenta Science S.p.A. in the form of American Depositary Shares are being offered by the prospectus.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 19, 2021

PRELIMINARY PROSPECTUS

American Depositary Shares

Representing Ordinary Shares

We are offering up to American Depositary Shares, or ADSs, in an initial public offering. Each ADS represents one of our ordinary shares, par value € per share, or ordinary shares. The ADSs may be evidenced by American Depositary Receipts, or ADRs.

No public market currently exists for the ADSs or ordinary shares. We estimate the initial public offering price of the ADSs will be between $ and $ per ADS. We refer to the ADSs, and the underlying ordinary shares being offered hereby, collectively, as the securities.

We plan to apply to list the ADSs on the Nasdaq Capital Market, or Nasdaq, under the symbol "GNTA." There can be no assurance that we will be successful in listing the ADSs on Nasdaq.

We are an "emerging growth company" and a "foreign private issuer" under applicable U.S. federal securities laws and are eligible for reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company" and "Prospectus Summary—Implications of Being a Foreign Private Issuer" for additional information.

Investing in our securities involves a high degree of risk, including the risk of losing your entire investment. See "Risk Factors" beginning on page 12 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state or foreign securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per ADS	Total
Initial public offering price	$	$
Underwriting discounts and commissions [(1)]	$	$
Proceeds to us (before expenses)	$	$

(1) We have agreed to reimburse the underwriters for certain expenses. See "Underwriting" beginning on page 189 of this prospectus for additional disclosure regarding underwriter compensation and offering expenses.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to an additional ADSs to cover over-allotments, if any.

Delivery of the ADSs will be made on or about , 2021, subject to customary closing conditions.

Joint Book-Running Managers

Canaccord Genuity **Roth Capital Partners**

The date of this prospectus is , 2021

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You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different. We are offering to sell our securities, and seeking offers to buy our securities, only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

We are organized under the laws of Italy and our registered office and domicile is located in Milan, Italy. Under the rules of the U.S. Securities and Exchange Commission, or the SEC, we are currently eligible for treatment as a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Moreover, the chairman of the Board, the CEO and most of our directors are not residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our Italian counsel that there is doubt as to the enforceability in Italy of original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent solely predicated upon the federal and state securities laws of the United States. See "Enforceability of Civil Liabilities" in this prospectus for additional information.

Prior to the completion of this offering, we intend to change the legal form of our company under Italian law from a limited liability company (società a responsabilità limitata, or S.r.l.) to a joint stock company (società per azioni, or S.p.A.). Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms "we," "us," "our," the "Company" and "Genenta" refer to Genenta Science S.p.A. after the transformation of Genenta Science S.r.l. to a joint stock company, which is expected to occur prior to the completion of this offering. See "Corporate Conversion" in this prospectus for additional information.

All trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Our reporting currency and functional currency is the Euro. Unless otherwise expressly stated or the context otherwise requires, references in this prospectus to "dollars," "USD" or "$" mean U.S. dollars, and references to "euros," "EUR" or "€" are to the European Union euros. U.S. dollar translations of EUR amounts presented in this prospectus were done on different dates in accordance with the date as of such entry in our books and are derived from our audited financial statements included elsewhere in this prospectus. U.S. dollar translations of EUR amounts presented in this prospectus that are not derived from our audited financial statements included elsewhere in this prospectus are translated using the rate of EUR 1.00 to $, based on the euro foreign exchange reference rate provided by the European Central Bank on , 2021.

This prospectus includes statistical, market and industry data and forecasts which we obtained from publicly available information and independent industry publications and reports that we believe to be reliable sources. These publicly available industry publications and reports generally state that they obtain their information from sources that they believe to be reliable, but they do not guarantee the accuracy or completeness of the information. Although we believe that these sources are reliable, we have not independently verified the information contained in such publications.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. Before you decide to invest in our securities, you should read the entire prospectus carefully, including the "Risk Factors" section and the financial statements and related notes appearing at the end of this prospectus.

Our Company

We are a clinical-stage biotechnology company engaged in the development of hematopoietic stem cell gene therapies for the treatment of solid tumors. We have developed a novel biologic platform which involves the *ex-vivo* gene transfer of a therapeutic candidate into autologous hematopoietic stem/progenitor cells (HSPCs) to deliver immunomodulatory molecules directly to the tumor by infiltrating monocytes/macrophages (Tie2 Expressing Monocytes - TEMs). Our technology is designed to turn TEMs, which normally have an affinity for and travel to tumors, into a "Trojan Horse" to counteract cancer progression and to prevent tumor relapse. Our technology is not target dependent, and therefore we believe it can be used as a treatment for a broad variety of cancers.

Our technology incorporates the use of a lentiviral vector (LVV) that combines a therapeutic transgene sequence, or payload, with our proprietary platform. Our proprietary platform consists of (i) the Tie-2 promoter, that drives transgene sequence transcription specifically in TEMs, and (ii) miRNA-126 target sequences to downregulate transgene expression post-transcription in those cells where the Tie-2 promoter is active and the miRNA-126 is present. We believe there are many advantages to our approach:

- *Trojan Horse Mechanism of Action ("MoA"):* We use and modify TEMs, a subpopulation of tumor-associated myeloid cells, known to be involved in tumor growth and in the inhibition of immune system response, to allow the immune system to recognize the tumor and to deliver to the cancer site a chosen therapeutic.
- *Select Regulation of Transgene Expression:* Our selected control of the chosen therapeutic gene expression is designed to avoid off-target and systemic toxicity.
- *Potential Long-Term Effect:* Through the use of stem cells, our candidate is designed to be a "*living therapy*" that has the potential to break the cancer-induced immune tolerance and to establish a competent immune surveillance throughout the life of the patient.
- *Agnostic Response*: In contrast to antigen-restricted chimeric antigen receptor T cells (CAR-T), our platform is not restricted to a pre-selected tumor antigen, nor any one tumor type. As such, it may be applied to a broad number of solid tumors and cancer subtypes, thereby overcoming one of the central unresolved challenges of immune-oncology cancer therapies.

Our lead product candidate, Temferon, was developed using our platform and carries an interferon-alpha (IFN-α) payload. IFN-α is a well-known therapeutic that was previously administered intravenously for treatment of various cancers but is currently rarely used due to its systemic toxicity. The Temferon-modified TEMs express the transgene payload, IFN-α, in the tumor microenvironment resulting in the breakdown of tumor induced immune-tolerance. As a result, the immune system can recognize the tumor, respond, and inhibit tumor growth. Because Temferon delivers the IFN-α payload directly to the tumor, we believe it will demonstrate clinical activity without the side effect profile of systemic delivery of IFN-α. In preclinical mouse models treated with Temferon, both direct (anti-angiogenic, pro-apoptotic) and indirect (immune response) effects were observed.

We are currently developing Temferon for the treatment of glioblastoma multiforme (GBM). GBM is the most common malignant primary brain tumor accounting for more than half of all central nervous system (CNS) cancers. Patients suffering from GBM have limited, non-curative treatment options. Although these treatments may improve survival, the prognosis for GBM patients remains poor with a median overall survival (mOS) of approximately 15 months and only 5.5% of patients estimated to be alive five years after diagnosis. With no curative treatments available and such poor prognosis for patients, there remains a large, unmet medical need. We chose GBM among our first targets for clinical development after considering the medical need, the active role that TEMs have in GBM pathology, and the high number of newly diagnosed GBM patients potentially interested in participating in our study. As a result, we believe GBM offers a good profile for our initial proof of concept trial in humans. We are currently conducting a two-part, Phase 1/2a clinical trial with Temferon in newly diagnosed GBM patients in Italy. We anticipate completing enrollment of Part A of our study by the first quarter of 2021 and treatment by the second quarter of 2021. We intend to use the preliminary results of our Phase 1/2a clinical trial to support our IND application to the US Food and Drug Administration (FDA) for approval to conduct a Phase 1/2b trial in GBM in the U.S. As of April 30, 2021, we have treated a total of 13 patients. The preliminary results to date show that Temferon was generally well tolerated with no dose limiting toxicities identified so far.

We also intend to develop Temferon for the treatment of other solid tumor indications, and locally advanced hepatocellular carcinoma (HCC) and intra-hepatic cholangiocarcinoma (ICC) are our leading choices so far. HCC and ICC are gastrointestinal (GI) cancers affecting the digestive system. HCC is a primary malignancy of the liver that occurs predominantly in patients with underlying chronic liver disease and cirrhosis. ICC is a biliary tract cancer and represents approximately 3% of all GI malignancies. The prognosis for patients with locally advanced HCC or ICC remains poor with few therapeutic options which have limited clinical benefits. While we are considering development of Temferon for these liver indications for similar reasons as GBM (i.e. the high unmet need, TEMs' role in HCC and ICC pathology, and the number of newly diagnosed patients potentially eligible for our study), we are also evaluating development of Temferon for other solid tumor indications. We intend to submit a Clinical Trial Application (CTA) for conducting a Phase 1/2a study of Temferon in HCC and ICC or in a different second solid tumor indication to the Italian Medicines Agency (Agenzia Italiana del Farmaco, or AIFA), the public institution responsible for the regulatory activity of pharmaceuticals in Italy, and we anticipate initiating the trial in the second quarter of 2022.

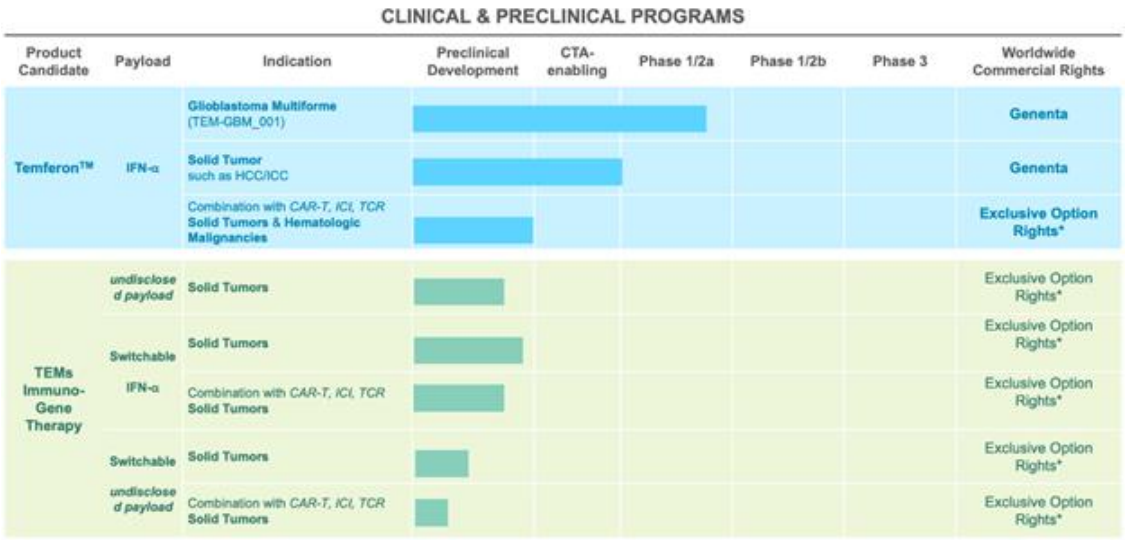
In addition to our Temferon programs being developed in GBM, or other solid tumor indications such as HCC and ICC, we have exclusive option rights to license (i) Temferon for the treatment of additional indications, and (ii) other drug candidates that are currently in the preclinical stage of development both as standalone treatments and as combination therapies.

We rely on our current contract manufacturing organization (CMO), AGC Biologics, based in Italy, to manufacture LVV and Temferon for us. After the completion of our Phase 1/2b study we intend to use a US-based CMO to supply our drug product (DP) for conducting larger trials in the U.S. Therefore, we are working with AGC Biologics to plan the required tech transfer activities for drug product manufacturing and the scale up of our LVV manufacturing process to support larger trials.

Research and Development Pipeline

Our portfolio of clinical and preclinical *ex-vivo* autologous gene cancer therapies is based on our technology platform, which was originally developed in our founders' laboratories at Ospedale San Raffaele, or OSR. Through our collaboration with OSR, we have worldwide commercial rights to Temferon for the treatment of GBM, HCC and ICC, as well as exclusive option rights to license all of our other programs. Specifically, we retain exclusive option rights to license (i) any platform improvements, including our second-generation technology, which includes developments to enable the on/off regulation of the therapeutic transgene, (ii) products for additional indications that utilize our platform technology but use different transgene payloads, and (iii) combinations of our platform with therapies in the immuno-oncology (IO) field, such as immune checkpoint inhibitors (ICI), CAR-T cell therapies and T cell receptor (TCR) therapies.

Our current pipeline, with clinical and preclinical stage programs, is summarized below:



**Genenta has options/rights on IP derived from preclinical data generated at SR-Tiget laboratories.*

Strategy

We are developing novel cancer therapeutics using our autologous *ex-vivo* gene therapy platform, to initially address the unmet medical needs of GBM patients and patients suffering from another solid cancer indication such as HCC and ICC. Ultimately, we hope to broaden our platform to treat a wide variety of cancers by pursuing the following strategies:

Advance development of our leading clinical-stage product candidate, Temferon in the U.S.

We are currently conducting a Phase 1/2a dose-escalation study to primarily evaluate the safety and tolerability of Temferon in up to 21 GBM patients who have an unmethylated MGMT promoter, following radiotherapy treatment. We plan to initiate a Phase 1/2b trial in the U.S., to evaluate the safety and efficacy of Temferon in up to 30 GBM patients who have an unmethylated MGMT promoter, following radiotherapy, where we intend to measure progression free survival (PFS) and overall survival (OS) as endpoints. We are planning a pre-IND meeting with the FDA by the end of the second quarter of 2021 to discuss the proposed clinical program and drug product manufacturing. The study design may change as a result of discussions with regulatory bodies, key opinion leaders and partnering clinical centers.

Expand our product pipeline across multiple indications

We intend to expand our product pipeline by:

- *Identifying additional indications suitable for Temferon. We are in the planning stages for a second study using Temferon in another solid tumor indication and locally advanced HCC and ICC are our current leading choice so far. The Istituto Superiore di Sanita (ISS), an independent committee with oversight from the Italian Ministry of Health, must issue a positive opinion regarding our CTA before AIFA will approve it. In addition to these indications, we believe there may be additional cancer indications which actively recruit TEMs to proliferate for which Temferon may be a suitable therapy.*
- *Using our platform with different transgene payloads.* Our platform technology is designed to enable us to use different transgene payloads to potentially achieve therapeutic outcomes in selected cancer indications. We are currently conducting preclinical studies for two therapeutics using our platform with different payloads targeting solid tumors.
- *Developing a second-generation platform that enables the "on-demand" release of the transgene payload*. We intend to develop a second-generation technology platform that allows the drug products to be switched on to exert the therapeutic effects and switched off if they are no longer needed, or to mitigate toxicity. This technology may enable us to expand our treatment options to broader patient populations.

- *Exploring combination therapies. We will seek to enter into collaborations with other companies to explore combination studies of our therapeutics with other cancer therapies, such as ICI, CAR-T cell therapies and TCR therapies. We believe our product candidate, as a result of its MoA, has the potential to enhance the durability and efficacy of the existing therapies, thus abolishing the immune tolerance to the tumor.*

- *Exploiting in-licensing opportunities with OSR.* We intend to exploit in-licensing opportunities with OSR, a co-founding shareholder.

Develop and maintain efficient manufacturing processes to support anticipated growth

To meet our drug product supply needs for conducting larger trials after the completion of our planned Phase 1/2b GBM study in the U.S., we intend to enter into a supply agreement with a US-based CMO for the manufacturing of our products. Currently, Temferon, is manufactured by AGC Biologics, a leading global contract development and manufacturing organization (CDMO). We are currently working with AGC Biologics on required technology transfer activities to enable drug product manufacturing by a US-based CMO and the scaling up of our LVV manufacturing process to support larger trials.

Establish a patient-centered infrastructure and strong relationships with key U.S. opinion leaders working in our disease area

Since cell and gene-based therapies are relatively new approaches in oncology, we intend to implement programs to improve patient and physician education regarding the availability of gene therapy-based products for those cancers with a high unmet medical need. To this end, we are discussing a GBM IND trial with Antonio Chiocca, MD, Professor Neurosurgeon-in-Chief and Chairman, Department of Neurosurgery at Brigham and Women's Hospital in Boston, MA, Frederick Lang, MD, Professor and Chairman of the Department of Neurosurgery at MD Anderson in Houston, TX, and David A. Reardon, MD, Department of Medical Oncology at Dana-Farber Cancer Institute in Boston, MA.

Develop opportunistic partnership(s) with pharmaceutical company(s)

We may choose to partner with larger pharmaceutical companies whose core competencies and oncology strategies are in line with ours.

Our Strengths

We believe that our growing body of early clinical data supporting the potential of our autologous *ex-vivo* gene therapy approach, coupled with our founders' expertise in the development, manufacturing and commercialization of gene and cell therapies, positions us well to provide potentially transformative therapies through a single administration to patients suffering from a broad range of cancers. We believe our key strengths include:

- ***Unique and valuable expertise.*** We are conducting our clinical trials at OSR, a leading center for *ex-vivo* gene therapy for inherited diseases. OSR has treated more than 121 patients worldwide (one of the highest number of patients treated with gene therapy for rare diseases in a research hospital) using an ex-vivo viral vector platform similar to the one we are developing for cancer treatment. Members of our executive leadership team have held senior positions at GSK, Merck, Annapurna-Adverum and other companies specializing in gene and cell therapies and rare diseases. We have partnered with academic institutions that are pioneers in autologous *ex-vivo* gene therapy and hold exclusive option rights to license additional patents and know-how to build our portfolio. Partnerships with leading academic institutions that are well recognized in the gene therapy field, such as SR-Tiget and OSR, are a core part of our research engine through which we are working to advance the clinical development of our product candidates and to identify new opportunities that we believe have comparably high probabilities of success in a preclinical setting. We believe our expertise, combined with our plan to leverage our relationships with leading academic institutions, will help expedite the commercialization of our lead clinical-stage product candidate and further expand our pipeline.

- ***Deep pipeline with broad utility.*** We believe that the flexibility of our technology platform combined with our exclusive option rights to in-license additional programs, give us the ability to grow our pipeline by targeting a broad set of cancer diseases.
- ***Durable therapeutic potential.*** Preliminary interim clinical data collected from GBM patients following a single administration of Temferon displayed modified cells at 18 months, the last measured timepoint to date.
- ***Tumor restricted therapeutic payload delivery and release.*** Due to the design of our transgene expression cassette, we restrict payload expression to the tumor microenvironment. The local and tumor restricted therapeutic gene deployment approach is designed to focus the pleiotropic anti-tumor activities of the selected payload, by limiting the toxic manifestation that results from standard systemic administration of the payload.
- ***Agnostic approach.*** Our immune-gene therapy approach is a tumor-agnostic immunotherapy since it does not rely on any specific target or tumor type, and therefore we believe it could be successfully applied to a potentially broad range of cancers and immune contexts.
- ***Solid tumors targeting.*** Our platform has the potential to efficiently target solid tumors. Solid tumors are difficult to treat, even by the most novel and leading-edge technologies such as ICIs and CAR-T cells. Our cellular carrier, TEMs, is spontaneously and actively recruited by growing tumors and is found in several human solid tumors, irrespective of location.
- ***Active and sustained tumor surveillance.*** Our immune-gene therapy is designed to trigger the patient's own immune response that establishes an active immune surveillance. Our preclinical work, which used different cancer models (B-cell acute lymphoblastic leukemia - B-ALL and GBM), as well as preliminary data collected from our GBM patients suggests the occurrence of changes in the immune system.
- ***Fine dose tuning.*** Our platform gives us the ability to fine tune the dose to be administered to each patient, based on the patient's own drug product characteristics (drug product's release specifications).
- ***Preliminary data indicate that our approach is feasible and well-tolerated.*** Temferon has been well-tolerated in the limited number of patients treated to date. Our *ex-vivo* modification of the patient's own HSPCs and cryopreservation allow us to formulate the patient's drug product prior to administering the therapy.
- ***LVV as transgene payload delivery vehicles.*** LVVs are particularly attractive for clinical applications due to their capacity to transfer large genes/payloads and their ability to efficiently transduce non-proliferating or slowly proliferating cells, such as hematopoietic stem and progenitor cells that allow a persistent gene expression in transduced cells. Moreover, LVVs have a reduced risk of genotoxicity compared to gamma-retroviral vectors (gRV). *Ex-vivo* transduction using LVVs has demonstrated a positive safety profile over the last 10 years. A large number of patients have been treated both with LVV gene therapy products approved for sale and with clinical-stage product candidates for rare diseases worldwide, and generally these therapies have been well tolerated. We believe that long-term extensive follow-up across multiple diseases, with vectors expressing different genes, demonstrates the potential safety of our LVV-based autologous *ex-vivo* gene therapy approach.
- ***Applicability to a potentially large number of patients and indications***. We believe our autologous *ex-vivo* gene therapy approach has broad therapeutic potential across a large number of malignancies. The *ex-vivo* transduction of HSPCs allows for the potentially long-term production of a differentiated cellular carrier loaded with the therapeutic gene and the consequent distribution of the therapeutic payload throughout multiple organs and tissues containing solid tumors.

Company History and Management Team

We were founded in 2014 by San Raffaele Hospital (OSR) in Milan, a globally recognized premier research hospital for *ex-vivo* gene therapy, with Pierluigi Paracchi (our CEO), Luigi Naldini (Chairman of our Executive Scientific Board) and Bernhard Gentner (a member of our Executive Scientific Board), to develop potential ground-breaking cell and gene cancer therapies. We leverage the vast experience in LVV technology of the San Raffaele Telethon Institute for Gene Therapy (SR-Tiget). SR-Tiget, a joint venture between OSR and Fondazione Telethon (Telethon), is a world leading cell and gene therapy research institution at the forefront of developing therapies for rare diseases. SR-Tiget has a proven track record for successful collaborative clinical research programs in *ex-vivo* gene therapy. Its research has resulted in a number of approved products, including Strimvelis, an *ex-vivo* gammaretroviral vector-based gene therapy for adenosine deaminase severe combined immunodeficiency (ADA-SCID), and Libmeldy, an *ex-vivo* gene therapy for the treatment of early-onset metachromatic leukodystrophy (MLD) patients, both marketed by Orchard Therapeutics. Our platform was developed in the SR-Tiget laboratories of our founders, Prof. Naldini and Dr. Gentner, and we hold exclusive rights and option rights, to certain intellectual property (IP) originating there.

Since closing our first round of funding in May 2015, we have recruited a leading management team, established a manufacturing process for our drug product candidate, completed preclinical activities (research and Good Laboratory Practice – GLP – grades), engaged with Italian, European and U.S. Key Opinion Leaders (KOLs) to identify our clinical lead indications, and submitted our first CTA (June 2018).

Our leadership team has a proven track record as biotech executives. Their expertise spans from finance and venture capital to medical affairs, from scientific research to clinical drug product development and clinical trial management. For example, members of our management team have been involved in the successful development of Ethical Oncology Science, which was acquired in 2013 for over $400 million, and Strimvelis the first ever ex-vivo approved gene therapy product that was developed under the guidance of Carlo Russo, our Chief Medical Officer and Head of Development (formerly Head of Development of R&D Biopharm and Rare Disease Units at GSK). Our management team members have played important roles in both large pharma companies such as Merck and GSK, and biotech startups, such as Adverum, Annapurna, VaxInnate Corporation, OncoSec Medical, Biological Dynamics and GenMark Diagnostics. We believe this multi-disciplinary competence, provides a unique blend for the development of innovative gene and cell therapy products, and constitutes a fertile ground for alliances with industrial partners that could help us bring new therapies to patients.

Risks Associated with Our Business

Our business, and investing in our securities, are subject to numerous risks and uncertainties, as more fully described in the section “Risk Factors” included elsewhere in this prospectus. You should read these risks before making a decision to invest in our securities. If any of these risks actually occur, our business, financial condition or results of operations would likely be materially adversely affected. In each case, the trading price of our securities would likely decline, and you may lose all or part of your investment. The following is a summary of some of the principal risks we face:

- We have a limited operating history and have incurred significant losses since our inception. We have never generated revenue and will require significant additional funds, which may not be available on acceptable terms or at all. As a result, you could lose your entire investment.
- Our lentiviral-based gene therapy product candidates are based on a novel technology that is in preliminary stages of evaluation, which makes it difficult to predict the time and cost of product candidate development or the likelihood of receiving required regulatory approvals. Our rights to the intellectual property underlying our novel technology derive solely from our license agreement with OSR and any failure to comply with the terms of such license agreement could have a material adverse effect on our intellectual property position and our ability to seek approval for and ultimately commercialize such product candidates.
- Even if we do receive regulatory approvals for our product candidates, they may face commercialization issues from significantly larger oncology competitors, unfavorable pricing regulations or lack of acceptance by doctors, hospitals, patients and insurers. Our product candidates and the process for administering them may also cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

- We currently have very few employees and rely almost entirely on the efforts of third parties over which we have limited control and in certain cases are reliant on a sole supplier for our materials. Our contract research organizations, or CROs, may fail to observe the standards to which our studies must be conducted and our product candidates may not be approved as a result. Likewise, our contract manufacturing organizations, or CMOs, may not continue producing the needed materials for preclinical and clinical testing, whether as a result of their commitments to other customers or otherwise. Any failure of these third parties to meet our expectations would have a materially adverse effect on our product development efforts.

- Our clinical trials for Temferon must be successful if we are to seek and obtain regulatory marketing application through the submission of a new Biological License Application (BLA) and marketing authorization application (MAA) with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively. Advanced clinical trials are often not successful even if prior trials were successful, and even if we are able to conduct advanced clinical trials and those trials are successful, we may not obtain necessary regulatory approvals for Temferon or we may be unable to successfully commercialize our products even if we receive the necessary regulatory approvals.

- The ongoing COVID-19 pandemic could adversely impact our ongoing and planned clinical trials, operations and financial condition, and our overall generation of revenues may not succeed on the time frames we expect or at all.

- Our Chief Executive Officer, directors and shareholders who own more than 5% of our outstanding ordinary shares before this offering currently own approximately [70.0]% of our outstanding ordinary shares and will own approximately % of our ordinary shares upon the completion of this offering and will therefore be able to exert significant control over matters submitted to our shareholders for approval.

- As a public company following the conclusion of this offering, we will need to comply with extensive additional U.S. and Italian governmental and Nasdaq regulations, which will be expensive, and which will require significant management attention.

- As a company organized under the laws of Italy and whose shares are represented by ADSs, the rights of investors in the company following this offering will differ in several material respects from the rights of holders of shares of common stock of a US domestic company and may not afford investors the same protections.

Corporate Information

Genenta was formed as an Italian limited liability company (società a responsabilità limitata, or S.r.l.) in 2014. Prior to the completion of this offering, we intend to complete the Corporation Conversion to change the legal form of our company under Italian law to a joint stock company (società per azioni, or S.p.A.).

Our principal executive offices are located at Via Olgettina No. 58, 20132 Milan, Italy. Our telephone number in Italy is +39.02.2643.6639. Our website address is www.genenta.com. The information contained on, or that can be accessed through, our website is not part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

The Securities and Exchange Commission, or the SEC, also maintains an Internet website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Our filings with the U.S. Securities and Exchange Commission, or the SEC, will also be available to the public through the SEC's website at http://www.sec.gov.

Implications of Being an "Emerging Growth Company"

We qualify as an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to, and intend to, take advantage of certain exemptions from various reporting requirements applicable to other public companies that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- an exemption from new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation.

We could remain an "emerging growth company" for up to five years, or until the earliest of (a) the last day of the first fiscal year in which our annual gross revenue exceeds $1.07 billion, (b) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our securities that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (c) the date on which we have issued more than $1 billion in nonconvertible debt during the preceding three-year period. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We have elected to avail ourselves of the exemption for the delayed adoption of certain accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Implications of being a "Foreign Private Issuer"

Upon consummation of this offering, we will be subject to the information reporting requirements of the Exchange Act that are applicable to "foreign private issuers," and under those requirements we will file reports with the SEC. As a foreign private issuer, we will not be subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we will be subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We also will have four months after the end of each fiscal year to file our annual report with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Our officers, directors and principal shareholders will be exempt from the requirements to report transactions in our equity securities and from the short-swing profit liability provisions contained in Section 16 of the Exchange Act. As a foreign private issuer, we will not be subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. In addition, as a foreign private issuer, we will be permitted to follow certain home country corporate governance practices instead of those otherwise required under the Nasdaq Stock Market rules for domestic U.S. issuers and will not be required to be compliant with all Nasdaq Stock Market rules as of the date of our initial listing on Nasdaq as would domestic U.S. issuers (see "Risk Factors—Risks Related to this Offering and Ownership of Our Securities"). These exemptions and leniencies will reduce the frequency and scope of information and protections available to you in comparison to those applicable to a U.S. domestic reporting company. We intend to take advantage of the exemptions available to us as a foreign private issuer during and after the period we qualify as a "foreign private issuer."

THE OFFERING

ADSs offered by us	ADSs, representing ordinary shares
Ordinary shares issued and outstanding prior to this offering	ordinary shares
Ordinary shares to be issued and outstanding after this offering	ordinary shares (or ordinary shares if the underwriters exercise their option to purchase additional ADSs within 30 days of the date of this prospectus from us in full) (includes ordinary shares represented by the ADSs)
The ADSs	Each ADS represents one of our ordinary shares, par value € per share. The ADSs may be evidenced by American Depositary Receipts, or ADRs. The depositary will hold in custody the ordinary shares underlying the ADSs and you will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and owners and holders of ADSs from time to time. To better understand the terms of the ADSs, you should carefully read the "Description of the Offered Securities" section of this prospectus. We also encourage you to read the deposit agreement, which is incorporated by reference as an exhibit to the registration statement that includes this prospectus.
Over-allotment option	We have granted to the underwriters an option exercisable for a period of 30 days after the date of this prospectus to purchase up to additional ADSs from us solely to cover over-allotments, if any. If the underwriters exercise all or part of this option, it will purchase securities covered by the option at the public offering price per ADS, less the underwriting discounts and commissions. See "Underwriting."
Use of proceeds	We estimate that the net proceeds from our issuance and sale of ADSs in this offering will be approximately $ million, assuming an offering price of $ per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and offering expenses payable by us. If the underwriters exercise the over-allotment option in full, we estimate that the net proceeds from this offering will be approximately $ million, assuming an offering price of $ per ADS, and after deducting underwriting discounts and commissions and offering expenses payable by us. We currently expect to use the net proceeds from this offering: ● to conduct a clinical trial in selected cancer patient populations in the United States; ● to support the ongoing Temferon TEM-GBM 001 trial and its long term follow up; ● to start a new Temferon clinical program in a second solid tumor indication; ● to fund further preclinical research for the development of Temferon across broad cancer indications; ● to fund Temferon manufacturing activities including LVV manufacturing, stability and process scalability studies, and tech transfer activities; and ● working capital and general corporate purposes. See "Use of Proceeds" for additional information. See "Use of Proceeds" for additional information.

Depositary	The Bank of New York Mellon
Custodian	The Bank of New York Mellon, as custodian, acting through an office located in the United Kingdom
Proposed Nasdaq trading symbol and listing	We plan to apply to list the ADSs on the Nasdaq Capital Market under the symbol "GNTA." No assurance can be given that such listing will be approved or that a liquid trading market will develop for the ADSs.
Lock-up	Our directors, executive officers, and certain shareholders have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our ordinary shares or securities convertible into ordinary shares for a period of 180 days following the date of this prospectus. See "Underwriting."
Risk factors	You should read the "Risk Factors" section starting on page 12 of this prospectus for a discussion of factors to consider carefully before deciding to invest in our securities.

The number of our ordinary shares that are and will be outstanding immediately before and after this offering as shown above is based on ordinary shares outstanding as of , 2021, after giving pro forma effect to the Corporate Conversion, and excludes:

- ordinary shares issuable upon vesting of stock options outstanding as of , 2021; and
- ordinary shares that are available for future issuance under our 2021-2025 Equity Incentive Plan.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the completion of the Corporate Conversion in which all outstanding quotas of Genenta Science S.r.l. will be converted into an aggregate of [15,000,000] ordinary shares of Genenta Science S.p.A.; and
- no exercise by the underwriters of their over-allotment option or the warrants to purchase ADSs at an exercise price per share equal to 125% of the initial public offering price per ADS or $, that will be issued to the representatives of the underwriters in connection with this offering (the "Representatives' Warrants").

SUMMARY FINANCIAL DATA

We have derived the following summary statements of operations data for the years ended December 31, 2020 and 2019 and summary balance sheet data as of December 31, 2020 from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus, and are qualified entirely by reference to such financial statements.

Our financial statements included in this prospectus are prepared and presented in accordance with accounting principles generally accepted in the United States, or U.S. GAAP.

	Year Ended December 31,	
in Euros, except share data	2020	2019
Research and development expenses	€ 4,688,461	€ 3,702,982
General and administrative expenses	901,765	921,520
Total operating expenses	5,590,226	4,624,502
Loss from operations	(5,590,226)	(4,624,502)
Other income	5,966	36,331
Finance expense	(7,754)	(9,552)
Net loss	(5,592,014)	(4,597,723)
Comprehensive loss:	—	—
Total comprehensive loss	€ (5,592,014)	€ (4,597,723)
Pro forma information (unaudited):		
Pro forma net loss		
Pro forma net loss per share - basic and diluted	€	€
Weighted average pro forma number of shares outstanding - basic and diluted		

(1) We have presented pro forma basic and diluted net loss per share which consists of our historical net loss attributable to Genenta Science S.r.l., divided by the pro forma basic and diluted weighted average number of shares outstanding after giving effect to the Corporate Conversion. See Note to our financial statements included elsewhere in this prospectus for additional information regarding the method used to calculate the pro forma basic and diluted net loss per share and the pro forma weighted average number of shares used in the computation of the per share amounts.

	As of December 31, 2020		
in Euros	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
Balance Sheet Data:			
Cash and cash equivalents	€ 15,465,243		
Total assets	17,502,115		
Total long-term liabilities	17,388		
Accumulated deficit	(21,490,475)		
Total equity	15,151,309		

(1) Reflects the Corporate Conversion.

(2) The pro forma as adjusted balance sheet data gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of ADSs, representing ordinary shares, in this offering at the assumed initial public offering price of $ per ADS, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per ADS would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets and total equity by approximately € , assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of ADSs offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, total assets and total equity by approximately € .

(3) The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

RISK FACTORS

An investment in our securities involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. You should consider carefully the risks described below, as well as the financial or other information included in this prospectus, including our financial statements and the related notes, before you decide to buy our securities. The risks and uncertainties described below are not the only risks facing us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. Any of the risks described below, and any such additional risks, could materially adversely affect our business, financial condition or results of operations. In such case, you may lose all or part of your original investment.

Risks Related to Our Financial Position and Capital Requirements

We are a clinical-stage biopharmaceutical company with limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an emerging biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. All of our product candidates are in early development and none have been approved for commercial sale. We have not demonstrated an ability to successfully complete late-stage clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third-party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will be materially harmed.

We have incurred significant losses in every year since our inception. We expect to continue to incur losses over the next several years and may never achieve or maintain profitability.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and have incurred net losses each year since our inception. Our net losses for the years ended December 31, 2020 and 2019 were approximately €5.6 million and €4.6 million, respectively. As of December 31, 2020, we had an accumulated deficit of approximately €(21.5) million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development activities, including pre- and non-clinical development of our gene therapy product candidates, namely our leading product candidate Temferon, and from general and administrative costs associated with our operations.

We expect that it will be several years, if ever, before we have any product approved for commercial sale. We have funded our operations to date primarily through proceeds from the private placement of ordinary shares to our founding shareholders. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we

- continue the research and development of our gene therapy product candidates, including continuing and conducting preclinical studies and clinical trials of Temferon and conducting preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- develop and obtain regulatory approval for registration studies for our current product candidate Temferon and any additional product candidates that we may pursue in the future;

- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies, if any, including obtaining orphan drug designation;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- industrialize our lentivirus *ex-vivo* gene therapy approach into a robust, scalable and, if approved, commercially viable process;
- maintain, protect, and expand our intellectual property portfolio;
- hire and retain qualified technical personnel, such as clinical, quality control, commercial and scientific personnel;
- expand our infrastructure and facilities to support our operations, including adding equipment and physical infrastructure to support our research and development; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

We have not generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenues from product sales for the next several years, if ever, and our ability to do so depends heavily on our success in many areas, including but not limited to:

- completing research and pre- and non-clinical development of our products candidates
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies, if any;
- establishing and maintaining supply and manufacturing processes and relationships with third parties that can provide adequate (in amount and quality) products and services, and at acceptable costs, to support clinical development and market demand for our product candidates, if marketing approval is received;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; and
- obtaining market acceptance of our product candidates, if approved for marketing, as viable treatment options.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercialization, with all associated risks and uncertainties. Therefore we cannot predict when, or if, we will be able to achieve profitability. Additional clinical trials or delays in the initiation and completion of clinical trials could cause our expenses to increase significantly and profitability to be further delayed.

Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We will need additional capital in the future. Raising additional capital by issuing securities may cause dilution to existing shareholders. Financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product candidate development efforts or other operations.

As of December 31, 2020, our cash and cash equivalents were approximately €15.5 million. If we continue to use cash at our historical rates of use we will need significant additional financing, which we may seek through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any such offerings may include liquidation or other preferences that may adversely affect the then existing shareholders rights. Debt financing, if available, would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaboration, strategic alliance or licensing arrangements with third parties, we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Our future funding requirements will depend on many factors, including but not limited to:

- the scope, progress, results and costs of drug discovery, laboratory testing, pre- and non-clinical development and clinical trials for our product candidates, including Temferon;
- the cost, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the cost of preparing, filing and prosecuting patent and trademark applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel; and
- the costs associated with being a public company.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our securities and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our securities to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the development or commercialization, if any, of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Risks Related to Product Development, Regulatory Approval and Commercialization

Our lentivirus ex-vivo gene transfer therapy product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development and likelihood of subsequently obtaining regulatory approval.

We have concentrated our research and development efforts on our lentivirus *ex-vivo* gene transfer strategy approach, and our future success is highly dependent upon our successful development of commercially viable gene therapy product candidates. There can be no assurance that we will not experience problems or delays in developing new product candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. Because lentivirus *ex-vivo* gene transfer cell therapies represent a relatively new field of cellular immunotherapy and cancer treatment generally, developing and commercializing our product candidates subjects us to a number of risks and challenges, including:

- obtaining regulatory approval for our product candidates, as the FDA, the EMA, the AIFA and other regulatory authorities have limited experience with lentivirus *ex-vivo* gene transfer therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient's HSPCs *ex vivo* and infusing the engineered HSPCs back into the patient;
- sourcing clinical and, if approved, commercial supplies of the materials used to manufacture our product candidates;
- developing programming modules with the desired properties, while avoiding adverse reactions;
- creating viral vectors capable of delivering multiple programming modules;
- developing a reliable and consistent *ex vivo* gene modification and manufacturing process;
- securing manufacturing capacity suitable for the manufacture of our product candidates in line with expanding enrollment in our clinical studies and our projected commercial requirements;
- minimizing and avoiding infection and contamination during production of product candidates;
- developing protocols for the safe administration of our product candidates;
- educating medical personnel regarding our lentivirus *ex-vivo* gene transfer technologies and the potential side effect profile of each of our product candidates, such as potential adverse effects related to pyrexia and infections;
- establishing integrated solutions in collaboration with specialty treatment centers in order to reduce the burdens and complex logistics commonly associated with the administration of lentivirus *ex-vivo* gene transfer cell therapies;
- if and when we obtain any required regulatory approvals, establishing sales and marketing capabilities or partnerships to successfully launch and commercialize our product candidates and gaining market acceptance of a novel therapy; and
- the availability of coverage and adequate reimbursement from third-party payors.

We may not be able to successfully develop our lentivirus *ex-vivo* gene transfer product candidates or our technology in a manner that will yield products that are safe, effective, scalable or profitable. Additionally, because our technology involves the genetic modification of patient cells *ex vivo*, we are subject to additional regulatory challenges and risks, including:

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. To date, few CAR-T cell therapy products that involve the genetic modification of patient cells have been approved in the United States and/or the European Union, and no lentivirus *ex-vivo* gene transfer product candidates have been approved by any regulatory authority. In this regard, the European Commission has granted conditional marketing authorization for ZYNTEGLO;

- genetically modified products could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells in the event of improper insertion of a gene sequence into a patient's chromosome;

- although our viral vectors are not able to replicate, there is a risk with the use of lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases; and

- the FDA recommends a 15-year follow-up observation period for patients who receive treatment using gene therapies and guidance promulgated by the EMA requires a similar follow-up observation period for patients who receive cell therapeutic products, which has to be sufficient to observe the subjects for risks that may be due to the characteristics of the product, the nature and extent of the exposure, and the anticipated time of occurrence of delayed adverse reactions and could be as long as life-time, and we may need to adopt an observation period for our product candidates.

Moreover, public perception and awareness of cell and gene therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of lentivirus *ex-vivo* gene transfer cell therapies. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Our gene therapy product candidates and the process for administering our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

Following treatment with our gene therapy product candidates, patients may experience changes in their health, including illnesses, injuries, discomforts or a fatal outcome. It is possible that as we study and test Temferon or other product candidates in larger, longer and more extensive clinical programs, or as use of our product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier clinical trials, as well as conditions that did not occur or went undetected in previous clinical trials, will be reported by patients. Gene therapies are also subject to the potential risk that occurrence of adverse events will be delayed following administration of the gene therapy due to persistent biological activity of the genetic material or other components of the vectors used to carry the genetic material. Many times, additional safety risks, contraindications, drug interactions, adverse events and side effects are only detectable after investigational products are tested in larger scale clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Moreover, as noted above the FDA generally requires a long-term follow-up of study subjects for potential gene therapy-related adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of study subjects. If additional clinical experience indicates that Temferon or any other product candidates or similar products developed by other companies has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked or limited.

There have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia with the use of gammaretrovirus vector and patient deaths in other clinical trials. Two recent case reports of myelodysplastic syndrome and acute myeloid leukemia relating to BlueBird Bio's product, were reported by that company to be unlikely related to the LVV, although FDA's review remains ongoing, and instead may be related to the patient population being studied, the genotoxic potential of the promoter incorporated as part of their transduction process, or the depth of conditioning used. Gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. Possible adverse side effects that may occur with treatment with gene therapy products include an immunologic reaction early after administration that could substantially limit the effectiveness of the treatment or represent safety risks for patients. Another traditional safety concern for gene therapies using viral vectors has been the possibility of insertional mutagenesis by the vectors, leading to malignant transformation of transduced cells. While our lentivirus *ex-vivo* gene transfer therapy approach is designed to avoid immunogenicity after administration, there can be no assurance that patients would not create antibodies that may impair treatment. Our approach involves the use of integrating vectors which have the potential for genomic disruption and therefore could interfere with other genes with adverse clinical effects. If any of our gene therapy product candidates demonstrates adverse side effects, we may decide or be required to halt or delay clinical development of such product candidates.

Potential risks for gene therapy products can be identified, in addition to side effects caused by the product candidate itself, as part of the entire process required for their manufacturing and administration. For Temferon manufacturing, each patient needs to be subjected to a mobilization and harvesting process for hematopoietic stem progenitor cells (HSPCs) collection. This procedure is associated with risks linked to the administration of mobilization agents. The conditioning regimen required for administering our product candidate and the associated procedures can also cause adverse side effects. A gene therapy patient is generally administered with cytotoxic drugs to remove stem cells from the bone marrow to create sufficient space for the modified stem cells to engraft and produce their progeny. This procedure compromises the patient's immune system, and adverse events related to preconditioning have been observed in our ongoing clinical trial. If in the future we are unable to demonstrate that such adverse events were caused by the conditioning regimens used, or by their administration process or related procedure, the FDA, EMA or other regulatory authorities could order us to cease further development of, or deny the approval of, Temferon or our other product candidates for any or all target indications. Even if we are able to demonstrate that adverse events are not related to our drug product, such occurrences could affect the ability to enroll patients to complete the clinical trial, or the commercial viability of any product candidates that obtain regulatory approval.

To date, Temferon has only been administered to a small number of human subjects in our ongoing Phase 1/2a study. Due to the lack of a broader experience in human subjects, there is limited information available about the relationship of adverse events to administration of Temferon. Adverse events experienced in our clinical trials and attributed to autologous stem cell transplant (ASCT), concomitant medications, and disease progression have included febrile neutropenia and other infectious complications, venous thromboembolism, poor performance status, liver enzyme elevation, brain abscess and hemiparesis. While most of these adverse events were managed with treatment and supportive care, one GBM patient died from progressive disease at day 403 and another died at day 60 due to complications following the conditioning regimen.

Patient deaths and severe adverse effects caused by any investigational product candidates could result in the delay, suspension, clinical hold or termination of clinical trials by Sponsors, ethics committees and regulatory authorities. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenue from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, and other non-U.S. regulatory authorities could impose other specific obligations as a condition of approval to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, and restrictions on how or where the product can be distributed, dispensed or used. Furthermore, if we or others later identify undesirable side effects caused by Temferon or any of our other product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such a product candidate;
- regulatory authorities may require additional warnings or limitations of use in product labeling;
- we may be required to change the way a product candidate is distributed, dispensed, or administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

We are evaluating Temferon in a Phase 1/2 clinical trial in newly diagnosed glioblastoma tumor patients (TEM-GBM Study). To date, the TEM-GBM Study is ongoing and not complete.

We are at a very early stage of development for all of our gene therapy product candidates. At this stage, only our lead product candidate Temferon has been authorized by the AIFA to be evaluated in a Phase 1/2 clinical trial in Italy. A study testing Temferon in multiple myeloma study was also approved by AIFA, but we are closing the study due to lack of enrollment feasibility, rather than clinical events, as no multiple myeloma patients have been treated with Temferon.

In order to commence a clinical trial in the United States, we will be required to seek FDA acceptance of an IND for each of our product candidates, including Temferon. We cannot be sure any IND we submit to the FDA, or any similar clinical trial application we submit in other countries, will be accepted. If we will be required by regulatory authorities to conduct additional preclinical testing prior to filing an IND or similar application to clinically evaluate any of our product candidates, including Temferon, this may result in delay in our product candidate development. The results of any such preclinical testing may not be positive and may not support an application to study Temferon or any of our other product candidates in additional clinical trials.

It is possible that the FDA or EMA will not view our ongoing or planned trials as providing adequate support for future clinical trials or for an application for marketing approval, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. If we are unable to confirm or replicate the results of our trials in larger patient group or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of Temferon or any of our other product candidates.

Additionally, the FDA or EMA may disagree with the sufficiency of our proposed reliance upon the preclinical, manufacturing or clinical data generated by third-party academic-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from our ongoing trials. If so, the FDA or EMA may require us to obtain and submit additional preclinical, manufacturing or clinical data.

We need to complete our Phase 1/2 clinical trial for Temferon, as well as additional clinical trials in order to obtain regulatory approvals to market Temferon. Carrying out later-stage clinical trials is a complicated process. We are a small organization with limited experience in preparing, submitting and prosecuting regulatory filings, and we have not previously submitted a biologics license application, or BLA, to the FDA for any product candidate.

In addition, we have not yet conducted clinical trials of any our product candidates in the United States, our interactions with the FDA are expected to be limited for the near future, and we cannot be certain how many clinical trials of Temferon or any of our other product candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to a BLA submission and approval of Temferon or any of our other product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing Temferon.

We may encounter substantial delays in commencement and completion of clinical trials.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. We cannot guarantee that any clinical studies will be conducted or completed on schedule, if at all. Clinical trials can be delayed or prevented for a number of reasons, including:

- delays in reaching a consensus with regulatory agencies on study design;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- failure to perform in accordance with the FDA's good clinical practices, or GCP, or applicable regulatory guidelines in other countries;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure by CROs, other third parties or us to adhere to clinical trial protocol and record keeping requirements;
- trial sites or patients dropping out of a study;
- the occurrence of SAEs associated with the product candidate that are viewed to outweigh its potential benefits;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites; and
- if the FDA or the EMA or other regulatory authorities elect to enact policy changes, as a result of the COVID-19 pandemic or otherwise.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, a data safety monitoring board overseeing the clinical trial at issue or by other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen safety issues (including those that result from the COVID-19 pandemic) or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues. This could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether.

In addition, if we make changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions, this will increase the costs and could delay our clinical development plan, or marketing approval for our product candidates. For example, among our preclinical candidates we are developing a “switchable” system. This system has the potential to be a “switchable” on/off system that may limit the long-term exposure to any selected therapeutic payloads, but it requires further preclinical testing as well as additional manufacturing validation. Moreover, our platform is designed to allow us to use other therapeutic payloads, other than IFN-α. This has the potential to open a multitude of therapeutic indications but further preclinical testing as well as additional manufacturing validation are required. Any modification of our product candidates will likely require updates to our clinical trial applications and INDs with the relevant regulatory authorities, which may result in delay, suspension or termination of ongoing or future clinical trials pending our submission, and the agencies’ review, of such updates. Clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

The results of preclinical studies, early-stage clinical trials, data obtained from real-world use, and published third-party studies may not be indicative of results in future clinical trials and we cannot assure you that any clinical trials will lead to results sufficient for the necessary regulatory approvals.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any completed clinical trials, including studies derived from real-world use and studies in published literature, or clinical trials we commence may not be predictive of the results of later-stage clinical trials. Additionally, interim results and analyses from our ongoing clinical trials do not necessarily predict final results. Moreover, preliminary data and analyses from our ongoing clinical trials may change as more patient data become available. In general, we conduct interim analyses at pre-specified times, which do not include data subsequent to the cut-off date and will not be available until the next planned interim analysis. From time to time, preliminary data and analyses might be presented, typically by academic investigators at scientific conferences or in scientific publications. Interim data and analyses are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available to us. Interim and preliminary data/analyses also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data available to us or that we previously published. As a result, preliminary and interim data/analyses should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the preliminary or interim data/analyses could significantly harm our business prospects.

Indeed, our product candidates may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints (or lack of trial endpoints in exploratory studies), subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. Our company has limited experience in designing and conducting clinical trials and we may be unable to design and execute a clinical trial to support regulatory approval. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a negative impact on our business. Any of our product candidates, including Temferon, may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies. Any such failure would cause us to abandon the product candidate.

Additionally, our ongoing clinical trial utilizes, and our planned clinical trials may utilize, an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on our ability and on the speed at which we can recruit patients to participate in testing our product candidates, as well as the completion of required follow-up periods. We may experience delays in our clinical trials if we encounter difficulties in enrollment. Patients may be unwilling to participate in our gene therapy clinical trials because of negative publicity from adverse events related to the biotechnology or gene therapy fields, the safety profile of our product candidate under study, the perceived risks and benefits of the product candidate under study; the perceived risks and benefits of gene therapy-based approaches to treatment of diseases, including any required pretreatment conditioning regimens, the existence of competitive clinical trials for similar patient populations.

In addition, we may not be able to identify, recruit and enroll a sufficient number of patients due to the existence of efficacious alternative treatments, the size of the patient population and process for identifying subjects, the design of the trial protocol, the exclusion/inclusion criteria that we are currently targeting may limit the pool of patients that may be enrolled in our ongoing or planned clinical trials, the proximity and availability of clinical trial sites for prospective subjects and the patient referral practices of physicians; the ability to obtain and maintain subject consent; the risk that enrolled subjects will drop out before completion of the trial.

In addition, the evolving COVID-19 pandemic may directly or indirectly impact the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices due to a health emergency and clinical trial staff can no longer get to the clinic. Additionally, such facilities and offices have been and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, thereby decreasing availability, in whole or in part, for clinical trial services. See "Risks Related to Our Business Operations – We face business disruption and related risks resulting from the recent outbreak of COVID-19, which could have a material adverse effect on our business and results of operations" for additional information.

If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential product candidates will be delayed.

If we experience delays in the commencement or completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product candidate revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product candidate sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The results of clinical trials conducted at clinical sites outside the United States may not be accepted by the FDA and the results of clinical trials conducted at clinical sites in the United States may not be accepted by international regulatory authorities.

To date our only ongoing recruiting clinical trial has been conducted in Europe but we are planning to globally develop Temferon, including in the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with, GCPs, ethical principles such as or IRB or ethics committee approval and informed consent. Generally, the subject population for any clinical trials conducted outside of the United States must be representative of the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance the FDA or international regulatory authorities will accept data from trials conducted outside of the location in which each regulatory authority is based as adequate support of a marketing application in a given jurisdiction. If the FDA does not accept the data from sites in our globally conducted clinical trials, or if international regulatory authorities do not accept the data from our U.S. clinical trials, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt the development of one or more of our product candidates.

Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country including the United States, is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with contract research organizations, or CROs, and physicians;
- different standards for the conduct of clinical trials;
- the absence in some countries of established groups with sufficient regulatory expertise for review of gene therapy protocols;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or delays in transferring that process to commercial partners, which may prevent us from initiating, completing or expanding our clinical trials or commercializing our products, if any, on a timely or profitable basis, if at all. For example, the anticipated transition of our cell processing to a different commercial partner in the U.S., or to a commercial partner(s) relying on automated closed system, if available, using all disposable supplies would require regulatory approvals, may not be successful or may experience unforeseen delays, which may cause shortages or delays in the supply of our products available for clinical trials and future commercial sales, if any. In addition, there is no assurance that products manufactured using a different commercial partner or an automated closed system, if and when available, will achieve the same results observed to date in Temferon clinical and preclinical and non-clinical studies. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing such as comparability studies, FDA or EMA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Even if we complete the necessary preclinical and clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate and the approval may be for a more narrow indication than we seek.

We cannot commercialize a product until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates demonstrate safety and efficacy in preclinical and clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Additional delays may result if an FDA Advisory Committee or other regulatory authority does not recommend approval or recommends restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. If we are unable to obtain necessary regulatory approvals, our business, prospects, financial condition and results of operations may suffer.

We may seek designations for our product candidates with the FDA and other comparable regulatory authorities that are intended to confer benefits such as a faster development process or an accelerated regulatory pathway, but there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA, and other comparable regulatory authorities, offer certain designations for product candidates that are intended to encourage the research and development of pharmaceutical and biotechnology products addressing conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. There can be no assurance that we will successfully obtain such designation for Temferon. In addition, while such designations could expedite the development or approval process, they do not change the standards for approval. Even if we obtain such designations for one or more of our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Breakthrough Therapy Designation from the FDA for one or more of our product candidates. A Breakthrough Therapy Designation is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, if preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have Breakthrough Therapy Designation, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies with Breakthrough Therapy Designation from the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for Breakthrough Therapy Designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for Breakthrough Therapy Designation, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

We may also seek Fast Track Designation from the FDA for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide assurance of ultimate FDA approval. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

In addition, we may seek a regenerative medicine advanced therapy, or RMAT, designation for some of our product candidates. An RMAT is defined as a cell therapy, therapeutic tissue engineering products, human cell and tissue products, or any combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine therapy. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates that the candidate has potential to address unmet medical needs for such disease or condition. A new drug application or a BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. RMAT designation is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a regenerative medicine advanced therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as for RMAT designation, the FDA may later decide that the biological products no longer meet the conditions for qualification.

We may seek a conditional marketing authorization in Europe for some or all of our current product candidates, but we may not be able to obtain or maintain such designation.

As part of its marketing authorization process, the EMA may grant marketing authorizations for certain categories of medicinal products on the basis of less complete data than is normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required or in the interests of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use, or CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product is positive;
- the applicant will provide the comprehensive clinical data post-authorization;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing trials or to conduct new trials with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

Granting a conditional marketing authorization allows medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product is generated, submitted, assessed and acted upon. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied and hence delay the commercialization of our product candidates.

We may be unable to obtain orphan drug designation for our product candidates and, even if we obtain such designation, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

Regulatory authorities in some jurisdictions, including the United States and EU, may designate drugs for relatively small patient populations as "orphan drugs." Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States or a patient population of 200,000 or more individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the European Commission grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biologic product. In either case, the applicant for orphan designation must also demonstrate that no satisfactory method of diagnosis, prevention, or treatment for the condition has been authorized (or, if a method exists, the new product would be a significant benefit to those affected compared to the product available).

If we request orphan drug designation (or the international equivalent) for Temferon or any of our other product candidates, there can be no assurances that the FDA or international regulatory authorities will grant any of our product candidates such designation. This designation of a product candidate as an orphan product does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates prior to our product candidates receiving exclusive marketing approval.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication for that time period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the applicable exclusivity period. The applicable period is seven years in the United States and ten years in the EU. The exclusivity period in the EU can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same indication. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;

- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

Even if we obtain and maintain regulatory approval for a product candidate, our products will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates also may be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, as noted above in the United States, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. FDA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events for as long as 15 years. The holder of an approved marketing application also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA or comparable foreign regulatory authorities, Department of Justice, Department of Health and Human Services', or HHS, Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our current product candidates and any future product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA or a comparable foreign regulatory authority's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we and any third parties engaged on our behalf are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted any of our current product candidates and any future product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the European Union, the advertising and promotion of our products are subject to European Union laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising, and unfair commercial practices. In addition, other legislation adopted by individual European Union Member States may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising for medicinal products are consistent with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the European Union. The applicable laws at European Union level and in the individual European Union Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the European Union could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public, and may also impose limitations on our promotional activities with health care professionals.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or GMP, requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements, a regulatory authority may:

- issue an untitled letter or warning letter that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;

- suspend any ongoing clinical trials;
- refuse to approve BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the products or require the withdrawal of the product from the market;
- refuse to permit the import or export of the products; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

In addition, the FDA's policies, and those of the EMA and other regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations and prospects.

Both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual European Union Member States both before and after grant of the manufacturing and marketing authorizations. This includes control of compliance with GMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third-party manufacturers would be required to ensure that all of our processes, quality systems, methods, and equipment are compliant with GMP. Failure by us or by any of our third-party partners, including suppliers, manufacturers, and distributors to comply with European Union laws and the related national laws of individual European Union Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, both before and after grant of marketing authorization, and marketing of such products following grant of authorization may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties. operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

In addition, European Union legislation related to pharmacovigilance, or the assessment and monitoring of the safety of medicinal products, provides that EMA and the competent authorities of the European Union Member States have the authority to require companies to conduct additional post-approval clinical efficacy and safety studies. The legislation also governs the obligations of marketing authorization holders with respect to additional monitoring, adverse event management and reporting. Under the pharmacovigilance legislation and its related regulations and guidelines, we may be required to conduct a burdensome collection of data regarding the risks and benefits of marketed products and may be required to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical trials, which may be time-consuming and expensive and could impact our profitability. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

We do not have sales, distribution, and marketing capabilities. If we are unable to develop these capabilities or enter into agreements with third parties to market and sell Temferon and our other product candidates, we will be unable to generate any product revenue.

We currently have no sales, distribution or marketing organization. To successfully commercialize any of our current or future product candidates, if approved, we will need to develop these capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may enter into collaborations regarding any approved product candidates with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates, if approved. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

The commercial success of Temferon will depend upon the acceptance of each product by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of any approved product will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to available therapies;
- the convenience and ease of administration compared to alternative treatments;
- limitations or warnings, including use restrictions contained in the product's approved labeling;
- distribution and use restrictions imposed by the FDA, the EMA or other regulatory authority or agreed to by us as part of a mandatory or voluntary risk management plan;
- availability of alternative treatments, including competitive products expected to be commercially launched in the near future;
- pricing and cost effectiveness in relation to alternative treatments;
- if the product is included under physician treatment guidelines as a first-, second,- or third-line therapy;
- the strength of sales, marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors;
- the strength of sales, marketing and distribution support;
- the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage; and

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies.

If Temferon is approved but does not achieve an adequate level of acceptance by physicians, third party payors and patients, we may not generate sufficient revenue from the product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of the product may require significant resources and may never be successful.

In addition, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. Depending on the nature of the third-party relationship, we may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, any of which could harm our business.

Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and impact reimbursement levels.

Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if and when we will obtain an adequate level of reimbursement for our products by third party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval, and the royalties resulting from the sales of those products may also be adversely impacted.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be reimbursed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription drug pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary or cost-effective for a specific indication, or that coverage or an adequate level of reimbursement will be available.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Our failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding clinical trial design, safety and efficacy. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drugs are subject to extensive regulation by the FDA in the United States and other regulatory authorities in other countries. These regulations differ from country to country. Even if we obtain and maintain regulatory approval of our product candidates in one jurisdiction, such approval does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries.

Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional non-clinical studies or clinical trials as investigations conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. These regulatory procedures can result in substantial delays in such countries. In other countries, product approval depends on showing superiority to an approved alternative therapy. This can result in significant expense for conducting complex clinical trials.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by the EMA or other regulatory authorities in other countries or jurisdictions, and approval by the EMA or another regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. We intend to submit an MAA to the EMA for approval of our product candidates in the European Union but obtaining such approval from the European Commission following the opinion of EMA is a lengthy and expensive process. Even if a product candidate is approved, the FDA or the European Commission may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Finally, we do not have any products approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval. If we, or any third parties with whom we work, fail to comply with regulatory requirements in United States or international markets or to obtain and maintain required approvals or if regulatory approvals in international markets are delayed, our target market may be reduced and our ability to realize the full market potential of our products will likely be harmed. The inability to meet continuously evolving regulatory standards for approval may result in our failing to obtain regulatory approval to market our current product candidates, which could significantly harm our business, results of operations and prospects.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as "Brexit." On March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty and the withdrawal of the United Kingdom from the EU took effect on January 31, 2020. There was a transition period, during which EU pharmaceutical law remained applicable in the United Kingdom, however this ended on December 31, 2020. Since a significant proportion of the regulatory framework governing the development and commercialization of medicinal products in the United Kingdom is derived from EU Directives and Regulations, Brexit, now that the transition period is over, could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU, as United Kingdom legislation now has the potential to diverge from EU legislation. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and materially harm our business.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of cancer. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates noncompetitive and obsolete.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance, which may render our treatments obsolete or noncompetitive. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain EMA, FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position for either the product or a specific indication before we are able to enter the market.

Our product candidates may face competition sooner than anticipated from biosimilar products.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, our product candidates may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

There is a risk that any exclusivity we may be afforded if any of our product candidates are approved as a biologic product under a BLA could be shortened due to congressional action, the results of recent litigation, or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic or biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In addition, critics of the 12-year exclusivity period in the biosimilar pathway law will likely continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. In December 2019, the US agreed to remove from the United States-Mexico-Canada Agreement a requirement for at least 10 years of data exclusivity for biologic products. Also, the FDA is considering whether subsequent changes to a licensed biologic would be protected by the remainder of the reference product's original 12-year exclusivity period (a concept known in the generic drug context as "umbrella exclusivity"). If the FDA were to decide that umbrella exclusivity does not apply to biological reference products or were to make other changes to the exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, legislative and regulatory efforts to promote competition through policies enabling easier generic and biosimilar approval and commercialization, including efforts to lower standards for demonstrating biosimilarity or interchangeability, limit patents that may be litigated and/or patent settlements and implement preferential reimbursement policies for biosimilars.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In the EEA, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of marketing exclusivity. Data exclusivity prevents biosimilar applicants from referencing the innovator's preclinical and clinical trial data when applying for a biosimilar marketing authorization, during a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no biosimilar product can be marketed until the expiration of the market exclusivity period. This 10-year marketing exclusivity period may be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. However, even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an application with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

If product liability lawsuits are brought against us, we may incur substantial liabilities, even if we have appropriate insurance policies, and we may be required to limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical and biotechnology products. Currently, we have no products that have been approved for marketing or commercialization; however, the use of our product candidates in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers, biotechnology and pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities, even if we have product liability or such other applicable insurance policies in effect. We may not be able to maintain adequate levels of insurance for these liabilities at reasonable cost and/or reasonable terms. Excessive insurance costs or uninsured claims would add to our future operating expenses and adversely affect our financial condition. As a result of such lawsuits and their potential results, we may be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and negative media attention;
- product recalls or increased warnings on product labels;
- withdrawal of clinical trial participants;
- costs of to defend the related litigation;
- diversion of management and our resources;
- substantial monetary awards to, or costly settlements with, clinical trial participants, patients or other claimants;
- higher insurance premiums;
- loss of initiation of investigations by regulators or other authorities; and
- the inability to successfully commercialize our product candidates, if approved.

Gene therapies are novel, complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs or otherwise adversely affect our business.

Biological products are inherently difficult to manufacture, and gene therapy products are complex biological products, the development and manufacture of which necessitates substantial expertise and capital investment.

Temferon is individually manufactured for each patient using complex processes in specialized facilities. Our production process requires a variety of raw materials, some of which are highly specialized, including the viral vector that encodes for the therapeutic payload. Some of these raw materials have limited and, in some cases, sole suppliers. Even though we plan to have back-up supplies of raw materials whenever possible, we cannot be certain such supplies will be sufficient if our primary sources are unavailable. A shortage of a critical raw material or a technical issue during manufacturing may lead to delays in clinical development or commercialization of our product candidates.

Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers. We have limited experience manufacturing our product candidates. We have contracted with a third party CMO for the manufacture of our viral vectors and drug product for clinical trials. We expect this CMO will be capable of providing sufficient quantities of our viral vectors and gene therapy products to meet the anticipated scales for our clinical trials, in due course, and commercial demands, if approved. However, to meet our projected needs for further commercial manufacturing and large scale clinical trials, third parties with whom we currently work might need to increase their scale and frequency of production, and we will likely need to secure alternate suppliers or develop our own capabilities. We believe that there are alternate sources of supply that can satisfy our requirements, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs.

In addition, two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

All manufacturers of pharmaceutical products must comply with strictly enforced requirements and complex regulations. Any failure by our CMO to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of our product candidate for clinical trials or result in sanctions, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of raw materials, product candidates or products, operating restrictions and criminal prosecutions, any of which could have significant adverse consequences on us. Our potential future dependence upon others for the manufacture of our gene therapies may also adversely affect our future profit margins and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis.

Delays in obtaining regulatory approval of our or our CMOs' manufacturing process and facility or disruptions in our manufacturing process may delay or disrupt our commercialization efforts.

Before we can begin to commercially manufacture our viral vector or product candidates in our own facility, or the facility of a CMO, we must obtain regulatory approval from the FDA for our manufacturing processes and for the facility in which manufacturing is performed. A manufacturing authorization must also be obtained from the appropriate European Union regulatory authorities. In addition, we must pass a pre-approval inspection of our or our CMOs manufacturing facility by the FDA and other relevant regulatory authorities before any of our gene therapy product candidates can obtain marketing approval. Since March 2020, foreign and domestic inspections by FDA have largely been on hold with FDA announcing plans in July 2020 to resume prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. In order to obtain approval, we will need to ensure that all of our processes, quality systems, methods, equipment policies and procedures are compliant with GMP, and perform extensive audits of vendors, contract laboratories, CMOs and suppliers. If any of our vendors, contract laboratories, CMOs or suppliers is found to be out of compliance with GMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The GMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with GMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any products that we may develop.

Failure to comply with ongoing regulatory requirements could cause us to suspend production or put in place costly or time-consuming remedial measures.

The regulatory authorities may, at any time following approval of a product for sale, audit the manufacturing facilities for such product. If any such inspection or audit identifies a failure to comply with applicable regulations, or if a violation of product specifications or applicable regulations occurs independent of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly or time-consuming to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a manufacturing facility. Any such remedial measures imposed upon our CMO or us could harm our business, financial condition, results of operations and prospects.

If our CMOs or we fail to comply with applicable GMP regulations, FDA and foreign regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate or suspension or revocation of a pre-existing approval. Such an occurrence may cause our business, financial condition, results of operations and prospects to be harmed.

Additionally, if supply from any CMO or us is delayed or interrupted, there could be a significant disruption in the clinical or commercial supply of our product candidates. We have agreements in place with our CMO pursuant to which we are collaborating on GMP manufacturing processes and analytical methods for the manufacture and release of our viral vectors and drug product. Therefore, if we are unable to enter into an agreement with our CMO to manufacture clinical or commercial material for our product programs, or if our agreement with our CMOs were terminated, we would have to find suitable alternative manufacturers. This could delay our or our collaborators' ability to conduct clinical trials or commercialize our current and future product candidates. The regulatory authorities also may require additional clinical trials and other nonclinical and or analytical evaluations if a new manufacturer is relied upon for clinical or commercial production. Switching manufacturers may involve substantial costs, require significant comparability studies and could result in a delay in our desired clinical and commercial timelines.

Any contamination in our manufacturing process, shortages of materials or failure of any of our key suppliers to deliver necessary components could result in interruption in the supply of our product candidates and delays in our clinical development or commercialization schedules.

Given the nature of biologics manufacturing, there is a risk of contamination in our manufacturing processes. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage.

Some of the materials required in our manufacturing process are derived from biologic sources. Such materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Patients' cellular source material must be transported from the clinical collection site to the manufacturing facility and the cryopreserved drug product must be returned to the clinical site for administration into the patient using controlled temperature shipping containers.

Once collected from the patient, the cellular source material must be transported to the manufacturing facility using a shipping container that maintains the material at a required temperature and be delivered typically within three days of collection. While we intend to use reputable couriers and agents for the transport of such materials, if the shipping container is opened or damaged such that the required temperature is not maintained, the cellular source material may be adversely impacted and it may not be feasible to manufacture a drug product for the patient. Similarly, if a shipment is delayed due to adverse weather, misrouting, other events or held up at a customs point, the cellular source material may not be delivered within a time window that will allow for its use for the successful manufacture of a drug product. Similarly, the patient's autologous drug product must be returned to the clinical site for administration into the patient using a specialized shipping container that maintains the material at a very low temperature for a period of typically up to ten days. While we intend to use reputable couriers and agents for the transport of our drug products, if the shipping container is opened or damaged such that the very low temperature is not maintained, the drug product may be adversely impacted and it may be unsuitable for administration to the patient or harmful. Similarly, if a shipment is delayed due to adverse weather, misrouting, held up at a customs point or other events, and is not delivered to the clinical site within the time period that the very low temperature is maintained, the drug product may be unsuitable for administration to the patient or harmful.

Our gene therapies are for autologous use only. Therefore, if a drug product is administered to the wrong patient, the patient could suffer harm.

Our gene therapies are autologous, so they must be administered back only to the patient from which the cellular source material was collected. While we implement specific identifiers, lot numbers and labels with cross checks for our products and operations from collection of cellular source material, through manufacture of drug product, transport of product to the clinical site up to thawing and administration of the product, it is possible that a product may be administered into the wrong patient. If an autologous gene therapies were to be administered into the wrong patient, the patient could suffer harm, including experiencing a severe adverse immune reaction and this event, should it happen, could adversely affect our business, financial condition, results of operations and prospects.

Our focus on developing our current product candidates may not yield any commercially viable products, and our failure to successfully identify and develop additional product candidates could impair our ability to grow.

As part of our growth strategy, we intend to identify, develop and market additional product candidates beyond our existing product candidate, namely Temferon. We may spend several years completing our development of any particular current or future product candidates, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential than Temferon or our other product candidates. Our spending on current and future research and development programs may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

In addition, certain of our current or future product candidates may not demonstrate in patients any or all of the pharmacological benefits we believe they may possess or compare favorably to existing, approved therapies. We have not yet succeeded and may never succeed in demonstrating efficacy and safety of our product candidates or any future product candidates in preclinical studies, clinical trials or in obtaining marketing approval thereafter and, therefore, may not result in the discovery and development of commercially viable products.

If we are unsuccessful in our development efforts, we may not be able to advance the development of our product candidates, commercialize products, raise capital, expand our business or continue our operations.

Risks Related to Our Reliance on Third Parties

We utilize, and expect to continue to utilize, third parties to conduct some or all aspects of our vector production and product manufacturing for the foreseeable future, and these third parties may not perform satisfactorily.

We currently rely on our CMO and for the production of our viral vectors and product candidate for our ongoing clinical trials and preclinical studies. For future clinical trials we intend to utilize materials manufactured by GMP-compliant CMOs. If our partners do not successfully carry out their contractual duties, meet expected deadlines or manufacture our viral vector and product candidates in accordance with regulatory requirements or if there are disagreements between us and our CMO, we will not be able to complete, or may be delayed in completing, the clinical trials required to support approval of our product candidates or the FDA, EMA or other regulatory agencies may refuse to accept our clinical or preclinical data. In such instances, we may need to enter into an appropriate replacement third-party relationship, which may not be readily available or available on acceptable terms, which would cause additional delay or increased expense prior to the approval of our product candidates and would thereby have a negative impact on our business, financial condition, results of operations and prospects.

We have partnered with a commercial GMP-compliant CMO and intend to utilize viral vectors and gene therapy products manufactured by such CMO for our future clinical trials and products for which we obtain marketing approval. There is no assurance that our CMO, or any other future third-party manufacturer that we engage, will be successful in producing any or all of our viral vector or product candidates, that any such product will, if required, pass the required comparability testing, or that any materials produced by any other third-party manufacturer that we engage will have the same effect in patients that we have observed to date. We believe that our manufacturing network will have sufficient capacity to meet demand for our clinical and existing and expected initial commercial needs, but there is a risk that if supplies are interrupted or result in poor yield or quality, it would materially harm our business. Additionally, if the gene therapy industry were to grow, we may encounter increasing competition for the raw materials and consumables necessary for the production of our product candidates. Furthermore, demand for CMO GMP manufacturing capabilities may grow at a faster rate than existing manufacturing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of our viral vectors or product candidates for future clinical trials or to meet expected initial commercial demand.

Under certain circumstances, our current CMO is entitled to terminate their engagements with us. If we need to enter into alternative arrangements, it could delay our development activities. Our reliance on our CMO for certain manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. In addition to our current CMO, we may rely on additional third parties to manufacture ingredients of our viral vectors and or drug product in the future and to perform quality testing, and reliance on these third parties entails risks including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize any of our product candidates. Some of these events could be the basis for FDA, EMA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

We rely on third parties to conduct our preclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not expect to independently conduct all aspects of our lentiviral vector protocol development, research and preclinical and clinical testing. We currently rely, and plan to continue to rely, upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. Pursuant to the OSR License Agreement, we agreed to use OSR as the primary site in any preclinical study or clinical trial (including all phases thereof) relating to any licensed products in the field of use, subject to OSR maintaining any required quality standards and providing its services on customary and reasonable terms and consistent with then-applicable market standards. We rely on these parties, including OSR, for execution of our preclinical and clinical studies, but we can only control limited aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current GMP, Good Clinical Practices, or GCP, and Good Laboratory Practices, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, the EMA or other comparable regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with product candidates which are produced under GMP regulations. These risks may be heightened as a result of the evolving COVID-19 pandemic due to difficulties in recruiting study subjects during times of travel restriction, delays in obtaining required regulatory inspections, and potential unavailability of our CROs due to their involvement with COVID-related development activities. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not meet regulatory requirements and have limited capacity.

Contract manufacturers and their facilities are required to comply with extensive regulatory requirements, including ensuring that quality control and manufacturing procedures conform to GMPs. These GMP regulations cover all aspects of manufacturing relating to our product candidates and components used in clinical studies. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational product candidates and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of an BLA or MAA on a timely basis and must adhere to GLP and GMP regulations enforced by the FDA and other regulatory authorities through their facilities inspection program. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the product candidates may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. Moreover, if our contract manufacturers fail to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or there are substantial manufacturing errors, this could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business.

We are dependent on a limited number of suppliers and, in some instances, a sole supplier, for some of our components and materials used in our product candidates.

We currently depend on a limited number of suppliers and, in some instances, a sole supplier, for some of the components and equipment necessary for the production of our viral vectors and drug product. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. Our use of a sole or a limited number of suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. There are, in general, relatively few alternative sources of supply for these components, and in some cases, no alternatives. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we are required to switch to a replacement supplier, the manufacture and delivery of our viral vectors and product candidates could be interrupted for an extended period, adversely affecting our business. Establishing additional or replacement suppliers may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. For example, the FDA or EMA could require additional supplemental data, manufacturing data and comparability data up to and including clinical trial data if we rely upon a new supplier. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. While we seek to maintain adequate inventory of the components and materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to conduct our clinical trials and, if our product candidates are approved, to meet the demand of our customers and cause them to cancel orders.

In addition, as part of the FDA's approval of our product candidates, the FDA must review and approve the individual components of our production process, which includes raw materials, the manufacturing processes and facilities of our suppliers. Some of our current suppliers have not undergone this process nor have they had any components included in any product approved by the FDA.

Our reliance on these suppliers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things:

- the interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- the inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- a delay in delivery due to our suppliers prioritizing other customer orders over ours;

- damage to our reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to conduct our clinical trials and, if our product candidates are approved, to meet demand for our products could be impacted.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

We may seek collaboration arrangements with biotechnology or pharmaceutical companies for the development or commercialization of our current and potential future product candidates. We may enter into these arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with other biotechnology or pharmaceutical companies for each product candidate, both in the United States and internationally. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so choose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with biotechnology or pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or otherwise disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our principal investigators, physicians and academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Intellectual Property

We depend on license agreements with OSR to permit us to use patents and patent applications, as well as to exploit specific OSR know-how. Termination of these rights or the failure to comply with obligations under these agreements could materially harm our business and prevent us from developing or commercializing our product candidates (Temferon in particular).

We are party to a license agreement with OSR under which we were granted rights to patents and patent applications, as well as proprietary technologies, that are important and necessary to our business, including our Temferon based product candidates. Our rights to use these patents and patent applications and employ the inventions claimed in these licensed patents, as well as the exploitation of OSR proprietary technology, are subject to the continuation of, and our compliance with, the terms of our license agreement.

Our license agreement with OSR imposes upon us various diligence, payment and other obligations, including the following:

- our obligation to pay OSR various milestone payments in the aggregate amount of up to €10 million related to the Lympho-Hematopoietic Indication of each Licensed Product and up to €53 million related to each Solid Cancer indication, contingent upon our achievement of certain late-stage regulatory and sales milestones with respect to use of Temferon for GBM, and additional amounts for milestones with other solid cancer indications upon exercising those rights. However, starting with the fifth Solid Cancer indication, the first two related milestone payments totaling €7.0 million are reduced to €3.5 million.
- our obligation to pay OSR royalties based on net sales of each licensed product that we commercialize under the agreement.
- our obligation to pay a percentage of income derived from sublicensees for each licensed product sublicensed under the agreement.
- our obligation to pay fees associated with the prosecution, maintenance, or filing of the patents and patent applications we have licensed.

If we fail to comply with any of our obligations under the OSR license agreement, or we are subject to a bankruptcy or dissolution, OSR may have the right to terminate the license agreement, in which event we would not be able to market any product candidates covered by the license.

We do not currently own any patents, and we are heavily reliant upon license from OSR to certain patent rights that are important or necessary to the development of our technology and product candidates, including the patents relating to Temferon. Our license is exclusive only to specific fields of use, namely: GBM, solid liver cancer and any lympho-hematopoietic indication. Although we have exclusive option rights to license additional fields of use, or indications, upon the payment of additional fees to OSR, there is no guarantee that we will be in a position to do so within the time period specified to exercise such right. As a result, we may not be able to prevent competitors from developing and commercializing competitive products.

We do not control the prosecution, maintenance, or filing of the patents and patent applications that are licensed to us under the OSR license agreement (unless OSR chooses i) not to file and/or prosecute certain patent applications, or ii) to abandon such patent application and issued patents, in which cases we have the right to – at our expense – file, prosecute and/or maintain such patent applications), or the enforcement of these patents and patent applications against infringement by third parties. Thus, these patents and patent applications were not drafted by us or our attorneys, and we do not control or have any input into the prosecution of these patents and patent applications. We cannot be certain that drafting or prosecution of the patents and patent applications licensed to us has been conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. OSR controls the preparation, filing and prosecution of patent applications, and is responsible for maintaining the patents, covering technology that we license.

Pursuant to our license, we are required to file an IND regarding Temferon for GBM prior to February 2022. If we fail to comply with the obligations under our license agreement, including as a result of COVID-19 impacting our operations or due to lack of funds, or if we use the licensed intellectual property in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidates covered by our agreement and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

Disputes may arise regarding intellectual property subject to, and any of our rights and obligations under, any license or other strategic agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or violate the intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights to third parties under any such agreement or collaborative relationships;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights.

In addition, if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to seek alternative options, such as developing new product candidates with design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

We have been granted licenses in certain fields of use to patent applications. There can be no assurance that any of the patent applications that we have licenses to will result in issued patents. As a result, our ability to protect our proprietary technology in the marketplace may be limited.

We have been granted licenses in certain fields of use to patent applications in many countries worldwide. These applications cover a range of areas including: applications relating, in general terms, to the use of gene vectors comprising a miRNA target sequence, and the use of gene vectors comprising an interferon-alpha transgene operably linked to a miRNA-130a or miRNA-126 target sequence. Unless and until the pending patent applications are issued, their protective scope is impossible to determine. It is also impossible to predict whether or how many of the patent applications will result in issued patents. Even if pending applications are issued, they may be issued with coverage significantly narrower than what is currently sought.

Our proprietary position for our product candidates currently depends in part upon licenses to patents protecting methods of use, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition of matter patent claims on the active pharmaceutical ingredient, or API, in pharmaceutical drug products are generally considered to be the favored form of intellectual property protection for pharmaceutical products, as such patents generally provide protection without regard to any particular method of use, manufacture or formulation of the API used. Method of use patent claims protect the use of a product for the specified method and dosing. These types of patent claims do not prevent a competitor or other third party from making and marketing an identical API for an indication that is outside the scope of the method claims or from developing a different dosing regimen. Moreover, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Even if patents are issued based on patent applications to which we have been granted a license, because the patent positions of pharmaceutical and biotechnology products are complex and uncertain, we cannot predict the scope and extent of patent protection for our product candidates.

Any patents that may be issued based on patent applications that we have been granted licenses to will not ensure sufficient protection with respect to our activities for a number of reasons, including without limitation the following:

- any issued patents may not be broad or strong enough to prevent competition from other gene therapy products including identical or similar products;
- if patents are not issued or if issued patents expire, there would be no protections against competitors making generic equivalents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be other patents existing, now or in the future, in the patent landscape for Temferon, or any other product candidates that we seek to commercialize or develop, if any, that will affect our freedom to operate;
- if patents that we have been granted licenses to are challenged, a court could determine that they are not valid or enforceable;
- a court could determine that a competitor’s technology or product does not infringe patents that we have been granted licenses to;
- patents to which we have been granted licenses could irretrievably lapse due to failure to pay fees or otherwise comply with regulations, or could be subject to compulsory licensing; and
- if we encounter delays in our development or clinical trials, the period of time during which we could market our products under patent protection would be reduced.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the United States Patent and Trademark Office (USPTO) and foreign Intellectual Property Offices in several stages over the term of the patent. Maintenance fees are also due for pending patent applications in some countries. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The life of patent protection is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly with us after the patent licensed to us expires, which could materially and adversely affect our ability to commercialize our products and technologies.

The life of a patent and the protection it affords is limited. For example, in the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. In Europe, the expiration of an invention patent is 20 years from its filing date. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of the patents underlying our technology in court or before a patent office, and the patent holder may not be successful in enforcing or defending those intellectual property rights and, as a result, we may not be able to develop or market the relevant product candidate exclusively, which would materially adversely affect any potential sales of that product.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, the patents and patent applications licensed to us may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that the patents involved are eligible for certain (and time-limited) patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to such patents, or may grant more limited extensions than requested. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of the U.S. patents licensed to us may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested. If we are unable to obtain patent term extension or term of any such extension is less than requested, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The patents and pending patent applications licensed to us for our product candidates are expected to expire on various dates as described in “Business—Intellectual Property.” Upon the expiration, we will not be able to assert such licensed patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms or at all.

There may be intellectual property rights existing now, or in the future, relevant to Temferon, or any other product candidates that we seek to commercialize or develop, if any, that may affect our ability to commercialize such product candidates. Although the Company is not aware of any such intellectual property rights, a third-party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. Even if all our main product candidates are covered by patents, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, our business could be harmed.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

In addition to the possibility of litigation relating to infringement claims asserted against it, we may become a party to other patent litigation and other proceedings, including *inter partes* review proceedings, post-grant review proceedings, derivation proceedings declared by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future technologies or product candidates or products. Pursuant to the OSR License Agreement, OSR has the right to enforce the patents at its own expense. However, if OSR fails to do so, we have the right to enforce the licensed patents in the field of use, at our expense. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Competitors may infringe or otherwise violate our intellectual property, including patents that may issue to or be licensed by us. As a result, we may be required to file claims in an effort to stop third-party infringement or unauthorized use. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights, and/or that any of our IP, including licensed IP, is invalid and/or unenforceable. This can be prohibitively expensive, particularly for a company of our size, and time-consuming, and even if we are successful, any award of monetary damages or other remedy we may receive may not be commercially valuable. In addition, in an infringement proceeding, a court may decide that our asserted intellectual property is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our intellectual property does not cover its technology. An adverse determination in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

If the breadth or strength of our patent or other intellectual property rights is compromised or threatened, it could allow third parties to exploit and, in particular, commercialize our technology or products or result in our inability to exploit and/or commercialize our technology and products without infringing third-party intellectual property rights. Further, third parties may be dissuaded from collaborating with us.

Interference or derivation proceedings brought by the USPTO or its foreign counterparts may be necessary to determine the priority of inventions with respect to our patent applications, and we may also become involved in other proceedings, such as re-examination proceedings, before the USPTO or its foreign counterparts. Due to the substantial competition in the pharmaceutical space, the number of such proceedings may increase. This could delay the prosecution of our pending patent applications or impact the validity and enforceability of any future patents that we may obtain. In addition, any such litigation, submission or proceeding may be resolved adversely to us and, even if successful, may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation, even if some jurisdictions have specific rules so as to maintain confidentiality during the proceedings. Moreover, intellectual property law relating to the fields in which we operate is still evolving and, consequently, patent and other intellectual property rights in our industry are subject to change and are often uncertain. We may not prevail in any of these suits or other efforts to protect our technology, and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of this type of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock and negatively impact our ability to raise additional funds. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks, including Temferon, as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. Other than Temferon, which we have registered in the EU and the U.S., we have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for any other of our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our clinical-stage product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. The EMA may also object to our proposed proprietary product name that infringes the existing rights of third parties.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

We may not be able to enforce intellectual property rights throughout the world.

Filing, prosecuting, and defending patent applications and issued patents on product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights that we have been granted licenses to in some countries outside the United States and Italy can be less extensive than those in the United States and Italy. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as laws in the United States and Italy. Consequently, we may not be able to seek to prevent third parties from practicing inventions that are the subject of patents that we have been granted licenses to in all countries outside the United States and Italy, or from selling or importing products made using inventions that are the subject of patents that we have been granted licenses to in and into the United States or other jurisdictions. Competitors, for example, may use technologies that are the subject of patents that we have been granted licenses to in jurisdictions where we have not licensed patents to develop their own products and further, may export otherwise infringing products to territories where we have been granted licenses to patents, but enforcement is not as strong as that in the United States and Italy.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of patents that we have been granted licenses to or marketing of competing products in violation of our proprietary rights generally. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. Proceedings to enforce patent rights that we have been granted licenses to in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put patents that we have been granted licenses to at risk of being invalidated or interpreted narrowly and patent applications that we have been granted licenses to at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights that we have been granted licenses to around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to maintain effective proprietary rights for our product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by any issued patents to which we have been granted licenses and future patents that may be granted, our license agreement with OSR provides rights to access know-how, or trade secrets. We seek to preserve the integrity and confidentiality of our data, trade secrets and intellectual property by maintaining physical security of our premises and physical and electronic security of our information technology systems, as well as by entering into confidentiality agreements. Agreements or security measures may be breached or could expire, and we may not have adequate remedies for any breach and/or expiration. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

We cannot provide any assurances that trade secrets and other confidential proprietary information will not be disclosed in violation of confidentiality agreements or that competitors will not otherwise gain access to trade secrets or independently develop substantially equivalent information and techniques. Also, misappropriation or unauthorized and unavoidable disclosure of trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain trade secrets and intellectual property are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our platform technology without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such judicial litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology or use of our technology does not infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing, which is referred to as the priority date in cases where priority is claimed. Therefore, patent applications covering our technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our technology.

In March 2013, the United States transitioned to a 'first to file' system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art prior to the issuance of a patent by the USPTO and may become involved in post-grant review or derivation proceedings for applications filed on or after March 16, 2013, interference proceedings for applications filed before March 16, 2013, *ex parte* reexamination, or *inter partes* review challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could adversely affect our competitive position with respect to third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our technology, including *inter partes* review, interference, or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

We are aware of issued patents in the United States that cover the lentiviral vectors used in the manufacture of our product candidates.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our technology or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets, inventions or intellectual property rights of their current or former employers or claims asserting ownership of what we regard as intellectual property that we have been granted licenses to.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Our licensors may face similar risks, which could have an adverse impact on intellectual property that is licensed to us.

In this respect, our key people Mr. Luigi Naldini and Mr. Bernhard Gentner are also employees of Ospedale San Raffaele, and have been appointed, according to a consultancy agreement, as directors of our scientific committee for the purpose of designing and developing the preclinic research and clinic experimentation program in the area of cancers (Prof. Naldini) and mieloma (Dr. Gentner) gene therapy. The relevant consultancy agreements do not set forth any specific representation and warranty in our favor that their activities do not infringe any third-party's intellectual property rights (in particular, of OSR). In this respect, Mr. Naldini and Mr. Gentner have executed a statement whereby they have declared that their consultancy activities in our favor have been carried out by the same without infringing upon the intellectual property rights of OSR. OSR is not part of this statement and, therefore, OSR could in any case address claims against us with respect to an infringement of its intellectual property right by Mr. Naldini and Mr. Gentner in relation to their activity in our favor.

There may be claims challenging the inventorship of patents and other intellectual property that we have been granted licenses to.

There may be claims that former employees, collaborators or other third parties have an interest in patents or other intellectual property that we have been granted licenses to as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, there may be a loss of valuable intellectual property rights to us or our licensors, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. In addition, we may receive less revenue from future products if any of our employees successfully claim for compensation for their work in developing intellectual property, which in turn could impact our future profitability.

Under applicable employment laws, we may not be able to prevent our employees or key consultants, after the termination of their relationship with us or - with reference to key consultants - during the same, to perform competitive activity in favor of other companies nor to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of such employees or consultants. In addition, employees and consultants may be entitled to seek compensation for their inventions irrespective of their agreements with us.

To date, we have not entered into non-competition agreements with our current employees in order to prevent them, after the termination of their employment, to perform competitive activity in favor of other employers. Therefore, we cannot exclude that, after the termination of the employment, such employers may benefit from the expertise of our current employees developed while working for us. We sometimes enter into non-competition agreements with certain key consultants. These agreements prohibit key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our consultants work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former consultants developed while working for us. Under Italian law, a non-competition agreement could be invalidated if, for example, the geographic scope of the non-competition agreement is too broad, or, alternatively, such an agreement could be deemed by an Italian court to be an occupation ban. Such actions would make enforcing our non-competition agreements more challenging and could make it easier for our competitors to employ or benefit from the expertise of our key consultants. In addition, we cannot exclude that our current independent consultants may perform activities –during their relationship with us- which could result in competition / conflict with our activity (e.g., in case they perform their activity for the benefit of other employers or companies). Lastly, with reference to the key consultants with whom no non-competition agreement has been entered into, we cannot exclude that, after the termination of their relationship with us or during the same, other employers or companies may benefit from the expertise of such consultants developed while working for us.

In addition, under Italian law, if we wish to obtain ownership over inventions developed by our employees, which inventions were developed while performing their employment activities, but outside the performance of their contractual duties, we are required to compensate the employee for the rights to their respective inventions. Moreover, Italian law provides that, save for the case in which the inventive activity of the independent consultant has been set forth as the subject of the consulting agreement and compensated for this purpose, the rights to economically exploit the original contributions and inventions realized in the execution of the consulting agreement will belong to consultant. There can be no guarantee that we will be able to obtain any such inventions and the failure to obtain such ownership rights over employees' or independent consultants' inventions could have a material adverse effect on our operations and ability to effectively compete. In addition, employees and independent consultants may ask for a fair compensation due to such inventions.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- any product candidates we may develop will eventually become commercially available in generic or biosimilar product forms;
- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we may own or license now or in the future;
- we, or any future license partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license now or in the future;
- we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that pending patent applications currently licensed or those to which we may enter into a license regarding in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate the issued patents that have been licensed to us, or parts of such issued patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- issued patents to which we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- the claims of patent applications, if and when issued, may not cover our product candidates;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of license partners or current or future collaborators to the same extent as the laws of the United States;
- the inventors of our patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- we engage in scientific collaborations and will continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the patents of others may harm our business;
- we may not develop additional proprietary technologies that are patentable; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal, technical and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain.

Risks Related to Our Business Operations

As a company currently with substantial operations outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company with substantial operations in Italy, our business is subject to risks associated with conducting business outside the United States. Many of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;

- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- foreign exchange risks and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our share incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or by employees of third party contractors or consultants, individually or as part of class actions, including: (i) claims of wrongful terminations and payment of the related damages, (ii) discrimination, (iii) misclassification, (iv) claims for salary differences or for a different classification according to national collective bargaining agreement, (v) claims for the payment of social security charges or severance benefits, (vi) claims from suppliers' employees or external consultants such as, by way of example, claims for reclassification as employees, rather than independent contractors, or, as indicated above, requests for payment of salary / social security charges, (vii) any sanctions due to the above-mentioned obligations, (viii) or other violations of labor law or other alleged conduct;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

We manage our business through a small number of employees, key consultants and third-party contractors.

Our key people include our Chief Executive Officer and current Chairman, Pierluigi Paracchi, who co-founded our company in 2014 along with Luigi Naldini, our Executive Scientific Board Chairman, and Bernhard Gentner, a member of our Executive Scientific Board. Our other key people include Carlo Russo, our Chief Medical Officer & Head of Development, Richard Slansky, our Chief Financial Officer, Stefania Mazzoleni, our Scientific Project Manager and Communications Officer, Tiziana Magnani our Clinical Project Manager and Valentina Brambilla our Clinical Trials Administrator & Regulatory Expert. With the exception of Ms. Mazzoleni, Ms. Magnani and Ms. Brambilla, our key personnel are not (currently) engaged as full-time employees and we expect that some of these key personnel and other key personnel that join us after the completion of this offering will be engaged as full-time employees in the immediate future. Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees and key consultants. The loss of the services of our Chief Executive Officer or any of our key personnel or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Although we expect to enter into employment agreements with management, these agreements will likely be terminable at will with notice.

In addition, laws and regulations on executive compensation, including legislation in our home country, Italy, may restrict our ability to attract, motivate and retain the required level of qualified personnel.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific and technical consultants. In particular, the loss of one or more of our key personnel could be detrimental to us if we cannot recruit suitable replacements in a timely manner. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel, including in gene therapy research and vector manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical or clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or the loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives. We do not currently carry "key person" insurance on the lives of members of senior management. The competition for qualified personnel in the biotechnology and pharmaceutical fields is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

We face business disruption and related risks resulting from the recent outbreak of the COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of February 2021, has spread to over 200 countries and territories, including Italy and the United States. The spread of COVID-19 from China to other countries has resulted in the World Health Organization declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Authorities around the world have and may continue implementing similar restrictions on businesses and individuals in their jurisdictions. While COVID-19 is still spreading and the final implications of the pandemic are difficult to estimate at this stage, it is clear that it has affected the lives of a large portion of the global population, including significant infections in Italy and the United States.

Our operations and business have experienced disruption due to the unprecedented conditions surrounding the COVID-19 pandemic spreading throughout Italy and the world. There can be no assurance we will be able to enact any remedial measures that will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular. In addition, the impact of COVID-19 may cause delays to our preclinical studies and future clinical trials, and may make it difficult for us to enroll patients to clinical trials.

It is not possible at this time to estimate the full impact that the COVID-19 pandemic, the continued spread of COVID-19, and any additional measures taken by governments, health officials or by us in response to such spread, could have on our business, including the timing of our future clinical trials, results of operations and financial condition. The COVID-19 pandemic and mitigation measures have also negatively impacted global economic conditions, which, in turn, could adversely affect our business, including the timing of our future clinical trials, results of operations and financial condition. We continue to monitor our operations and government recommendations. A significant reduction in our workforce and our compliance with instructions imposed by Italian and other European authorities may harm our ability to continue operating our business and materially and adversely affect our operations and financial condition. Therefore, there can be no assurances that we will be able to immediately comply with all government regulations and we may be subject to authorities' inspections which may result, in case of non-compliance, in the application of sanctions (in the worst case, even the suspension of work activity). Moreover, we cannot foresee whether the Italian or other European authorities or the U.S. federal government will impose further restrictive instructions, which if implemented may lead to significant changes. The spread of COVID-19 may also result in the inability of our suppliers to deliver components or raw materials on a timely basis. The extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. See "*Risks Related to Product Development, Regulatory Approval and Commercialization – We may find it difficult to enroll patients in our clinical trials. Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates*" for additional information.

We will need to significantly increase the size of our organization, and we may experience difficulties in managing growth.

We currently have a very limited number of employees. If we are successful in executing our business strategy and in order to commercialize our products, if approved, we will need to substantially increase our operations, including expanding our employee base of managerial, operational and financial personnel. Any future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. To that end, we must be able to:

- manage our clinical trials and the regulatory process effectively;
- develop our administrative, accounting and management information systems and internal controls;
- hire and train additional qualified personnel; and
- integrate current and additional management, administrative, financial and sales and marketing personnel.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA, EMA or of other foreign regulatory authorities, provide accurate information to the FDA, EMA and other foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. in particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We plan to adopt a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, requires manufacturers of drugs, devices and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require biotechnology and pharmaceutical companies to comply with the biotechnology and pharmaceutical industries' voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers, and the European General Data Protection Regulation, or GDPR, which became effective in May 2018 and contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation, including companies like us that conduct clinical trials in the EU; we anticipate that over time we may expand our business operations to include additional operations in the EU and with such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR and all relevant data protection rulings and further legislation.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, disgorgement, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Efforts to ensure that our business arrangements comply with applicable healthcare laws and regulations, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a sweeping measure intended to, among other things, expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the law may affect us and increase certain of our costs.

In addition, other legislative changes have been adopted since the PPACA was enacted. These changes include aggregate reductions in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, following passage of the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the reimbursement our customers may receive for our products. Further, there have been, and there may continue to be, judicial and Congressional challenges to certain aspects of the PPACA. For example, the U.S. Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additional legislative and regulatory changes to the PPACA, its implementing regulations and guidance and its policies, remain possible. However, it remains unclear how any new legislation or regulation might affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

In addition, the delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in the price of our securities or limit our ability to raise capital or to enter into collaboration agreements for the further development and potential commercialization of our products.

The use of any of our product candidates could result in product liability or similar claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability or similar claims. The biotechnology and pharmaceutical industries has historically been litigious, and we face financial exposure to product liability or similar claims if the use of any of our products were to cause or contribute to injury or death. There is also the possibility that defects in the design or manufacture of any of our products might necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

Our internal information technology systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches or other unauthorized or improper access, which could result in a significant disruption of our product development programs, give rise to significant liability, subject us to costly and protracted litigation, cause significant reputational harm and impact our ability to operate our business effectively.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors and other contractors and consultants who have access to our confidential information.

Our internal information technology systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants may be vulnerable to a variety of disruptive elements, including data breaches, cyber-attacks by malicious third parties (including the deployment of computer viruses, harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures and persons with access to systems inside our organization. In particular, the risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. Because the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates or terrorist organizations, we and our partners may be unable to anticipate these techniques or implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of third parties that collect, process and store personal data on our behalf.

While we have not experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or a loss of, or damage to, our data or applications, or those of our third-party vendors and other collaborators, contractors and consultants, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other confidential, personal or proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, personal or proprietary information, we could incur significant liability, our competitive position could be harmed, our reputation could be damaged, and the further development and commercialization of our product candidates could be delayed.

Unauthorized disclosure of sensitive or confidential data, including personal information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, damage to our reputation and/or compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. The costs related to significant security breaches or disruptions could be material. If the information technology systems of our third-party vendors and other collaborators, contractors and consultants become subject to disruptions or security breaches, we may be exposed to material liability and have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Any of the foregoing could adversely affect our business, financial condition, results of operations or prospects.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business, financial condition, results of operations and prospects.

Unsuccessful compliance with certain European privacy regulations could have an adverse effect on our business and reputation.

The collection and use of personal health data in the EU is governed, as of May 2018, by the General Data Protection Regulation 2016/679 (GDPR) as implemented by European Data Protection Board (EDPB) guidelines and EU Member States national legislations. General EU data protection rules impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The GDPR also extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles and creates new obligations for companies and new rights for individuals. Failure to comply with the requirements of the GDPR, the EDPB guidelines and the related national data protection laws of the EU Member States may result in fines and other administrative penalties. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules, including violation of articles 44 to 49 GDPR related to transfer of personal data to a recipient in a non-EU country. The GDPR regulations impose additional responsibility and liability in relation to personal data that we process, and we intend to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. In addition, other jurisdictions, including Italy, have implemented regulations similar to GDPR. With regard to Italian legislation, the national Privacy and Data Protection Code has been amended according to GDPR provisions (Legislative Decree n. 196/2003 as amended and updated by Legislative Decree n. 101/2018) and imposes additional fines and administrative penalties in relation to the processing of health data and processing of data for scientific research purposes. Moreover, European data protection background is constantly changing under the drive of the European Data Protection Board (EDPB) on the correct interpretation and application of GDPR and the ruling activity of the Court of Justice of the European Union (see, for instance, the recent CJEU case C-3111/18, also known as Schremes II which invalidated the EU-US Privacy Shield Framework for transfer of data to United States).

The Company is compliant with most recent legislative changes in European data protection rules, adopting Data Processing Agreements containing Standard Contractual Clauses with all partners based in the United States and (for the transition period until June 2021) in the United Kingdom. However, changes to these European privacy regulations (and similar regulations in other jurisdictions) and unsuccessful compliance may be onerous and adversely affect our business, financial condition, prospects, results of operations and reputation.

Risks Related to this Offering and Ownership of Our Securities

An active trading market for the ADSs may not develop and you may not be able to resell the ADSs at or above the initial offering price, or at all.

This offering constitutes the initial public offering of the ADSs, and no public market has previously existed for the ADSs. Any delay in the commencement of trading of the ADSs on Nasdaq would impair the liquidity of the market for the ADSs and make it more difficult for holders to sell the ADSs. There can be no assurance that an active trading market for the ADSs will develop or be sustained after this offering is completed. The lack of an active trading market may also reduce the fair market value of the ADSs. The initial offering price was determined by negotiations among the lead underwriters and us. Among the factors considered in determining the initial public offering price were our future prospects and the prospects of our industry in general, our revenue, net income and certain other financial and operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. However, there can be no assurance that, following the completion of this offering, the ADSs will trade at a price equal to or greater than the initial public offering price.

Our management will have broad discretion as to the use of the net proceeds from this offering and may not use the proceeds effectively.

We currently intend to use the net proceeds of this offering for working capital and general corporate purposes, possible in licensing of additional intellectual property and product candidates, and next generation product development. See “Use of Proceeds.” However, our management will have broad discretion in the application of the net proceeds. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from this offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income. The decisions made by our management may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

If you purchase the ADSs in this offering, you will incur immediate and substantial dilution in the book value of the ADSs.

Because the price per ADS being offered is substantially higher than our net tangible book value per ADS, you will suffer substantial dilution in the net tangible book value of any ADSs you purchase in this offering. After giving effect to the sale by us of ADSs in this offering, based on an assumed public offering price of $ per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and offering expenses payable by us, our as adjusted net tangible book value of the ADSs would be approximately $ million, or approximately $ per ADS, as of December 31, 2020. If you purchase ADSs in this offering, you will suffer immediate and substantial dilution of our as adjusted net tangible book value of approximately $ per ADS. As a result of this dilution, investors purchasing shares in this offering may receive significantly less than the purchase price paid in this offering in the event of liquidation. See "Dilution" for additional information.

ADS representing a substantial percentage of our outstanding ordinary shares may be sold in this offering, which could cause the price of the ADSs to decline.

We may sell in this offering ADSs representing ordinary shares, or approximately %, of our outstanding ordinary shares as of , 2021. This sale and any future sales of a substantial number of ADSs in the public market, or the perception that such sales may occur, could materially adversely affect the price of the ADSs. We cannot predict the effect, if any, that market sales of those ADSs or the availability of those ADSs for sale will have on the market price of the ADSs. While the ADSs sold to non-affiliates in this offering will be freely tradable in the public market, substantially all of the securities owned prior to this offering or purchased in this offering by our existing shareholders are expected to be subject to lock-up agreements with the underwriters that restrict the ability of these shareholders to transfer our securities held by them for at least six months from the date of this prospectus. These outstanding securities that are subject to lock-up agreements are expected to become eligible for unrestricted sale upon expiration of the lock-up period. In addition, securities issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of securities by these shareholders could have a material adverse effect on the trading price of the ADSs.

We do not know what the trading price of the ADSs will be following this offering and as a result it may be difficult for you to sell the ADSs.

The trading price of the ADSs is likely to be volatile. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of the ADSs:

- adverse results or delays in pre- and non-clinical studies or clinical trials;
- reports of adverse events in other gene therapy products or clinical studies of such products;
- inability to obtain additional funding;
- inability to obtain the approvals necessary to commence clinical trials;
- unsatisfactory results of clinical trials;
- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;

- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to the treatment of cancer tumors, or any other indication that we may seek to develop;
- any adverse changes to our relationship with manufacturers or suppliers;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the biotechnology and pharmaceutical industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of, or involvement in, litigation;
- any major changes in our board of directors or management;
- our ability to recruit and retain qualified regulatory, research and development personnel;
- legislation in the United States relating to the sale or pricing of biotechnology or gene therapy products;
- the depth of the trading market in the ADSs;
- termination of the lock-up agreements or other restrictions limiting our ability or that of any of our existing shareholders to sell our securities (or any other securities that we may issue, if any) after this offering;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- business interruptions resulting from a local or worldwide pandemic, such as COVID-19, geopolitical actions, including war and terrorism, or natural disasters;
- the granting or exercise of employee stock options or other equity awards;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation; and
- changes in investors' and securities analysts' perception of the business risks and conditions of our business.

In addition, the stock market in general, and the Nasdaq Stock Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. Broad market and industry factors may negatively affect the market price of the ADSs, regardless of our actual operating performance. Further, a systemic decline in the financial markets and related factors beyond our control may cause our ADS price to decline rapidly and unexpectedly.

Holders of ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The Depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses and subject to the terms of the deposit agreement. You will receive these distributions in proportion to the number of ordinary shares the ADSs represent. However, in accordance with the limitations set forth in the deposit agreement the Depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend made in respect of deposited ordinary shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the Depositary may determine not to distribute such property and hold it as "deposited securities" or may distribute the net cash proceeds from the sale of the dividends. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the Depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the Depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the Depositary to exercise voting rights relating to the ordinary shares.

Holders of the ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the Deposit Agreement. When a shareholder meeting is convened, holders of ADSs may not receive sufficient notice of a shareholder meeting to permit them to cancel their ADSs and withdraw their ordinary shares to allow them to directly cast their vote with respect to any specific matter. In addition, the Depositary and its agents may not be able to send voting instructions to holders of ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the Depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the Depositary to vote their ordinary shares underlying their ADSs. Furthermore, the Depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ordinary shares underlying their ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholder meeting.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could augur less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our shares provides that owners and holders of ADSs, including those who purchase the ADSs in a secondary transaction, irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court in New York, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement, our shares and the ADSs and the transactions contemplated thereby. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement, our shares or the ADSs or the transactions contemplated thereby. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any owner or holder of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other owner or holder of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement, our shares or the ADSs or the transactions contemplated thereby, you or such other owner or holder may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary, lead to increased costs to bring a claim, limited access to information and other imbalances of resources between such owner or holder and us, or limit such holder's ability to bring a claim in a judicial forum that such holder finds favorable. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

We have identified material weaknesses in our internal control over financial reporting and, if our remediation of the material weaknesses is not effective or if we identify additional material weaknesses in the future, we may not be able to accurately or timely report our financial results, or prevent fraud, and investor confidence in our Company and the market price of our shares may be adversely affected.

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

To date, we have had limited financial and accounting personnel, which has resulted in a limited segregation of duties to fully execute our accounting processes and address our internal control over financial reporting. In connection with the audits of our financial statements as of and for the years ended December 31, 2020 and 2019, we identified certain material weaknesses in our internal control over financial reporting, including but not limited to our lack of adequate staff to: (i) process financial information in a timely manner; (ii) analyze and account for complex, non-routine transactions - including those subject to our critical accounting policies; and, (iii) maintain adequate segregation of duties; and, the lack of documentation related to our internal control over financial reporting including our policy over related party relationships and transactions.

We plan to take steps to address the internal control deficiencies that contributed to the material weaknesses, including the following:

- hiring of additional finance and accounting personnel with prior experience working for finance departments and technical accounting experience, supplemented by third-party resources;
- documenting and formally assessing our accounting and financial reporting policies and procedures; and
- increasing the use of third-party consultants in assessing significant accounting transactions and other technical accounting and financial reporting issues, preparing accounting memoranda addressing these issues and maintaining these memoranda in our corporate records.

While we believe that these efforts will improve our internal control over financial reporting, the implementation of these measures is ongoing and will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles. We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that these deficiencies or others could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis.

Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies amounting to material weaknesses may have been identified. If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

We may be subject to securities litigation, which is expensive and could divert management attention.

In the past, companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could seriously hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our Chief Executive Officer, directors and shareholders who own more than 5% of our outstanding ordinary shares before this offering currently own approximately % of our outstanding ordinary shares and will own approximately % of our ordinary shares upon the completion of this offering. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

After this offering, our Chief Executive Officer and directors, and shareholders who own more than 5% of our outstanding ordinary shares before this offering will, in the aggregate, beneficially own approximately % of our ordinary shares (assuming no exercise of the underwriters' over-allotment option). This significant concentration of share ownership may adversely affect the trading price for the ADSs because investors often perceive disadvantages in owning securities in companies with controlling shareholders. As a result, these shareholders, if they acted together, could significantly influence or even unilaterally approve matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders. Also, the concentration of our beneficial ownership may have the effect of delaying, deterring or preventing a change in our control, or may discourage bids for our shares at a premium over the market price of the shares. The significant concentration of share ownership may adversely affect the trading price of our ordinary shares due to investors' perception that conflicts of interest may exist or arise.

If we were to be characterized as a "passive foreign investment company" for U.S. tax purposes, U.S. holders of the ADSs could have adverse U.S. income tax consequences.

In general, we will be treated as a passive foreign investment company, or a PFIC, for U.S. federal income tax purposes in any taxable year in which either (1) at least 75% of our gross income is "passive income" or (2) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. We have not made the formal analysis necessary to determine whether or not we are currently a PFIC or whether we have ever been a PFIC, although based upon the general composition of our income and assets, and upon a review of our financial statements, we believe that we most likely are and have been a PFIC. The tests for determining PFIC status depend, in part, on the application of complex U.S. federal income tax rules, which are subject to differing interpretations. In addition, whether any corporation will be a PFIC for any taxable year depends on the assets and income of such corporation over the course of each such taxable year and, as a result, it is difficult to make accurate projections of future income and assets which are relevant to this determination for the current taxable year or any future period. If we are a PFIC in any taxable year during which a U.S. taxpayer holds the ADSs, such U.S. taxpayer would be subject to certain adverse U.S. federal income tax rules. In particular, if the U.S. taxpayer did not make a "mark-to-market" election, then "excess distributions" to the U.S. taxpayer, and any gain realized on the sale or other disposition of the ADSs by the U.S. taxpayer: (1) would be allocated ratably over the U.S. taxpayer's holding period for the ADSs; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the U.S. Internal Revenue Service, or the IRS, determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. taxpayer to make a timely QEF or mark-to-market election. U.S. taxpayers that have held the ADSs during a period when we were a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. taxpayer who made a timely mark-to-market election. U.S. taxpayers that hold the ADSs are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a mark-to-market election with respect to the ADSs in the event that we are a PFIC. See "Taxation —U.S. Federal Income Tax Consequences—Passive Foreign Investment Companies" for additional information.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our securities, our ADS price and trading volume could decline.

The trading market for the ADSs will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our securities, or provide more favorable relative recommendations about our competitors, our ADS price would likely decline. If any analyst who may cover us were to cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our ADS price or trading volume to decline.

We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.

We have never declared or paid cash dividends on our ordinary shares. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Consequently, investors may need to rely on sales of their ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Investors seeking cash dividends should not purchase the ADSs. Moreover, Italian law imposes certain restrictions on our ability to declare and pay dividends. In particular, Italian law prohibits distributing dividends other than from net income or distributable reserves set forth in a company's statutory accounts approved by a meeting of shareholders and after the establishment of certain compulsory reserves. In addition, if losses from previous fiscal years have reduced a company's capital, dividends may not be paid until the capital is reconstituted or its stated amount is reduced by the amount of such losses. The application of these restrictions limits our ability to make distributions to holders of our shares See "Dividend Policy" and "Description of Share Capital and Governing Documents—Dividends and Other Distributions" for additional information.

The requirements associated with being a public company will require significant company resources and management attention.

Following this offering, we will become subject to the reporting requirements of the Exchange Act, Nasdaq listing requirements and other applicable securities rules and regulations. The Exchange Act requires that we file periodic reports with respect to our business and financial condition and maintain effective disclosure controls and procedures and internal control over financial reporting. In addition, subsequent rules implemented by the SEC and the Nasdaq Stock Market may also impose various additional requirements on public companies. As a result, we will incur additional legal, accounting and other expenses that we did not incur as a nonpublic company, particularly after we are no longer an "emerging growth company" as defined in the JOBS Act. In the period following this offering, we estimate that these expenses will be at least several hundred thousand dollars annually. Further, the need to establish the corporate infrastructure demanded of a public company may divert management's attention from implementing our development plans. We have made changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to meet our reporting obligations. The measures we take, however, may not be sufficient to satisfy our obligations as a public company, which could subject us to delisting of our securities, fines, sanctions and other regulatory action and potentially civil litigation.

The JOBS Act allows us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our Company and adversely affect the market price of the ADSs.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various requirements that are applicable to public companies that are not "emerging growth companies" including:

- the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- Section 107 of the JOBS Act, which provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This means that an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay such adoption of new or revised accounting standards. As a result of this election, our financial statements may not be comparable to companies that comply with the public company effective date;
- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements; and
- our ability to furnish two rather than three years of income statements and statements of cash flows in various required filings.

We intend to take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the completion of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, as defined in the rule under the Exchange Act, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for the ADSs, and our ADS price may be more volatile and may decline.

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.

Our status as a foreign private issuer exempts us from compliance with certain SEC laws and regulations and certain regulations of the Nasdaq Stock Market, including the proxy rules, the short-swing profits recapture rules, and certain governance requirements such as independent director oversight of the nomination of directors and executive compensation. In addition, we will not be required under the Exchange Act to file current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we will generally be exempt from filing quarterly reports with the SEC. Furthermore, as a foreign private issuer, we are also not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you are entitled as an investor. See "Management – Differences between Italian Laws and Nasdaq Requirements" for additional information.

As a foreign private issuer, we are permitted, and intend, to phase-in our compliance with certain Nasdaq Listing Rules, as permitted by Nasdaq Listing Rule 5615(b)(1), instead of otherwise having to be in compliance with such rules as of the date of our initial listing on Nasdaq, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers and if we do not obtain compliance within the allotted time, we could become subject to delisting by Nasdaq.

In accordance with Nasdaq Listing Rule 5615(b)(1), as a foreign private issuer, we are permitted, and intend, to phase-in our compliance with certain Nasdaq Listing Rules, instead of otherwise having to be in compliance with such rules as of the date of our initial listing on Nasdaq. For instance, although we are a foreign private issuer and have opted into following our home country rules, which are the laws of the Italy, in lieu of following certain Nasdaq Listing Rules, we are still required to have an audit committee that satisfies Nasdaq Listing Rule 5605(c)(3) and ensure that such audit committee members meet the independence requirement in Nasdaq Listing Rule 5605(c)(2)(A)(ii), provided, however, that in light of Nasdaq Listing Rule 5615(b)(1), we have up to one year from the date of our listing to have an audit committee and members who meet such requirements. This phased-in period of compliance may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers and if we do not obtain compliance within the allotted time, we could become subject to delisting by Nasdaq.

We may become taxable in a jurisdiction other than Italy and this may increase the aggregate tax burden on us.

Since incorporation, we have, on a continuous basis, had our place of effective management in Italy. We are therefore a tax resident of Italy under Italian tax law. However, we may become subject to limited income tax liability in other countries with respect to our operations in other countries, for example, the United States, due to the existence of a permanent establishment or a permanent representative. The applicable tax laws or interpretations thereof may change. We have our place of effective management in Italy and, as such, we believe we are tax residents in Italy, although that determination is largely a matter of fact and degree based on all the circumstances, rather than a question of law, which facts and degree may also change. Changes to applicable laws or interpretations thereof and changes to applicable facts and circumstances (for example, a change of board members or the place where board meetings take place), may result in us becoming a tax resident of a jurisdiction other than Italy. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects. However, if there is a double tax treaty between Italy and the respective other country, double taxation of income may be avoided and the detrimental tax effects mitigated by the application of the treaty.

Risks Related to Italian Law and Our Operations in Italy

We are an Italian corporation. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are an Italian corporation. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in Italy. The rights of our shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and directors of companies governed by the laws of U.S. jurisdictions. While performing its duties, our board of directors is required by Italian law to act with the diligence required by the nature of their assignment and by their specific expertise. Italian corporate law limits the ability of our shareholders to challenge resolutions made or other actions taken by our board of directors in court. Our shareholders generally are not permitted to file a suit to reverse or void a decision or an action taken by our board of directors, except for those decisions that are detrimental to their rights. If a board resolution has not been taken in accordance with the Italian law or the company's articles of association, only the board of statutory auditors and the absent or dissenting members of the board of directors may challenge it within 90 days of such resolution. However, the shareholders may, where they represent the thresholds provided for by Italian law, bring corporate liability action against our directors where they have acted in violation of their duties of conduct. The individual shareholder may also take action for compensation for the damage directly caused to them by the director's conduct. Under Italian law, shareholders' claims against a member of our board of directors for breach of their duties of conduct must be filed in Milan, Italy, as the place where the company was incorporated. See "Share Capital Description and Reference Documents" and "Comparison between Delaware Law and Italian Law".

Our shares are not listed in Italy, our home jurisdiction. As a result, our shareholders will not benefit from certain provisions of Italian law that are designed to protect shareholders in a public takeover offer or a change-of-control transaction and may not be protected in the same degree in a public takeover offer or a change-of-control transaction as are shareholders of certain U.S. companies or in an Italian company listed in Italy.

Because the ADSs will be listed exclusively on Nasdaq and not in Italy's stock exchange, our shareholders will not benefit from the protection afforded by certain provisions of Italian law that are designed to protect shareholders in the event of a public takeover offer or a change-of-control transaction. For example, Article 120 of the Italian Financials' Consolidated Act and its implementing provisions require investors to disclose their interest in the relevant listed company if they reach, exceed or fall below certain ownership thresholds. Similarly, the Italian takeover regime imposes a duty on any person or group of persons who acquires more than the 30% of a company's voting rights (or the 25% if such company is not a small-medium enterprise, where there is no other shareholder holding a higher stake) to make a mandatory offer for all of the company's outstanding listed equity securities. In addition, the Italian takeover regime imposes certain restrictions and obligations on bidders in a voluntary public takeover offer that are designed to protect shareholders. However, these protections are applicable only to issuers that list their equity securities in Italy and, because the ADSs will be listed exclusively on Nasdaq, will not be applicable to us. Furthermore, since Italian law restricts our ability to implement rights plans or U.S.-style "poison pills," our ability to resist an unsolicited takeover attempt or to protect minority shareholders in the event of a change of control transaction may be limited. Therefore, our shareholders may not be protected in the same degree in a public takeover offer or a change-of-control transaction as are shareholders in certain U.S. companies or in an Italian company listed in Italy.

The process of seeking to raise additional funds is cumbersome, subject to the verification of an Italian notary public in compliance with our bylaws and applicable law and may require prior approval of our shareholders at an extraordinary shareholder meeting.

We are incorporated under the laws of the Republic of Italy. The principal laws and regulations that apply to our operations, those of Italy and the European Union, are different from those of the United States. With some exceptions, in order to issue new equity or debt securities convertible into equity, we must increase our authorized capital. In order to do so, our board of directors must meet and resolve to recommend that our shareholders approve an amendment to our bylaws increasing our capital. The holders of the majority of our outstanding shares must then approve that amendment at an extraordinary shareholder meeting duly called. These meetings take time to call and it might be very difficult to get a majority of the holders of all outstanding shares to vote in favor of the proposed resolution. In addition, an Italian notary public must verify that the capital increase is in compliance with our bylaws and with applicable Italian law. Further, under Italian law, our existing shareholders and any holders of convertible securities have preemptive rights (except in specific cases) to acquire any such shares pro-rated on their percentage interest in our company, and on the same terms as approved for such capital increase. Alternatively, our shareholders can delegate the power to increase our capital to the board of directors, but the board's right to exercise such power, if delegated, will expire after five years. If the board does not approve a capital increase by the end of those five years, our board and shareholders would need to meet again to re-delegate this authority.

With respect to shareholder resolutions approving a capital increase, Italian law provides that in the absence of meeting minutes, or in the event of the impossibility or illegality of the resolution, any interested person may, for a period of 180 days following the filing of the shareholder resolution with the competent Register of Companies, challenge such resolution. If a shareholder meeting was not called to approve the capital increase, the relevant resolution should be considered invalid and, any interested person may challenge the capital increase for a period of 90 days following the approval of the financial statements referring to the year during which the shareholder resolution has been, also partially, executed. In addition, once our shareholders authorize a capital increase, all those authorized shares that have been subscribed need to be entirely paid-up before the shareholders may perform/execute a new capital increase. These restrictions could limit our ability to issue new equity or convertible debt securities on a timely basis.

Italian law places restrictions on the amount of debt securities that we may issue relative to our equity to the extent that such debt securities are not listed on regulated markets or do not otherwise provide the holder of such securities the right to purchase or convert the same into our shares.

Under Italian law, we may issue debt securities in an amount not to exceed twice the sum of our capital, our legal reserve and any other disposable reserves appearing on our latest Italian GAAP balance sheet approved by our shareholders, unless the debt securities are listed on regulated markets or provide the holder of such securities the right to purchase or convert the same into our shares, in which case such restrictions do not apply. The legal reserve is a reserve to which we allocate 5% of our Italian GAAP net income each year until it equals at least 20% of our capital. One of the other reserves that we maintain on our balance sheet is a "share premium reserve," meaning amounts paid for our ordinary shares in excess of the amount of such ordinary shares that is allocated to the capital. At December 31, 2020, the sum of our capital, legal reserves and other reserves on our unaudited Italian GAAP financial statements was € million. If, in the future, we issue debt securities that are not listed on regulated markets or do not provide the holder of the securities the right to purchase or convert the same into our shares, until such debt securities are repaid in full, we may not voluntarily reduce our capital or allocate our reserves (such as by declaring dividends) if it results in the aggregate of the capital and reserves being less than half of the outstanding amount of the debt. In such a case, if our equity is reduced by losses or otherwise such that the amount of the outstanding debt securities is more than twice the amount of our equity, some legal scholars are of the opinion that the ratio must be restored through a recapitalization of our company. If our equity is reduced, we could recapitalize by issuing new shares or having our shareholders contribute additional capital to us, although there can be no assurance that we would be able to find purchasers of new shares or that any of our current shareholders would be willing to contribute additional capital.

If we suffer losses that reduce our capital to less than €50,000, we would need to recapitalize, change our form of entity or be liquidated.

Italian law requires us to reduce our shareholders' equity and, in particular, our capital, to reflect on-going losses, in certain cases of losses exceeding 1/3 of the capital of the company. Also, as an S.p.A., we are also required to maintain a minimum capital of €50,000. At December 31, 2020, our unaudited Italian GAAP capital was approximately € million. If we suffer losses from operations that reduce our capital to less than €50,000, then we must either increase our capital (which we could do by issuing new shares or having our shareholders contribute additional capital to our company) to at least €50,000 (or convert the form of our company into an S.r.l. but such conversion would not be applicable since the S.r.l. form is not consistent with being listed pursuant to Italian law). If we do not take these steps, our company could be liquidated.

We apply our operational losses against our legal reserves and capital. If our capital is reduced more than one-third as a result of losses, our board of directors must call a shareholder meeting as soon as possible. The shareholders should take appropriate measures, which may include, inter alia, reducing the legal reserves and capital by the amount of the remaining losses, or carrying the losses forward for up to one year. If the shareholders vote to carry the losses forward up to one year, and the losses are still more than one-third of the amount of the capital at the end of the year, then we must reduce our capital by the amount of the losses.

Italian labor laws could impair our flexibility to restructure our business.

In Italy, our employees are protected by various laws which afford them consultation rights with respect to specific matters regarding their employers' business and operations, including the downsizing or closure of facilities and employee terminations. In particular, among other applicable Italian laws: (i) Laws no. 604/1966, 300/1970 and 92/2012 regulate the individual dismissals; (ii) Law no. 223/1991, concerns the collective dismissal procedure; (iii) Law no. 428/1990 as amended by legislative decree no. 18/2001, provides for the information and consultation procedure in case of a transfer of the undertaking or a part thereof; (iv) Legislative decree no. 25/2007, introduces a general right to information and consultation for employees and (v) Legislative Decree no. 23/2015 regulates the consequences of individual dismissals with specific reference to the employees hired starting from March 7, 2015. In addition, due to COVID-19 emergency, various government decrees have introduced a specific ban on dismissals for objective reasons and collective dismissal procedures. These laws and the collective bargaining agreements to which we are subject could impair our flexibility if we need to restructure our business.

Purchasers of our Ordinary Shares and ADSs may be exposed to increased transaction costs as a result of the Italian financial transaction tax or the proposed European financial transaction tax.

On February 14, 2013, the European Commission adopted a proposal for a directive on the financial transaction tax ("EU FTT") to be implemented under the enhanced cooperation procedure by eleven Member States initially (Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Slovenia, Slovakia and Spain). Following Estonia's formal withdrawal on March 16, 2016, ten Member States are currently participating in the negotiations on the proposed directive. Member States may join or leave the group of participating Member States at later stages and, subject to an agreement being reached by the participating Member States, a final directive will be enacted. The participating Member States will then implement the directive in local legislation. If the proposed directive is adopted and implemented in local legislation, investors in Ordinary Shares and ADSs may be exposed to increased transaction costs.

The Italian financial transaction tax (the "IFTT") applies with respect to trades entailing the transfer of (i) shares or equity-like financial instruments issued by companies resident in Italy, such as the Ordinary Shares; and (ii) securities representing the shares and financial instruments under (i) above (including depositary receipts such as the ADSs), regardless of the residence of the issuer. The IFTT may also apply to the transfer of Ordinary Shares and ADSs by a U.S. resident. The IFTT does not apply to companies having an average market capitalization lower than €500 million in the month of November of the year preceding the year in which the trade takes place. In order to benefit from this exemption, companies whose securities are listed on a foreign regulated market, such as the Company, need to be included on a list published annually by the Italian Ministry of Economy and Finance. The Company is in the process of starting the relevant procedures to be included in such list by the end of 2020. For so long as the Company is not included in such list, investors in the Ordinary Shares and ADSs may be exposed to increased transaction costs. See "Taxation."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements made under "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this prospectus constitute forward- looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" "intends" or "continue," or the negative of these terms or other comparable terminology.

Forward-looking statements include, but are not limited to, statements about:

- the timing, progress and results of preclinical studies and clinical trials for our programs and product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the interactions with the regulatory bodies, key opinion leaders and partnering clinical centers that may result in changes to clinical trials and manufacturing programs;
- the timing, scope or likelihood of regulatory filings and approvals;
- our ability to develop and advance product candidates into, and successfully complete, clinical studies;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the implementation of our business model and our strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing and reimbursement of our product candidates, if approved;
- the scalability and commercial viability of our manufacturing methods and processes;
- the rate and degree of market acceptance and clinical utility of our product candidates, in particular, and gene therapy, in general;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our competitive position;
- the scope of protection we and/or our licensors are able to establish and maintain for intellectual property rights covering our product candidates;
- developments and projections relating to our competitors and our industry;
- our expectations related to the use of proceeds from this offering;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to remediate the material weaknesses that we and our independent registered public accounting firm identified and avoid any findings of material weaknesses or significant deficiencies in the future;

- the impact of laws and regulations;
- the ability of our management team to lead the development of our product candidates;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; and
- our expectations regarding the impact of the COVID-19 pandemic, including on our planned clinical trials, operations and financial position.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this prospectus in greater detail under the heading "Risk Factors" and elsewhere in this prospectus. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this prospectus.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ million, assuming an offering price of $ per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and offering expenses payable by us. If the underwriters exercise the over-allotment option in full, we estimate that the net proceeds from this offering will be approximately $ million, assuming an offering price of $ per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and offering expenses payable by us.

A $1.00 increase or decrease in the assumed public offering price of $ per ADS would increase or decrease the net proceeds from this offering by approximately $ million, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1,000,000 in the number of ADSs offered by us would increase or decrease our proceeds by approximately $ million, assuming the assumed public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. This information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing

We currently estimate that we will use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ million to conduct a clinical trial of Temferon in GBM patients in the United States;
- approximately $ million to support the ongoing Temferon TEM-GBM 001 trial and its long-term patient monitoring program;
- approximately $ million to start a new Temferon clinical program in a second solid tumor indication;
- approximately $ million to fund further preclinical research for the development of Temferon™ across broad cancer indications;
- approximately $ million to fund Temferon manufacturing activities, including LVV manufacturing, stability and process scalability studies and tech transfer activities; and
- the remainder to fund ongoing business development activities, general and administrative expenses, the costs of operating as a public company, working capital, and other general corporate purposes.

We believe that the expected net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to enable us to fund our operating expenses through at least the next 24-36 months, including expenses related to:

- the initiation of our US-based clinical trial;
- the completion of our ongoing Temferon TEM-GBM 001 trial, the reporting of preliminary results on exploratory endpoints and the start of the long-term monitoring program;
- the design of the second solid tumor indication program; and
- the advancement of the preclinical research activity on Temferon biological effects.

It is difficult to predict the cost and timing required to complete such trials due to, among other factors; the final study design, the timeline for regulatory agency approval, the rate of enrollment of patients, and/or the timing and costs of manufacturing and supplying our product candidates for our planned trials. Furthermore, we estimated our budget for US activities by referencing the rates we are paying to sites and third-party vendors involved in our ongoing programs in Italy, and subsequently applying an adjustment to those rates. Our estimated rates may change as a result of discussions with regulatory bodies, key opinion leaders and partnering clinical centers. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products and/or assets. Therefore, we cannot predict with certainty all of the particular uses of the net proceeds from the offering or the actual amounts that we will spend on the uses set forth above.

The expected net proceeds from this offering, together with our existing cash and cash equivalents, will only allow us to initiate our US-based clinical trial and complete our ongoing Temferon TEM-GBM 001 trial and will not be sufficient for us to fund certain manufacturing-associated activities needed to expand the Temferon programs in the United States and/or in Europe as well as any of our product candidates through regulatory approval. Accordingly, we will need to raise additional capital to complete the development and commercialization of our product candidates after the read out from our preclinical and clinical trials. Additional capital will also be needed prior to conducting clinical studies on our second solid tumor indication program as well as for continued advancement of the preclinical research activity on Temferon biological effects. We expect to finance our cash needs primarily through equity offerings and potentially through debt financings, collaborations, license and development agreements. We have based these estimates on assumptions that may prove to be incorrect, and we could expend our available capital resources at a rate greater than we currently expect.

The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our development and commercialization efforts, the status of and results from our clinical trials, whether or not we enter into strategic collaborations or partnerships and our operating costs and expenditures. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering.

Pending our use of the net proceeds from this offering, we may invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, and interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our shareholders, upon proposal by our board of directors, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Under Italian law, Italian companies are required to furnish certain information to the Italian tax authorities regarding the identity of non-resident shareholders in connection with the payment of dividends. Shareholders are required to provide their Italian tax identification number, if any, or alternatively, in the case of legal entities, their name, country of establishment and address, or in the case of individuals, their name, address and place and date of birth, or in the case of partnerships, the information required for individuals with respect to one of their representatives. Payment of dividends may be subject to Italian withholding taxes. See "Taxation—Italy Tax Considerations" for additional information. However, beneficial U.S. holders are entitled to a reduction of the withholding taxes applicable to dividends paid to them under the income tax convention for the avoidance of double taxation between the United States and Italy, which was signed on August 25, 1999 and went into effect on December 16, 2009 (the "Income Tax Convention"); provided, however, that conditions set out in the Income Tax Convention are met and subject to the applicable anti-avoidance provisions contained therein. In order for you to benefit from that reduction, we are required to furnish certain information about you to the Italian tax authorities and, therefore, any claim by you for those benefits would need to be accompanied by the required information.

CORPORATE CONVERSION

We currently operate as an Italian limited liability company under the name Genenta Science S.r.l. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part and following approval by the Quotaholders' Meeting of Genenta Science S.r.l., we will convert Genenta Science S.r.l. from a limited liability company to an Italian joint-stock company pursuant to Italian law and change its name to Genenta Science S.p.A. The purpose of the Corporate Conversion is to reorganize our corporate structure so that the entity that is offering ADSs to the public in this offering is a corporation rather than a limited liability company.

In conjunction with, and a result of, the Corporate Conversion, all of the quotas held by the existing quotaholders of the various classes of Genenta Science S.r.l. will be converted into an aggregate of 15,000,000 ordinary shares of Genenta Science S.p.A. The number of ordinary shares issuable to each quotaholder in connection with the Corporate Conversion will be determined pursuant to the applicable provisions of the plan of conversion approved by the Quotaholders Meeting of Genenta Science S.r.l. under Italian law and based on each quotaholder's percentage ownership of Genenta Science S.r.l.

As a result of the Corporate Conversion, Genenta Science S.p.A. will retain all of the properties and assets, all of the debts and obligations of Genenta Science S.r.l. Genenta Science S.p.A. will be governed by articles of association and bylaws (*Statuto*), the material provisions of which are described under the heading "Description of Share Capital and Governing Documents". On the effective date of the Corporate Conversion, each of our directors and executive officers will be the persons as described elsewhere in this prospectus. See "Management".

Except as otherwise noted herein, the financial statements included elsewhere in this prospectus are those of Genenta Science S.r.l. and its operations. We do not expect that the Corporate Conversion will have an effect on our results of operations.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2020:

- on an actual basis;
- on a pro forma basis to reflect the Corporate Conversion; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of ADSs in this offering at an assumed public offering price of $ per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and to the application of the net proceeds as described in "Use of Proceeds," as if the sale of the ADSs had occurred on December 31, 2020.

The pro forma as adjusted information set forth in the table below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

You should read this table in conjunction with the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	As of December 31, 2020		
in Euros, except share data	**Actual**	**Pro Forma [1]**	**Pro Forma As Adjusted [2]**
Cash and cash equivalents	€ 15,465,243		
Shareholders' deficit:			
Ordinary shares, par value of € , shares registered: shares issued, actual; shares, pro forma	37,056		
Additional paid in capital	36,604,728		
Accumulated deficit	(21,490,475)		
Total (deficit) equity	15,151,309		
Total capitalization	€ 15,151,309		

(1) Reflects the Corporate Conversion.

(2) A $1.00 increase or decrease in the assumed public offering price of $ per ADS would increase or decrease the amount of each of cash and cash equivalents and total shareholders' deficit by approximately $ million, assuming that the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1,000,000 in the number of ADSs offered by us would increase or decrease each of cash and cash equivalents and total shareholders' deficit by approximately € million, assuming the assumed public offering price remains the same, after deducting estimated underwriting discounts and commissions and any estimated offering expenses payable by us.

The number of our ordinary shares to be outstanding immediately after this offering is ordinary shares based on ordinary shares outstanding as of , 2021, after giving pro forma effect to the Corporate Conversion, and excludes:

- ordinary shares that are available for future issuance under our 2021-2025 Equity Incentive Plan;
- ordinary shares issuable upon exercise of the Representatives' Warrants; and
- ordinary shares and/or debentures convertible into ordinary shares issuable by the board of directors in connection with certain events such as the acquisition of stocks, assets or convertible notes and certain private placements and/or public offerings.

DILUTION

If you invest in our securities, your interest will be diluted immediately to the extent of the difference between the public offering price per ADS you will pay in this offering and the pro forma net tangible book value per ADS after the offering. At December 31, 2020, we had net tangible book value of €15,151,309, corresponding to a net tangible book value of € per ordinary share or $ per ADS (using the ratio of ordinary shares to one ADS). Net tangible book value per ordinary share or per ADS represents the amount of our total tangible assets less our total liabilities, divided by , the total number of ordinary shares outstanding at December 31, 2020, or , the total number of ADSs that would represent such total number of shares based on a share-to-ADS ratio of one-to-one.

After giving pro forma effect to the Corporate Conversion and the sale of the ADSs offered by us in this offering and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma estimated net tangible book value at December 31, 2020 would have been approximately € , representing € per ordinary share or $ per ADS. At the assumed public offering price for this offering of $ per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus, this represents an immediate increase in pro forma net tangible book value of € per ordinary share or $ per ADS to existing shareholders and an immediate dilution in pro forma net tangible book value of € per ordinary share or $ per ADS to purchasers of ADSs in this offering. Dilution for this purpose represents the difference between the price per ADS paid by these purchasers and pro forma net tangible book value per ADS immediately after the completion of this offering.

The following table illustrates this dilution on a per ADS basis to purchasers of ADSs in this offering:

Assumed public offering price per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus		$
Historical net tangible book value (deficit) per ADS as of December 31, 2020	€	
Increase in net tangible book value per ADS attributable to new investors in this offering	$	
Pro forma as adjusted net tangible book value per ADS after offering		$
Dilution in tangible book value per ADS to new investors		$
Percentage of dilution in net tangible book value per ADS for new investors		%

The dilution information set forth in the table above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

A $1.00 increase or decrease in the assumed initial public offering price of $ per ADS would increase or decrease our as adjusted net tangible book value per ADS after this offering by $ and the dilution per ADS to new investors by $, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We may also increase or decrease the number of ADSs we are offering. An increase or decrease of 1,000,000 in the number of ADSs offered by us would increase or decrease our as adjusted net tangible book value after this offering by approximately $ million and the pro forma net tangible book value per ADS after this offering by $ per ADS and would increase or decrease the dilution per ADS to new investors by $, assuming the assumed public offering price remains the same, after deducting estimated underwriting discounts and estimated offering expenses payable by us.

If the underwriters exercise their over-allotment option in this offering in full, the pro forma net tangible book value per ADS after this offering would be $ per ADS, and the dilution in pro forma as adjusted net tangible book value per ADS to new investors purchasing ADSs in this offering would be $ per ADS, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, on an as adjusted basis as of December 31, 2020, the differences between the number of ordinary shares acquired from us, the total amount paid and the average price per ordinary share paid by the existing holders of our ordinary shares and by investors in this offering and based upon an assumed public offering price of $ per ADS, the midpoint of the estimated price range set forth on the cover page of this prospectus.

	Shares		Total Consideration		Average Price Per Ordinary Share
	Number	Percent	Amount	Percent	
Existing shareholders					
New investors					
Total		100%		100%	

The number of our ordinary shares to be outstanding immediately after this offering is based on ordinary shares outstanding as of , 2021, after giving pro forma effect to the Corporate Conversion, and excludes:

- ordinary shares that are available for future issuance under our 2021-2024 Equity Incentive Plan;
- ordinary shares issuable upon exercise of the Representatives' Warrants; and
- ordinary shares and/or debentures convertible into ordinary shares issuable by the board of directors in connection with certain events such as the acquisition of stocks, assets or convertible notes and certain private placements and/or public offerings.

In addition, to the extent that options are granted under our 2021-2025 Equity Incentive Plan, there will be further dilution to investors purchasing ordinary shares in this offering.

If the representatives of the underwriters exercises the over-allotment option to purchase additional ADSs in full in this offering, the number of ordinary shares represented by ADSs held by new investors will increase to , or % of the total number of ordinary shares outstanding after this offering and the percentage of ordinary shares held by existing shareholders will decrease to % of the total ordinary shares outstanding.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of the prospectus contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.

Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, Genenta Science S.r.l. will modify its charter to become a S.p.A. (società per azioni) pursuant to our corporate reorganization. See "Corporate Conversion". Prior to this offering, we were a limited liability company, but the change in incorporation did not affect the financial information herein presented, except for the transformation of our quotas into ordinary shares. As such the historical financial statements will not be retrospectively adjusted.

Overview

We are a clinical-stage biotechnology company engaged in the development of hematopoietic stem cell gene therapies for the treatment of solid tumors. We have developed a novel biologic platform which involves the *ex-vivo* gene transfer of a therapeutic candidate into autologous hematopoietic stem/progenitor cells (HSPCs) to deliver immunomodulatory molecules directly to the tumor by infiltrating monocytes/macrophages (Tie2 Expressing Monocytes - TEMs). Our technology is designed to turn TEMs, which normally have an affinity for and travel to tumors, into a "Trojan Horse" to counteract cancer progression and prevent tumor relapse. Because our technology is not target dependent, we believe it can be used for treatment across a broad variety of cancers.

Since our inception in 2014, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights, conducting discovery, research and development activities for our programs and planning for eventual commercialization. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations with proceeds from the sales of equity securities, which through December 31, 2020, aggregated gross cash proceeds of approximately €33.6 million.

We do not have any products approved for sale, have not generated any revenue from commercial sales of our product candidates, and have incurred net losses each year since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates and programs. Our net losses for the years ended December 31, 2020 and 2019 were approximately €5.6 million and approximately €4.6 million, respectively. As of December 31, 2020, we had an accumulated deficit of approximately €21.5 million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development activities, including preclinical and clinical development of our gene therapy product candidates, namely our leading product candidate Temferon, and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses for at least the next several years as we advance our product candidates from discovery through preclinical development and clinical trials and seek regulatory approval of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, we expect to continue incurring additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses.

As a result, for our long term strategy, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations with proceeds from outside sources, with most of such proceeds to be derived from sales of equity securities, including the net proceeds from our IPO and follow-on offerings. We also plan to pursue additional funding from outside sources, including but not limited to our entry into or expansion of new borrowing arrangements; research and development incentive payments, government grants, pharmaceutical companies and other corporate sources; and our entry into potential future collaboration agreements with pharmaceutical companies or other third parties for one or more of our programs. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and eventual commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

We are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability, mainly due to the numerous risks and uncertainties associated with product development and related regulatory filings, which we expect to make in multiple jurisdictions. When we are eventually able to generate product sales, those sales may not be sufficient to become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2020, we had cash and cash equivalents of approximately €15.5 million. We believe that our existing cash and cash equivalents as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources." To finance our continuing operations, we will need to raise additional capital, which cannot be assured.

COVID-19 Update

As of the date of this filing, the global healthcare community continues to respond to the COVID-19 pandemic. In February 2020, the COVID-19 pandemic commenced in Italy. Regulatory guidance was issued in March and updated in April 2020 relating to the management of clinical trials during the pandemic. As the global healthcare community continues to respond to the COVID-19 pandemic, many hospitals, including our clinical sites, temporarily paused elective medical procedures, including dosing of new patients in clinical trials of our investigational gene therapies. While dosing of new patients and data collection from enrolled patients has resumed at clinical sites, the extent to which clinical activities continue to be delayed or interrupted will depend on future developments that are highly uncertain. We have not experienced significant interruptions related to COVID-19, although one patient tested positive for COVID-19 and had to delay treatment with Temferon. We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates. We continue to closely monitor this rapidly evolving situation and the potential impact on us.

Components of Operating Results

Operating Expenses

Our current operating expenses consist of two components – research and development expenses, and general and administrative expenses.

Research and Development Expenses

We expense research and development costs as incurred. These expenses consist of costs incurred in connection with the development of our product candidates, including:

- license fees and milestone payments incurred in connection with our license agreements;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and, in due course, clinical trial materials and commercial materials, including manufacturing validation batches;
- employee-related expenses, including salaries, social security charges, related benefits, severance indemnity in case of termination of employees' relationships, travel and stock-based compensation expense for employees engaged in research and development functions and consulting fees;
- costs related to compliance with regulatory requirements; and
- facilities costs, depreciation and other expenses, which include rent and utilities.

Our research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs, and central laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our research and development expenses by program also include fees incurred under license agreements, as well as option agreements with respect to licensing rights. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We primarily use internal resources to oversee research and discovery activities as well as for managing our preclinical development, process development, manufacturing, and clinical development activities. These employees work across programs, and therefore, we do not track their costs by program. We elected to present the research and development credit net of the related research and development expenditure on the statements of operations and comprehensive loss. However, not all of our research and development expenses are allocated by program:

	Year Ended December 31,	
	2020	2019
Direct research and development expenses by program:		
TEM-GBM	€ 3,353,369	€ 1,853,929
TEM-MM	190,764	769,146
Option fee – second indication [1]	500,000	—
Unallocated costs:		
Personnel (including share-based compensation)	472,100	753,238
Consultants and other third party	70,035	73,736
Materials & supplies	62,600	64,151
Travel & entertainment	34,466	133,573
Other	5,127	55,209
Total research and development expenses	€ 4,688,461	€ 3,702,982

[1] Although the second indication is currently liver cancer, the Company has the right to change the indication.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially over the next several years, particularly as we increase personnel costs, including stock-based compensation, contractor costs and facilities costs, as we continue to advance the development of our product candidates. We also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license agreements to acquire the rights to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- the impact of the COVID-19 pandemic on our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety profile with IND-enabling studies;
- successful patient enrollment in, and the design, initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishing and maintaining clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- qualifying for, and maintaining, adequate coverage and reimbursement by the government and other payors for any product candidate for which we obtain marketing approval;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- addressing any competing technological and market developments; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect, or be forced by regulatory authorities, to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the EMA, FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in or treatment as part of any of our ongoing and planned clinical trials for any reason, including as a result of the ongoing COVID-19 pandemic, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and consulting fees, related benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting, and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will continue to incur additional accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

Other Income (Expense)

Other income (expense) consists primarily of interest income/(expense), foreign exchange income/(loss) and, for the year ended December 31, 2019, an award given to the Company by international institutions for the successful results achieved in clinical trials.

Income taxes

We are subject to taxation in Italy. Taxes are recorded on an accrual basis. They therefore represent the allowances for taxes paid or to be paid for the year, calculated according to the current enacted rates and applicable laws. Due to the tax loss position reported, no income taxes were due for the years ended December 31, 2020 and 2019.

As of each reporting date, we consider existing evidence, both positive and negative, that could impact our view regarding to future realization of deferred tax assets. We believe that it is more likely than not that the benefit for deferred tax assets will not be realized. In recognition of this uncertainty, a full valuation allowance was applied to the deferred tax assets. Future realization depends on our future earnings, if any, the timing and amount of which are uncertain as of December 31, 2020. In the future, should management conclude that it is more likely than not that the deferred tax assets are partially or fully realizable, the valuation allowance would be reduced to the extent of such expected realization and the amount would be recognized as a deferred income tax benefit in our statements of operations.

There are open statutes of limitations for Italian tax authorities to audit our tax returns. There have been no material income tax-related interests or penalties assessed or recorded.

There is no liability related to uncertain tax positions reported in our financial statements.

In line with the legislation in force until December 31, 2019, companies in Italy that invested in eligible research and development activities, regardless of the legal form and economic sector in which they operate, could benefit from a tax credit up to 50% of the increase of annual research and development expenses compared to the median expense for the years 2012-2014, which could be used as compensation in order to reduce most taxes payable, including income tax or regional tax on productive activities, as well as of social security contributions.

The 2020 Italian Budget Law established that: (i) the tax credit due is up to 12% of the research and development costs incurred (up to a maximum of Euro 3 million); (ii) the actual support of eligible expenditure and its correspondence with the accounting documents must result from a specific certification issued by the person responsible for the legal audit; (iii) the tax credit due can only be used as compensation in three equal annual instalments. The 2021 Italian Budget Law established that: (i) the tax credit due is up to 20% of the costs incurred (up to a maximum of Euro 4 million); (ii) the tax credit can be used for 2021 and 2022 fiscal years; (iii) it is necessary to have, besides the audit report, a technical report.

Results of Operations

Comparison of the Year Ended December 31, 2020 to the Year Ended December 31, 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(in Euros)	
Operating expenses		
Research and development	€ 4,688,461	€ 3,702,982
General and administrative	901,765	921,520
Total operating expenses	5,590,226	4,624,502
Loss from operations	(5,590,226)	(4,624,502)
Other income (expense)		
Other income	5,966	36,331
Finance expense	(7,754)	(9,552)
Total other income (expense), net	(1,788)	26,779
Loss before income taxes	(5,592,014)	(4,597,723)
Income tax benefit (expense)	-	-
Net loss	(5,592,014)	(4,597,723)
Comprehensive loss	-	-
Total comprehensive loss	€ (5,592,014)	€ (4,597,723)
Pro forma information (unaudited):		
Pro forma net loss		
Pro forma net loss per share - basic and diluted		
Weighted average pro forma number of shares outstanding - basic and diluted		

We have presented pro forma basic and diluted net loss per share which consists of our historical net loss attributable to Genenta Science S.r.l., divided by the pro forma basic and diluted weighted average number of ordinary shares outstanding after giving effect to the Corporate Conversion. See our disclosures in this prospectus for additional information regarding the method used to calculate the pro forma basic and diluted net loss per ordinary share and the pro forma weighted average number of ordinary shares used in the computation of the per share amounts.

Research and Development Expenses

Research and development expenses were approximately €4.7 million for the year ended December 31, 2020, as compared to approximately €3.7 million for the year ended December 31, 2019. The increase of approximately €1.0 million was primarily due to the increase of approximately €1.6 million related the Company's GBM research and clinical activities partially offset by €0.6 million related to the decrease of MM related expenses. In addition, we exercised our option with OSR for our second cancer indication, which triggered an option fee of €0.5 million; however, this was offset by a decrease of €0.3 million of personnel costs and €0.2 million of other research, development, and clinical related expenses.

General and Administrative Expenses

General and administrative expenses were approximately €0.9 million for the year ended December 31, 2020, as compared to approximately €0.9 million for the year ended December 31, 2019. The general and administrative expenses remained essentially flat due to our ability to control expenses and focus our resources on research, development, and clinical activities.

Other Income

Other income was €6,000 for the year ended December 31, 2020, as compared to approximately €36,000 for the year ended December 31, 2019. The decrease of approximately €30,000 was primarily due to the awards granted to the Company in 2019, i.e., the Company won two international prizes for its results on research programs in 2019 without a corresponding award in 2020.

Finance Expense

Finance expense was approximately €7,800 for the year ended December 31, 2020, as compared to approximately €9,600 for the year ended December 31, 2019. The increase of approximately €1,800 was primarily due to small exchange rate gains and losses.

Net Loss

Our net loss was approximately €5.6 million for the year ended December 31, 2020, as compared to approximately €4.6 million for the year ended December 31, 2019. The increase of approximately €1.0 million was primarily due to the increased spending related to our GBM research and clinical activities.

Liquidity and Capital Resources

Overview

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sales of quotas. Through December 31, 2020, we had received gross cash proceeds of approximately €33.6 million from sales of our quotas. As of December 31, 2020, we had approximately €15.5 million in cash and cash equivalents.

The table below presents our cash flows for the periods indicated:

(in Euros)	For the Year Ended December 31,	
	2020	**2019**
Net cash used in operating activities	€ (6,044,581)	€ (2,490,187)
Net cash used in investing activities	(20,871)	-
Net cash provided by financing activities	1,389,316	14,768,202
Net (decrease) increase in cash and cash equivalents	€ (4,676,136)	€ 12,278,015
Cash and cash equivalents at beginning of year	20,141,379	7,863,364
Cash and cash equivalents at end of year	€ 15,465,243	€ 20,141,379

Operating Activities

During the year ended December 31, 2020, operating activities used approximately €6.0 million of cash and cash equivalents, resulting from our net loss of approximately €5.6 million and by cash used for changes in our operating assets and liabilities of approximately €0.9 million and partially offset non-cash charges of approximately €0.5 million. The net changes in our operating assets and liabilities were primarily due to an increase in payment of related party research and clinical accrued expenses as well as an increase of prepaid and other current assets mainly related to a VAT (value added tax) receivable. The non-cash charges primarily included approximately €0.5 million of stock-based compensation expense and a de minimus amount of depreciation and retirement benefit obligation expense.

During the year ended December 31, 2019, operating activities used approximately €2.5 million of cash and cash equivalents, resulting from our net loss of approximately €4.6 million partially offset by cash provided by changes in our operating assets and liabilities of approximately €1.4 million and non-cash charges of approximately €0.7 million. The net changes in our operating assets and liabilities were primarily due to an increase in accruals and liabilities linked to the clinical trials made in cooperation with Ospedale San Raffaele and the related clinical manufacturers. The non-cash charges relate primarily to approximately €0.7 million of share-based compensation expense.

Financing Activities

During the year ended December 31, 2020, net cash provided by financing activities was approximately €1.4 million, primarily consisting of net cash proceeds from the sale of our class E quota, which raised net proceeds of approximately €1.4 million.

During the year ended December 31, 2019, net cash provided by financing activities was approximately €14.8 million, consisting of net cash proceeds received from the rounds of equity fundraising that occurred in 2019.

Current Outlook

We have financed our operations to date primarily through proceeds from sales of our quotas to our founding quota holders and other third-party investors. We have incurred losses and generated negative cash flows from operations since inception in 2014. To date we have not generated revenue, and we do not expect to generate significant revenues from the sale of our product candidates in the near future.

As of December 31, 2020, our cash and cash equivalents were approximately €15.5 million. Our primary cash obligations relate to payments to OSR pursuant to our license agreement and other providers of clinical trial related services. We believe that our existing cash and cash equivalents will be sufficient to fund our projected cash requirements through the fourth quarter of 2022. Therefore, we will require significant additional financing in the future to fund our operations. As we continue to assess the effects of the COVID-19 pandemic, we do believe that it is possible that the COVID- 19 pandemic may make financing opportunities scarcer or more difficult or, if such funds are available to us, that such additional financing may not be available in an amount that is sufficient to meet our needs. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or terminate our planned clinical trials or other operations, or grant rights to develop and commercialize product candidates that we would otherwise prefer to develop and commercialize ourselves.

We currently anticipate that we will require approximately €4.5 million for research and development activities over the course of the next twelve months. We also anticipate that we will require between approximately €4.0 million to approximately €4.2 million for operational expenditures over such twelve-month period, which consists primarily of expenditures for supporting preclinical studies required for obtaining approval to conduct such clinical studies for our product candidates, general and administration labor costs, and fundraising activities. In light of our financial condition, we reduced our operating expenses, including for those purposes listed above, before the start of the COVID-19 pandemic. There can be no assurance that the analysis that we have undertaken or remedial measures that have been enacted will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to commercialize approved products and develop product candidates can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, our plans to develop our in-house drug product and vector manufacturing capabilities, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash, we estimate that such funds will be sufficient to fund our operations and capital expenditure requirements into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

In addition, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future capital requirements will depend on many factors, including:

- the length of the COVID-19 pandemic and its impact on our planned clinical trials, operations and financial condition;
- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- any cost that we may incur under in- and out-licensing arrangements relating to our product candidate that we may enter into in the future;
- the costs and timing of obtaining regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of, and timing for, amending current manufacturing agreements for production of sufficient clinical and commercial quantities of our product candidates, or entering into new agreement with existing or new CMOs;
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the costs of acquiring or undertaking the development and commercialization efforts for additional, future therapeutic applications of our product candidates and the magnitude of our general and administrative expenses.

Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through our existing cash, cash equivalents and short-term deposits, the net proceeds from this current offering, loans, debt or equity financings. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to, one or more applications of our product candidates.

Critical Accounting Policies

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

We believe that the accounting policies described below are critical in order to understand the judgements and estimates used in the financial statements and to fully understand and evaluate our financial condition and results of operations.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including central laboratories, in connection with preclinical development activities, especially, OSR, a co-founding quotaholder, significant related party vendor and a leading center for ex-vivo gene therapy for inherited diseases;
- CROs and investigative sites in connection with preclinical and clinical studies; and
- CMOs in connection with drug substance and drug product formulation of preclinical and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Share-based compensation

To reward the efforts of employees, directors, and certain consultants to promote our growth, our Board of Directors has historically approved, during its existence, various share-based awards, although no share-based awards were granted during the year ended December 31, 2020. All options have been awarded with an exercise price of €1 per quota and, when exercised, were first converted to Quota B of Genenta Science S.r.l. and then to ordinary shares giving effect to our Corporate Conversion. The options granted have the vesting condition that the individual has to remain with us at least one year or as otherwise specified for each person.

We measure share-based awards granted to employees and directors based on the fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is the vesting period of the respective award. Forfeitures are accounted for as they occur. The measurement date for option awards is the date of the grant. We classify share-based compensation expense in our statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

With the adoption of Accounting Standards Update ("ASU") No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07") on January 1, 2019, the measurement date for non-employee awards is the date of the grant. The compensation expense for non-employees is recognized, without changes in the fair value of the award, over the requisite service period, which is the vesting period of the respective award.

Quota B valuations

The fair value of the Quota B of Genenta Science S.r.l. underlying our stock-based compensation grants prior to our Corporate Conversion has historically been determined by our board of directors, with input from management and third-party valuations. We believe that the board of directors has the relevant experience and expertise to determine the fair value of the Quota B, when also securing third-party assistance. Given the absence of a public trading market of our equity, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, the board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our equity at each grant date. These factors include:

- valuations of the Quota B equity performed by third-party specialists;
- the price of our equity to third-party, arms-length, sophisticated, and qualified investors, which was used in the OPM backsolve model;
- the prices, rights, preferences, and privileges of our Quota C, D, and E preferred equity classes relative to those of our equity;
- lack of marketability of the Quota B;
- lack of voting rights of the Quota B;
- current business conditions and projections;
- hiring of key personnel and the experience of management;
- our stage of development;
- the timing, progress and results of our preclinical studies and clinical trials for our programs and product candidates; including statements regarding the timing of initiation and completion of trials or studies and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- likelihood of achieving a liquidity event, such as an initial public offering, a merger or acquisition given prevailing market conditions, or other liquidation events for us;
- the market performance of comparable publicly traded companies; and
- the European, U.S. and global capital market conditions.

In valuing the Quota B, the board of directors determined the equity value of our business using various valuation methods. The board of directors engaged a third-party valuation firm who performed analyses in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. Our option valuations were prepared using an option pricing method ("OPM"), which used market approaches to estimate our enterprise value.

The OPM treats each equity class as a call options on the total equity value of a company, with exercise prices *(i.e.*, breakpoints) based on the value thresholds at which the allocation among the various holders of a company's securities changes. A discount was considered for Lack of Marketability ("DLOM"), which is an amount or percentage that is deducted from the value in order to reflect the absence of a viable market. The DLOM was then applied to arrive at an indication of value for the option. Also, considered in the valuation was volatility and the fact that the Quota B did not carry voting rights. The expected volatility used in the OPM is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development.

Application of our approach involved the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding the selection of comparable companies, and the expected timing of an initial public offering ("IPO") or other liquidity event. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact the valuations at each valuation date and may have a material impact on the valuation of the Quota B, and consequently, our share-based compensation expense could be materially different. For valuations after the completion of an initial public offering, the board of directors will determine the fair value of each share of underlying equity shares based on the closing price of the shares as reported on the date of grant.

Research and development tax credit receivables

We account for our research and development tax credit receivable in accordance with IAS 20 *Accounting for Government Grants and Disclosure of Government Assistance*. The receivable is recognized when there is reasonable assurance that: (1) the recipient will comply with the relevant conditions and (2) the grant will be received. We elected to present the credit net of the related expenditure on the statements of operations and comprehensive loss. While these tax credits can be carried forward indefinitely, we recognized an amount which reflects management's best estimate of the amount that is reasonably assured to be realized or utilized in the foreseeable future based on historical benefits realized, adjusted for expected changes, as applicable.

Emerging Growth Company Status

We are an "emerging growth company." Under the JOBS Act, an emerging growth company can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements, such as the use of unconsolidated subsidiaries, structured finance, special purpose entities or variable interest entities.

We do not believe that our off-balance sheet arrangements and commitments have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our current investment policy is to invest available cash in bank deposits with banks that have a credit rating of at least A-. Accordingly, a substantial majority of our cash and cash equivalents is held in deposits that bear interest. Given the current low rates of interest we receive, we will not be adversely affected if such rates are reduced. Our market risk exposure is primarily a result of foreign currency exchange rates, which is discussed in detail in the following paragraph.

Foreign Currency Exchange Risk

Our results of operations and cash flow are not subject to significant fluctuations due to changes in foreign currency exchange rates. As discussed above, most of our liquid assets and our expenses are denominated in EUR. Changes of 5% and 10% in the USD/EUR exchange rate would not have significantly increased/decreased our operating expenses. As we continue to grow our business, our results of operations and cash flows might be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations.

We do not hedge our foreign currency exchange risk. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

BUSINESS

Overview

We are a clinical-stage biotechnology company engaged in the development of hematopoietic stem cell gene therapies for the treatment of solid tumors. We have developed a novel biologic platform that involves the *ex-vivo* gene transfer of a therapeutic candidate into autologous hematopoietic stem/progenitor cells (HSPCs) to deliver immunomodulatory molecules directly to the tumor by infiltrating monocytes/macrophages (Tie2 Expressing Monocytes - TEMs). Our technology is designed to turn TEMs, which normally have an affinity for and travel to tumors, into a "Trojan Horse" to counteract cancer progression and to prevent tumor relapse. Our technology is not target dependent, and therefore we believe it can be used as a treatment for a broad variety of cancers.

Our technology incorporates the use of a lentiviral vector (LVV) that combines a therapeutic transgene sequence, or payload, with our proprietary platform. Our proprietary platform consists of (i) the Tie-2 promoter, that drives transgene sequence transcription specifically in TEMs, and (ii) miRNA-126 target sequences to downregulate transgene expression post-transcription in those cells where the Tie-2 promoter is active and the miRNA-126 is present. We believe there are many advantages to our approach:

- *Trojan Horse Mechanism of Action ("MoA"):* We use and modify TEMs, a subpopulation of tumor-associated myeloid cells, known to be involved in tumor growth and in the inhibition of immune system response, to allow the immune system to recognize the tumor and to deliver to the cancer site a chosen therapeutic.
- *Select Regulation of Transgene Expression:* Our selected control of the chosen therapeutic gene expression is designed to avoid off-target and systemic toxicity.
- *Potential Long-Term Effect:* Through the use of stem cells, our therapeutic candidate is designed as a "*living therapy*" intended to break the cancer-induced immune tolerance and to establish a competent immune surveillance throughout the life of the patient.
- *Agnostic Response*: In contrast to antigen-restricted CAR-T cells, our platform is not restricted to a pre-selected tumor antigen, nor any one tumor type. As such, it may be applied to a broad range of solid tumors and cancer subtypes, which would overcome one of the central unresolved challenges of immune-oncology cancer therapies.

Our lead product candidate, Temferon, was developed using our platform and carries an interferon-alpha (IFN-α) payload. IFN-α is a well-known therapeutic that was previously administered intravenously for treatment of various cancers, but it is currently rarely used because of its systemic toxicity. The Temferon-modified TEMs express the transgene payload, IFN-α, in the tumor microenvironment resulting in the breakdown of tumor induced immune-tolerance. As a result, the immune system can recognize the tumor, respond, and inhibit tumor growth. Because Temferon is designed to deliver the IFN-α payload directly to the tumor, we believe it will demonstrate clinical activity without the side effect profile of systemic delivery of IFN-α. In preclinical mouse models treated with Temferon (Glioma, Breast Cancer, CRC, Metastasis from breast and CRC, B-ALL) both direct (anti-angiogenic, pro-apoptotic) and indirect (immune response) effects were observed.

We are currently developing Temferon for the treatment of glioblastoma multiforme (GBM). GBM is the most common malignant primary brain tumor, accounting for more than half of all central nervous system (CNS) cancers. Patients suffering from GBM have limited, non-curative treatment options. Although these treatments may improve survival, the prognosis for GBM patients remains poor, with a median overall survival (mOS) of approximately 15 months and only 5.5% of patients estimated to be alive 5 years after diagnosis. With no curative treatments available and such poor prognosis for patients, there remains a large, unmet medical need. We chose GBM among our first targets for clinical development after considering the medical need, the active role that TEMs have in GBM pathology, and the high number of newly diagnosed GBM patients potentially interested in participating in our study. As a result, we believe GBM offers a good profile for our initial proof of concept trial in humans. We are currently conducting a two-part, Phase 1/2a clinical trial with Temferon in newly diagnosed GBM patients in Italy. We anticipate completing enrollment of Part A of our study by the first quarter of 2021 and patient dosing by the second quarter of 2021. We intend to use the preliminary results of our Phase 1/2a clinical trial to support our IND application to the US Food and Drug Administration (FDA) for approval to conduct a Phase 1/2b trial in GBM in the U.S. As of April 30, 2021, we have dosed a total of 13 patients. The preliminary results show that Temferon has been generally well tolerated, with no dose limiting toxicities identified so far.

We also intend to develop Temferon for the treatment of other solid tumor indications, and including locally advanced hepatocellular carcinoma (HCC) and intra-hepatic cholangiocarcinoma (ICC) are our leading choices so far. HCC and ICC are gastrointestinal (GI) cancers affecting the digestive system. HCC is a primary malignancy of the liver that occurs predominantly in patients with underlying chronic liver disease and cirrhosis. ICC is a biliary tract cancer and represents approximately 3% of all GI malignancies. The prognosis for patients with locally advanced HCC or ICC remains poor, with few therapeutic options, having limited clinical benefits. While we are considering development of Temferon for these liver indications for similar reasons as GBM (i.e. the high unmet need, TEMs' role in HCC and ICC pathology, and the number of newly diagnosed patients potentially eligible for our study), we are also evaluating development of Temferon for other solid tumor indications. We intend to submit a Clinical Trial Application (CTA) for conducting a Phase 1/2a study of Temferon in HCC and ICC or in a different solid tumor indication to the Italian Medicines Agency (Agenzia Italiana del Farmaco, or AIFA), the public institution responsible for the regulatory activity of pharmaceuticals in Italy, and we anticipate initiating the trial in the second quarter of 2022, subject to feedback from these regulatory authorities.

In addition to our Temferon programs that target GBM or other solid tumor indications such as HCC and ICC, we have exclusive option rights to license (i) Temferon for the treatment of additional indications, and (ii) other drug candidates that are currently in the preclinical stage of development both as standalone treatments and as combination therapies.

We rely on our current contract manufacturing organization (CMO), AGC Biologics, based in Italy, to manufacture LVV and Temferon for us. After the completion of our Phase 1/2b study we intend to use a US-based CMO to supply our drug product (DP) for conducting larger trials in the U.S. Therefore, we are working with AGC Biologics to plan the required tech transfer activities for drug product manufacturing and the scale up of our LVV manufacturing process to support larger trials.

We were founded in 2014 by San Raffaele Hospital (Ospedale San Raffaele or OSR) in Milan, a globally recognized premier research hospital for *ex-vivo* gene therapy, with Pierluigi Paracchi (our CEO), Luigi Naldini (Chairman of our Executive Scientific Board) and Bernhard Gentner (a member of our Executive Scientific Board), to develop potential ground-breaking cell and gene cancer therapies. We leverage the vast experience in LVV technology of the San Raffaele Telethon Institute for Gene Therapy (SR-Tiget), a world leading cell and gene therapy research institution on the forefront of developing therapies for rare diseases that is a joint venture between OSR and Fondazione Telethon (Telethon). SR-Tiget has a proven track record for successful collaborative clinical research programs in *ex-vivo* gene therapy that give rise to approved products, including Strimvelis, an *ex-vivo* gammaretroviral vector-based gene therapy for adenosine deaminase severe combined immunodeficiency (ADA-SCID), and Libmeldy, an *ex-vivo* gene therapy for the treatment of early-onset metachromatic leukodystrophy (MLD) patients, both marketed by Orchard Therapeutics. Our platform was developed in the SR-Tiget laboratories of our founders, Prof. Naldini and Dr. Gentner and we hold exclusive rights, and exclusive option rights, to certain intellectual property originating there.

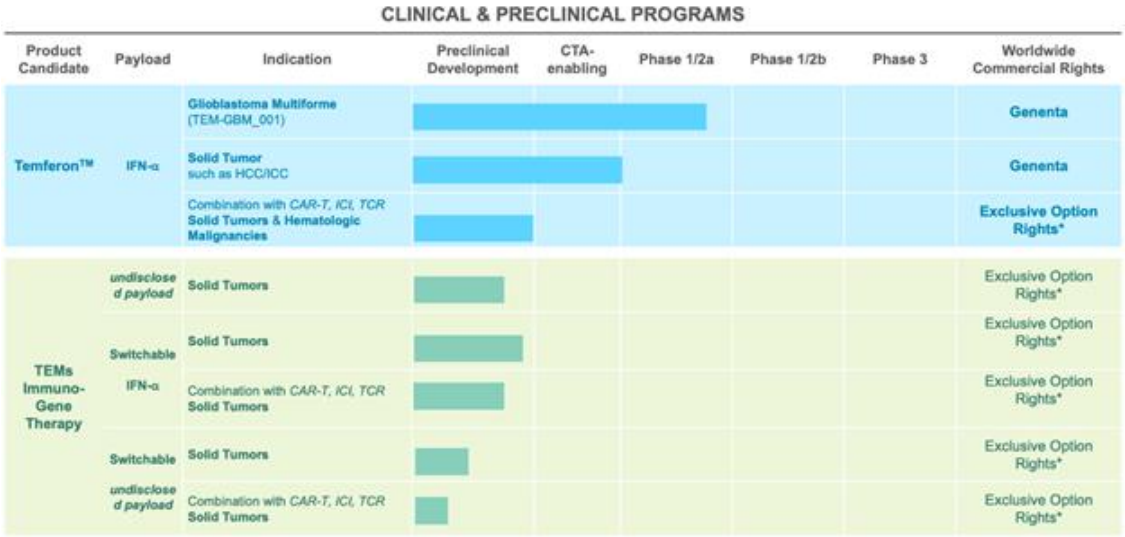
Since closing our first round of funding in May 2015, we have recruited a leading management team, established a manufacturing process for our drug product candidate, completed preclinical activities (research and Good Laboratory Practice – GLP – grades), engaged with Italian, European and U.S. Key Opinion Leaders (KOLs) to identify our clinical lead indications and submitted our first CTA.

Our leadership team has a proven track record as biotech executives. Their expertise span from finance and venture capital to medical affairs, scientific research, clinical drug product development and clinical trial management and conduction. For example, members of our management team have been involved in the successful development of Ethical Oncology Science, which was acquired in 2013 for over $400 million, and Strimvelis the first ever approved *ex-vivo* gene therapy product that was developed under the guide of Carlo Russo, our Chief Medical Officer and Head of Development (formerly Head of Development of the Biopharm Unit and Head of Research & Development of the Rare Disease Unit at GSK). Our management team members have played important roles in both large pharma companies such as Merck and GSK, and life science startups, such as Adverum, Annapurna, VaxInnate Corporation, OncoSec Medical, Biological Dynamics and GenMark Diagnostics. We believe this multi-disciplinary competence, provides a unique blend for the development of innovative gene and cell therapy products, and constitutes a fertile ground for alliances with industrial partners that could help us bring new therapies to patients.

Research and Development Pipeline

Our portfolio of clinical and preclinical *ex-vivo* autologous gene cancer therapies is based on our technology platform, which was originally developed in our founders' laboratories at OSR. Through our collaboration with OSR, we have worldwide commercial rights to Temferon (though our current trademark rights to Temferon are limited to the US and Europe) for the treatment of GBM, HCC and ICC, as well as exclusive option rights to license all of our other programs. Specifically, we retain exclusive option rights to license (i) any platform improvements, including our second-generation technology, which includes developments to enable the on/off regulation of the therapeutic transgene, (ii) products for additional indications that utilize our platform technology but use different transgene payloads, and (iii) combinations of our platform with therapies in the immuno-oncology (IO) field, such as ICI, CAR-T cell therapies and TCR therapies.

Our current pipeline, with clinical and preclinical stage programs, is summarized below:



**Genenta has options/rights on IP derived from preclinical data generated at SR-Tiget laboratories.*

Strategy

We are developing novel cancer therapeutics using our autologous *ex-vivo* gene therapy platform, to initially address the unmet medical needs of GBM patients and patients suffering from another solid cancer indication such as HCC and ICC, but ultimately, we hope to broaden our platform to treat a wide variety of cancers by pursuing the following strategies:

Advance development of our leading clinical-stage product candidate, Temferon in the U.S.

We are currently conducting a Phase 1/2a dose-escalation study in Italy to primarily evaluate the safety and tolerability of Temferon in up to 21 GBM patients who have an unmethylated MGMT promoter, following radiotherapy treatment. We plan to initiate a Phase 1/2b trial in the U.S. to evaluate the safety and efficacy of Temferon in up to 30 GBM patients who have an unmethylated MGMT promoter, following radiotherapy, where we intend to measure progression free survival (PFS) and overall survival (OS) as endpoints. We are planning a pre-IND meeting with the FDA by the end of the second quarter of 2021 to discuss the proposed clinical program and drug product manufacturing. The study design may change as a result of discussions with regulatory bodies, key opinion leaders and partnering clinical centers.

Expand our product pipeline across multiple indications

We intend to expand our product pipeline by:

- *Identifying additional indications suitable for Temferon. We are in the planning stages for a second study using Temferon in locally advanced HCC and ICC, our current leading solid tumor indications so far. The Istituto Superiore di Sanita (ISS), an independent committee with oversight from the Italian Ministry of Health, must issue a positive opinion regarding our CTA before AIFA will approve it. In addition to these indications, we believe there may be additional cancer indications which actively recruit TEMs to proliferate for which Temferon may be a suitable therapy.*

- *Using our platform with different transgene payloads*. Our platform technology is designed to enable us to use different transgene payloads to potentially achieve therapeutic outcomes in selected cancer indications. We are currently conducting preclinical studies for two therapeutics using our platform with different payloads targeting solid tumors.

- *Developing a second-generation platform that enables the "on-demand" release of the transgene payload*. We intend to develop a second-generation technology platform that allows the drug products to be switched on to exert the therapeutic effects and switched off if they are no longer needed, or to mitigate toxicity. This technology may enable us to expand our treatment options to broader patient populations.

- *Exploring combination therapies*. We will seek to enter into collaborations with other companies to explore combination studies of our therapeutics with other cancer therapies, such as ICI, CAR-T cell therapies and TCR therapies. We believe our product, as a result of its MoA, has the potential to enhance the durability and efficacy of the existing therapies, thus abolishing the immune tolerance to the tumor.

- *Exploiting in-licensing opportunities with OSR*. We intend to exploit in-licensing opportunities with OSR, a co-founding shareholder.

Develop and maintain efficient manufacturing processes to support anticipated growth

To meet our drug product supply needs for conducting larger trials after the completion of our planned Phase 1/2b GBM study in the United States, we intend to enter into a supply agreement with a US-based CMO for the manufacturing of our products. Currently, Temferon, is manufactured by AGC Biologics, a leading global contract development and manufacturing organization (CDMO), which is headquartered in Italy and specializes in the manufacturing of viral vectors and genetically engineered cells. Their facility is certified by AIFA. We are currently working with AGC Biologics to plan the required tech activities for transferring the drug product manufacturing to a US CMO and the scale up of our LVV manufacturing process to support larger trials.

Establish a patient-centered infrastructure and strong relationships with key U.S. opinion leaders working in our disease area

Since cell and gene-based therapies are relatively new approaches in oncology, we intend to implement programs to improve patient and physician education regarding the availability of gene therapy-based products for those cancers with a high unmet medical need. To this end, we are discussing a GBM IND trial with Antonio Chiocca, MD, Professor Neurosurgeon-in-Chief and Chairman, Department of Neurosurgery at Brigham and Women's Hospital in Boston, MA, Frederick Lang, MD, Professor and Chairman of the Department of Neurosurgery at MD Anderson in Houston, TX, and David A. Reardon, MD, Department of Medical Oncology at Dana-Farber Cancer Institute in Boston, MA.

Develop opportunistic partnership(s) with pharmaceutical company(s)

We may choose to partner with larger pharmaceutical companies whose core competencies and oncology strategies are in line with ours.

Our Strengths

We believe that our growing body of early clinical data evidencing the potential of our autologous *ex-vivo* gene therapy approach, coupled with our founders' expertise in the development, manufacturing and commercialization of gene and cell therapies, positions us well to provide potentially transformative therapies through a single administration to patients suffering from a broad range of cancers. We believe our key strengths include:

- ***Unique and valuable expertise.*** We are conducting our clinical trials at OSR, a leading center for *ex-vivo* gene therapy for inherited diseases. OSR has treated more than 121 patients worldwide (one of the highest number of patients treated with gene therapy for rare diseases in a research hospital), using an ex-vivo viral vector platform similar to the one we are developing for cancer treatment. Members of our executive leadership team have held senior positions at GSK, Merck, Annapurna-Adverum and other companies specializing in gene and cell therapies and rare diseases. We have partnered with academic institutions that are pioneers in autologous *ex-vivo* gene therapy and hold exclusive option rights to license additional patents and know-how to build our portfolio. Partnerships with leading academic institutions well recognized in the gene therapy field, such as SR-Tiget and OSR, are a core part of our research engine through which we are working to advance the clinical development of our product candidates and to identify new opportunities that we believe have comparably high probabilities of success in a preclinical setting. We believe our expertise, combined with our plan to leverage our relationships with leading academic institutions, will help expedite the commercialization of our lead clinical-stage product candidate and further expand our pipeline.

- ***Deep pipeline with broad utility*.** We believe that the flexibility of our technology platform combined with our exclusive option rights to in-license additional programs, gives us the ability to grow our pipeline by targeting a broad set of cancer diseases.

- ***Durable therapeutic potential*.** Preliminary interim clinical data collected from treated GBM patients following a single administration of Temferon displayed modified cells at 18 months, the last measured timepoint to date.

- ***Tumor restricted therapeutic payload delivery and release*.** Due to the design of our transgene expression cassette, we restrict payload expression to the tumor microenvironment. The local and tumor restricted therapeutic gene deployment approach is designed to focus the pleiotropic anti-tumor activities of the selected payload, by limiting the toxic manifestation that results from standard systemic administration of the payload.

- ***Agnostic approach.*** Our immune-gene therapy approach is a tumor-agnostic investigational immunotherapy since it does not rely on any specific target or tumor type, and therefore could be successfully applied to a potentially broad range of cancers and immune contexts.

- ***Solid tumors targeting.*** Our platform has the potential to efficiently target solid tumors. Solid tumors are difficult to treat, even by the most novel and leading-edge technologies such as ICIs and CAR-T cells. Our cellular carrier, TEMs, is spontaneously and actively recruited by growing tumors and is found in several human solid tumors, irrespective of location.

- ***Active and sustained tumor surveillance.*** Our immune-gene investigational therapy is designed to trigger the patient's own immune response and establish an active immune surveillance. Our preclinical work, which used different cancer models (B-cell acute lymphoblastic leukemia - B-ALL and GBM) as well as preliminary data collected from our GBM patients, suggests the occurrence of changes in the immune system.

- ***Fine dose tuning.*** Our platform gives us the ability to fine tune the dose to be administered to each patient, based on the patient's own drug product characteristics (drug product's release specifications).

- ***Preliminary data indicate that our approach is feasible and well-tolerated.*** Temferon has been well-tolerated in the limited number of patients treated to date. Our *ex-vivo* modification of the patient's own HSPCs and cryopreservation allow us to formulate the patient's drug product prior to administering the therapy.

- ***LVV as transgene payload delivery vehicles.*** LVVs are particularly attractive for clinical applications due to their capacity to transfer genes/payloads without size constraints and their ability to efficiently transduce non-proliferating or slowly proliferating cells, such as hematopoietic stem and progenitor cells, allowing persistent gene expression in transduced cells. Moreover, LVVs have a reduced risk of genotoxicity compared to gRV. *Ex-vivo* transduction using LVVs has demonstrated a positive safety profile over the last 10 years. A large number of patients have been treated with LVV marketed gene therapy products and clinical-stage product candidates for rare diseases worldwide, and each of these therapies has been generally well tolerated. We believe that long-term extensive follow-up across multiple diseases, with vectors expressing different genes, demonstrates the potential safety of our autologous *ex-vivo* gene therapy approach.

- ***Applicability to a potentially large number of patients and indications***. We believe our autologous *ex-vivo* gene therapy approach has broad therapeutic potential across a large number of malignancies. The *ex-vivo* transduction of HSPCs allows for the potentially long-term production of a differentiated cellular carrier loaded with the therapeutic gene and the consequent distribution of the therapeutic payload throughout multiple organs and tissues containing solid tumors.

Status of Current IO Treatments

The need for innovation and improvement in cancer treatment has never been a higher priority for the healthcare industry and patients. Despite new therapeutic approaches and new drugs having been developed or approved, substantial unmet need remains for many of the most common cancers. Immuno-oncology therapies seek to work in conjunction with the patient's own immune system to recognize and attack cancer cells selectively, without affecting normal cells, or to deliver immune system components that prevent the spread of cancer. Immuno-oncology therapy is recognized as an important type of cancer treatment in addition to more established options such as surgery, chemotherapy, targeted therapy and radiation therapy. Indeed, the number of IO therapeutics in development worldwide grew 233% from 2017 to 2020. IO therapeutics, which rely on the natural activity of the immune system to fight cancers in various ways, are grouped, by the Cancer Research Institute, in five main classes reported in the tables below.

Class 1 - Cell-based immunotherapy	Class 2 - Immunomodulators
Cell-based immunotherapy approaches employ an immune cell transplant (***adoptive cell therapy***) to physically supplement a patient's immune system and include: • ***Tumor-Infiltrating Lymphocyte (TIL) Therapy:*** Naturally occurring T cells that have already infiltrated a patient's tumors are harvested, activated, expanded *in vitro* and finally re-infused into the patient, where they can then seek out and destroy the tumors. The antigen to which TIL are directed need to be bound by the major histocompatibility complex (MHC) in the tumor cells. • ***T Cell Receptor (TCR) Therapy***: T cells are taken from the patient, equipped with a new T cell receptor that enables them to target specific cancer antigens bound by the MHC, activated, expanded *in vitro* and finally re-infused into the patient. • ***Chimeric Antigen Receptor (CAR) T Cell Therapy:*** T cells are taken from the patient, equipped with a synthetic receptor that enables them to target specific cancer antigens, activated, expanded *in vitro* and finally re-infused into the patient. CAR-T cells may bind antigens that are not presented on the surface through MHC. The newest evolution of this approach is the use of allogeneic T cells, known as universal CAR-T. • ***Natural Killer (NK) Cell Therapy***: This recently developed cell-based immunotherapy is raising interest because NK cells have been shown to mediate graft-versus-leukemia immunity, sparing normal tissues and preventing graft-versus-host disease (GVHD). NK cells also have a natural killing mechanism recognizing MHC class I-negative targets and may be combined as well with CAR therapies. • ***Allogeneic Cell Therapy***: Allogeneic, or universal, cell therapies rely on a single source of cells to create a master cell bank, which is then used to treat multiple patients. Before introducing allogeneic cells into the body, the patient receives a conditioning regimen of chemotherapy and, sometimes, radiation therapy to weaken the patient's immune system to prevent rejection of the donated cells, which is a common complication with this therapy. As with NK cell therapy, another complication of allogeneic cell therapy is GVHD where the immune cells from the donor (the graft) may attack healthy cells in the patient's body (host). Allogeneic cell therapy is uncommon for patients who are older or have overall poor health due to their incompetent immune systems. Of these cell-based approaches, the only market approved therapy is CAR-T cell therapy.	Immunomodulators act directly on immune cells to promote anti-cancer activity and can generally be divided into four categories: • ***Immune Checkpoint Inhibitors (ICI):*** Presently, these are the most widely successful immunomodulators. They work by unlocking the "brakes" of the immune system, the so-called immune checkpoints that are activated by cancer cells to shut down immune responses and allow cancer growth. As a result, checkpoint inhibitors are able to release new immune responses against cancer as well as enhance existing responses to promote the elimination of cancer cells. Since the approval of the first ICI, ipilimumab, in 2011 for advanced melanoma, the FDA has approved seven checkpoint inhibitors to treat more than a dozen different types of cancer. • ***Cytokines:*** Cytokines are immunomodulatory molecules that are able to regulate immune cell maturation, growth and responsiveness. Currently, there are four FDA approved cytokine immunotherapies for the treatment of subsets of patients with kidney cancer, leukemia, lymphoma, melanoma and sarcoma. The first immunomodulatory approved by the FDA in 1986 for leukemia is the cytokine IFN-α. • ***Agonists:*** Agonists activate pathways that promote adaptive immune responses, either by helping to activate "killer" T cells, which directly attack cancer cells, or stimulating the activity of innate immune cells, such as dendritic cells, which coordinate overall immune responses against cancer by displaying cancer markers and enhancing T cell activity. • ***Adjuvants:*** Adjuvants activate pathways involved in the innate immune system that can stimulate general immune responses and ultimately promote adaptive immune responses. One FDA approved adjuvant immunotherapy is currently available for the treatment of subsets of patients with a type of skin cancer. The primary immunomodulators therapies target Pd-1/Pd-L1, which are immune checkpoint proteins found on the surface of T cells that cancer cells use to escape immune detection. Several large well-known pharmaceutical companies, such as Roche/Genentech and Merck, are currently pursuing this approach.

Class 3 - Vaccines	Class 4 - Antibody-based targeted therapies	Class 5 – Oncolytic viruses
Vaccines help educate, or arouse, the immune system against a potential threat. Vaccines have proven effective in preventing diseases caused by viruses and bacteria and work best as preventatives. For cancer, vaccines may be distinguished as preventive, therapeutic or personalized neoantigen vaccines. Preventive vaccines are effective for cancers clearly linked to a viral infection. Therapeutic cancer vaccines, such as Sipuleucel-T that was approved for prostate cancer patients in 2010, work to boost a patient's immune system to fight an established tumor. Personalized neoantigen vaccines aim to direct the immune responses precisely against a patient's tumor cells while sparing healthy cells from immune attack, thus possibly preventing side effects. Several types of neoantigen vaccines are currently being evaluated, both alone and in combination with other treatments, in a variety of cancer types in clinical trials.	Antibody-based targeted therapies can target either cancer cells directly or other cells/proteins that help tumors survive. There are three main categories of monoclonal antibodies: • ***"Naked" Monoclonal Antibodies*** **(mAbs)** may inhibit or block pathways that are essential to sustain cancer growth and progression or may induce other immune cells to eliminate the cancer cells. Rituximab, for the treatment of leukemia, was the first mAb approved by the FDA in 1997. • ***Antibody-Drug Conjugates (ADCs)*** are equipped with anti-cancer drugs delivered locally, after the ADC binds to its target on cancer cells. • ***Bispecific Antibodies*** may bind to two different targets at the same time. A well-known category is represented by bispecific T cell engagers, or BiTEs, that link T cells to cancer cells. Blinatumomab was the first bispecific antibody approved by the FDA in 2014 for subsets of leukemia patients.	Oncolytic viruses are natural viruses engineered to provide advantageous properties, including the decreased ability to infect healthy cells, the ability to deliver therapeutic payloads to tumor cells and the ability to induce the production of immune-boosting molecules by the infected cells. After infection, oncolytic viruses cause cancer cells to "burst," leading to the release of tumor associated antigens that can then stimulate immune responses. The oncolytic virus, T-Vec, was approved by the FDA for patients with advanced melanoma in 2015.

Current Limitations of IO Approaches

Despite significant advances, the clinical application of immunotherapy for cancer patients still faces challenges, including:

- Development of tumor resistance (positive selection of tumor cells bearing advantageous mutations);
- Dependence on specific targets;
- Poor response for many patients;
- Lack of a durable response;
- Side effects;
- Need for multiple dosing for most IO classes; and
- Inability to efficiently target many solid tumors.

In addition, manufacturing scalability of some IO approaches remains a challenge and significantly limits market penetration. The table below reports some of the main limitations for each IO class.

IO Class	Limitations
Cell-based immunotherapies	• Graft versus host disease (GVHD) • Only a limited number of antigens may be targeted currently • Inability to target multiple antigens at the same time • Some antigens targeting may be ineffective • The majority of TILs within the tumor microenvironment are exhausted so even tumor-specific T cells are hypo-responsive • CAR-T cells can only recognize antigens that are naturally expressed on the cell surface, so the range of potential antigen targets is smaller than with TCRs • Presence of target-negative tumor cells cause relapse in the long-term • Limited penetration and distribution into solid tumor tissues
Immunomodulators	• Loss of self-tolerance (establishment of autoimmunity associated with failure of tumor rejection) • Absence of reliable biomarkers and thresholds to identify the most likely responsive population • Induction of overactive immune responses as well off-target responses against healthy cells • Limited penetration and distribution into solid tumor tissues
Vaccines	• Absence of universal antigens (each individual's tumor is unique and has its own distinguishing antigens) • Presence of a compromised/weak/immunosuppressed immune system
Antibody-based targeted therapies	• Limited penetration and distribution into solid tumor tissues (mAbs directed against tumor-specific antigens largely remain in the blood and no more than 20% of the administered dose typically interacts with the tumor) • Low binding affinity between the antibody and its receptor • Antibody uptake limit • Competition for target binding between the therapeutic antibodies and a patient's antibodies • Speed of diffusion through tumors is mAb size dependent (large tumor masses may be more difficult to treat by mAb therapy)
Oncolytic viruses	• Development of neutralizing antibodies by the host, which limits the viral delivery to cancer sites and the therapeutic effect • Limited penetration and distribution of the virus into tumor tissues • Limited viral tropism and oncolysis capacity • Tricky dosing strategies • Induction of overactive immune responses as well off-target responses against healthy cells • Risk of infection

IO for Solid Tumors

Despite the success of IO therapies for some hematological cancers, significant gaps remain in the development of efficacious IO therapies for solid tumors. There are still a number of challenges that IO therapies need to resolve to treat solid tumors including the ability to target delivery of a therapeutic to the solid tumor and identification of suitable prominent cell surface targets. Cell therapies have not been as successful in solid tumors in comparison to blood cancers mainly because of the absence of a suitable prominent cell surface target and the high risk of toxicity when a potential solid tumor target is expressed, even at a low level, on normal tissue. Even if targets for solid tumors with a suitable tumor-selectivity profile can be identified, other factors may limit the activity of cell therapies, including limited cell-therapy penetration and distribution, low oxygen concentration (hypoxia) barriers around cancers that may prevent T cell access to the tumor, expression by tumor cells of certain checkpoint genes and an inability to target multiple antigens at the same time.

To overcome the current limitations of IO therapies in solid tumors, a new, effective tumor therapeutic must:

1. achieve a local and tumor-targeted delivery;
2. maximize on-target effects;
3. reach the desired therapeutic index;
4. minimize the off-target side effects; and
5. potentially provide long term results.

Our Platform

Our platform technology utilizes a novel mechanism of action that we believe has the potential to address the limitations and challenges of current IO technologies. Through a single administration, our platform is designed to provide a broadly applicable treatment to deliver a tumor-targeted therapeutic, including to solid tumors. It does so by exploiting a naturally occurring cancer-induced biological process, allowing for the local delivery of the payload with a potentially durable response, in a manner that we believe will limit systemic toxicity. The ability to deliver localized and tumor-targeted payloads, by avoiding systemic or off-target toxicity, may also allow for the use of well-established immunotherapies, such as the immunomodulator IFN-α, that has shown efficacy but has had limited therapeutic applications due to side effects associated with its intravenous delivery.

Specifically, we adapted an autologous *ex-vivo* gene therapy method to direct the patient's own hematopoietic stem and progenitor cells (HSPCs) by loading them with an immunotherapeutic transgene sequence, or payload, that is able to counteract cancer progression and prevent tumor relapse. We believe that by delivering a targeted therapeutic specific to cancer cells, we can reach the desired on-target anti-tumor effect while reducing off-target side effects.

Our platform technology employs the following key components:

a) use of the patient's own autologous HSPCs;

b) use of LVVs for *ex vivo* HSPCs transduction; and

c) payload delivery within the tumor microenvironment (TME) using specific tumor-associated myeloid cell (Tie2-expressing monocytes – TEMs). This "cell-confined" transgene expression is ensured by the selected promoter (Tie-2 promoter) and the imposed post-transcriptional regulation layer represented by a miRNA target sequence (miRNA-126 target sequences).

The image below illustrates the steps of our *ex-vivo* approach to transform patient's autologous HSPCs into a therapeutic product.

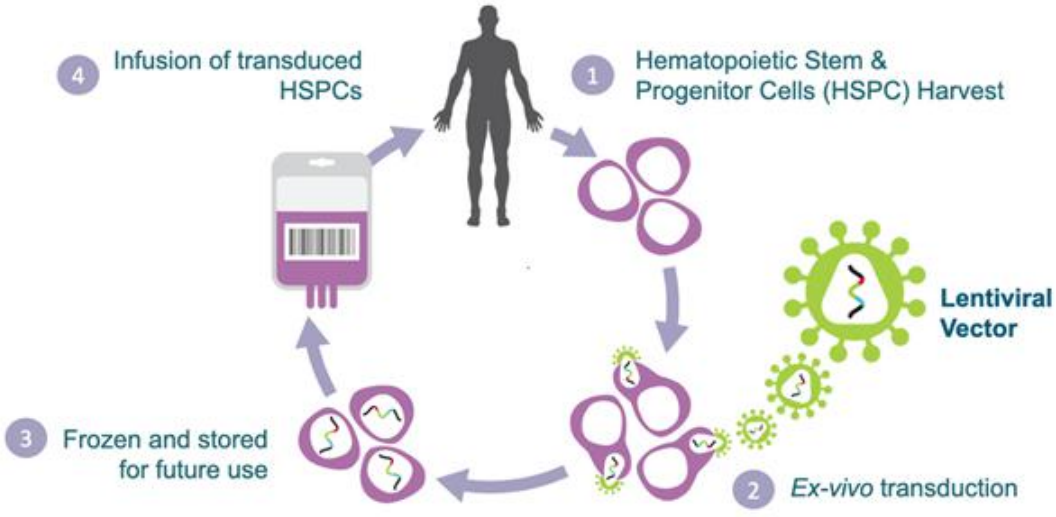


Illustration of our ex-vivo approach (steps 1-2-3) and treatment process (step 4)

(1) Patient's HSPCs are harvested by means of an apheresis process, and (2) *ex-vivo* modified by an LVV. The obtained drug product is frozen and stored for clinical use (3). When needed, the therapeutic product may be thawed and infused back in patient's blood stream (4). The engineered HSPCs will repopulate the entire hematopoietic system, giving rise to differentiated progeny bearing the introduced modification.

a) HSPCs are the Source of the Delivery Vehicle for Our Gene Therapy Approach

By re-introducing gene-modified HSPCs into the patient, we seek to take advantage of the self-renewing and multi-differentiation capability of HSPCs to enable durable and potentially long-term effects following a single treatment. HSPCs are self-renewing cells that can differentiate into all types of blood cells, including white blood cells, red blood cells and platelets. HSPCs can be obtained directly from the bone marrow or from the patient's peripheral blood with the use of a mobilizing agent that induces HSPCs to relocate from the bone marrow into the peripheral blood where they may be collected by apheresis. The advantages of using a patient's own HSPCs include the absence of graft versus host disease (GVHD) that could occur using allogeneic cells, and the potential long-term treatment durability of this approach.

b) Ex-vivo LVV based Transduction

After collection, a functional copy of the therapeutic gene is inserted into the patient's own HSPCs using a non-replicating LVV. This is an *ex-vivo* process called transduction. We have chosen an *ex-vivo* gene therapy approach because it enables us to optimize the quantity, or dose, of modified cells to be infused in each patient since we know, ahead of the administration, the drug product characteristics.

We believe that LVVs are the first choice for *ex-vivo* gene therapy in humans because they can (i) carry large transgenes that will allow us to expand the therapeutic options to a multitude of payloads without "size" limits and (ii) efficiently transduce non-proliferating, or slowly proliferating cells, such as hematopoietic stem and progenitor cells. Most importantly, there is already an abundance of safety data generated using these vectors to develop investigational products currently under clinical testing, including CARs, TCRs, as well as commercial products such as Kymriah® (CD-19 CAR-T, Novartis Pharma) and Zynteglo® (β-Thal, BlueBird Bio). With more than 100 clinical trials either completed or in progress using LVVs worldwide, this delivery method accounts for more than a third of *ex-vivo* modified gene therapy clinical trials.

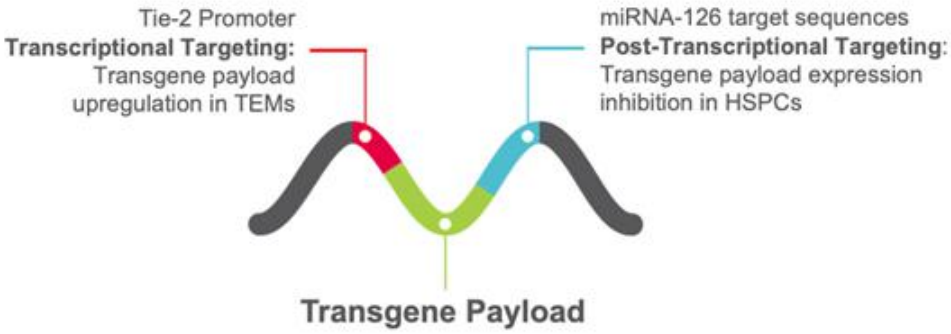
Accordingly, extensive clinical *ex-vivo* gene therapy studies, based on LVV gene transfer, have been performed in recent years by SR-Tiget for the prevention and treatment of some severe inherited disorders, resulting in approved drugs, such as Libmeldy™. These studies have shown that LVVs constitute a valuable and safer alternative to gamma-retroviral vectors (gRV), enabling a more efficient gene transfer into HSPCs and resulting in a robust and long-term transgene expression in their progeny. The studies also have demonstrated an alleviated risk of genotoxicity because of the vector design.

Differences exist between LVVs used for *ex-vivo* transduction that could, in theory, lead to differences in the long-term safety profile of products, particularly in terms of genotoxic potential. Use of strong promoters in conditions where a high pre-existing risk for hematologic malignancies exists, such as sickle cell disease (SCD), could in the long-term (i.e. 5 years or more) contribute to the development of leukemia. In February 2021, BlueBird Bio temporary suspended its gene therapy clinical trials for SCD (HGB-206 and HGB-210) and the marketing of Zynteglo® due to a suspected unexpected serious adverse reaction (SUSAR) of acute myeloid leukemia (AML) in a SCD patient who received the product more than five years ago. In March 2021BlueBird Bio announced that based on the analyses it completed, it was very unlikely the reported SUSAR was related to LVV and has since initiated engagement with regulators to begin the process of resuming clinical studies for sickle cell disease and β-thalassemia.

We believe that the intrinsic characteristics of the LVV we have selected as well as the properties of the promoter and control mechanisms, combined with HSPCs' ability to self-renew, allow for a stable integration of the modified gene into the HSPCs and their related differentiated progeny, potentially achieving long-term safety and protection after only a single treatment.

c) Tumor-Targeted Payload Delivery

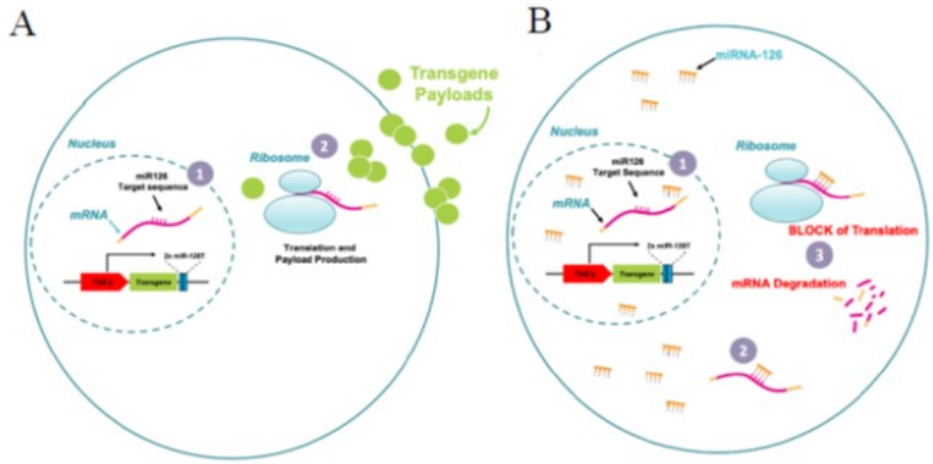
Our platform technology, used by all of our product candidates including Temferon, is designed to turn TEMs, which normally have an affinity for and travel to tumors, into a "Trojan Horse" to deliver a tumor-targeted payload. The technology ensures that the payload is only expressed in TEMs and not in other types of cells. The following key components make up our platform technology: (i) a Tie-2 promoter that drives transgene sequence transcription specifically in TEMs, and (ii) a post-transcriptional regulation layer represented by miRNA-126 target sequences that induces the downregulation of the transgene expression in those cells where the Tie2 promoter is active and the miRNA-126 target sequence is present. This transcriptional / post-transcriptional regulatory mechanism prevents off-target effects and allows the expression of the payload by the selected cellular carrier (TEMs).



Our transgene payload expression cassette consists of two key components: the Tie-2 promoter (RED) and miRNA-126 target sequences (LIGHT BLUE)

(i) ***Tie-2 promoter.*** The Tie-2 promoter enables the transformation of TEMs into a "Trojan Horse", to deliver the therapeutic payload within the tumor microenvironment. Tumor development and progression is a multi-step process leading to cancer growth. The so called "angiogenic switch" is one of the required steps and refers to a time-restricted event during tumor progression where the balance between pro- and anti-angiogenic factors tilts towards a pro-angiogenic outcome, resulting in the transition from a "dormant" avascularized tumor to an outgrowing vascularized cancer. It is well recognized that TEMs play an active role in this regard. Indeed, TEMs are actively recruited by proliferating tumors, through signals produced by the cancer cells or stromal/endothelial components, to promote the neo-vascularization and to contribute to the establishment of an immunosuppressive tumor microenvironment that leads to the failure in tumor eradication by the immune system. Amongst chemoattractant factors of monocytes, angiopoietins (Ang) play a crucial role. These are adhesion molecules and known vascular growth factors expressed by peritumoral blood vessels. One Ang in particular, Ang-2, attracts TEMs, which binds to the Tie-2 receptor. Expression of Ang-2 is upregulated by tumor hypoxia and may function as a chemoattractant for Tie2-expressing monocytes. Moreover, TEMs' penetration into the tumor microenvironment in response to these stimuli cause Tie-2 receptor upregulation, which enhances the delivery of the payload to the tumor. Since TEMs recruitment is a naturally occurring event in the tumor development process and is a key aspect shared by several different cancers, we believe that our platform which enables the tumor targeted delivery of therapeutics represents a unique approach that may have broad applicability.

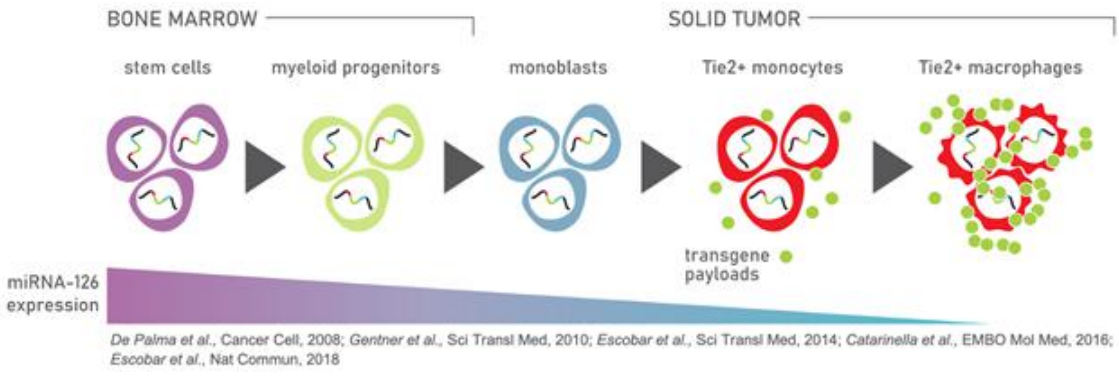
(ii) ***miRNA-126 target sequences***. The miRNA-126 target sequence serves as a post-transcriptional regulation layer that allows the expression of the transgene payload only in cells where miRNA-126 is not expressed. In our case, because miRNA-126 is highly expressed in HSPCs but down-regulated in the differentiated progeny, it switches off transgene expression in the stem and progenitor cell compartment. Indeed, Tie2 is a weak promoter expressed, in the hematopoietic compartment, by Tie2-expressing monocytes and by hematopoietic stem cells (HSC). In HSC, it works as a membrane-bound receptor that keeps HSC cell-to-cell interaction and adhesion with the bone marrow niche and preserves the HSC quiescent/low proliferating state.



Post-transcriptional control mechanism of transgene expression

A) Transgene expression is allowed only in cells where miRNA-126 is not expressed; (1) mRNA is transcribed into the nucleus (2) the transgene is then translated in the cytoplasm and released.

B) In those cells expressing miRNA-126 the payload production is prohibited; (1) mRNA is transcribed into the nucleus (2) miRNA-126 recognizes its target sequences on the mRNA and forms double strands of RNA (3) that are degraded or block the translation process.



Transgene payload expression as the result of the transcriptional (promoter) and post-transcriptional regulation (miRNA-126 target sequence) imposed by our expression cassette.

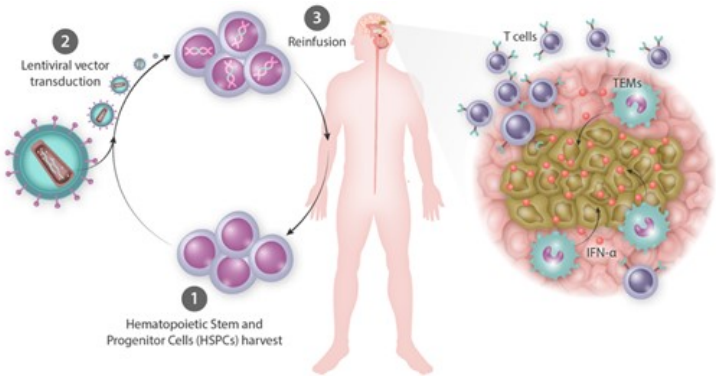
Modified HSPCs and their differentiated cell progeny, which bear the transgene whose expression is restricted to tumor-associated myeloid cell (Tie2-expressing monocytes – TEMs).

We believe that combining our built-in post-transcriptional control mechanism (*miRNA-126 target sequences*), with TEMs designed as a "Trojan Horse" allows our platform to restrict transgene expression and avoid systemic toxicity while reaching the therapeutic index to drive efficacy.

Our Leading Product Candidate: Temferon

Our lead product candidate, Temferon, consists of genetically modified HSPCs which use our platform to deliver interferon-alpha (IFN-α), within the tumor microenvironment via TEMs (HSPCs differentiated progeny). The IFN-α reduces angiogenesis, counteracts tumor cells proliferation and breaks the established immune-tolerance, enabling the immune system to recognize the tumor. IFN-α is a proven and known immunomodulatory molecule, or cytokine, that has limited clinical use due to the systemic toxicity associated with its intravenous administration. Our technology is designed to protect the HSPCs from IFN-α mediated activation that could negatively impact their repopulation capacity as reported in some studies of repeated systemic administration of high doses of IFN-α. We believe that this protection technology, whereby we restrict payload expression to TEMs, and the release of IFN-α within the TME, has the potential to provide efficacy without inducing systemic toxicity.

Because TEMs are associated with the growth of numerous cancer types, including solid tumors, we believe that Temferon is tumor type and tumor target agnostic and therefore may be used across a large variety of cancers. Currently, we are developing Temferon for GBM.



Overview of Temferon manufacturing process and mechanism of action.

*Patient's **HSPCs** are harvested, (1) **ex-vivo** modified by **LVVs** (2) and re-introduced back in patient's blood stream (3). Once recruited within the tumor microenvironment, TEMs release IFN-α that reduces angiogenesis, counteracts tumor cells proliferation and enables the immune system to recognize the tumor.*

GBM is a solid tumor affecting the brain. We have chosen this indication due to the following factors:

- ***High unmet medical need.*** The prognosis for GBM patients remains poor with few therapeutic options having limited clinical benefits.
- ***Temferon's MoA targets TEMs which have an active role in GBM pathology.*** GBMs are highly vascularized tumors that critically depend on the generation of tumor-associated blood vessels. Several studies demonstrate that infiltrating myeloid cells, including Tie2-expressing monocytes, contribute significantly to tumor angiogenesis, presumably by secreting pro-angiogenic factors and promoting malignant glioma growth by creating a local immunosuppressive microenvironment. Moreover, TEMs have been identified in the normal/tumor boundary from human biopsy samples of GBM patients who received treatment to reduce angiogenesis using the anti-VEGF treatment bevacizumab, and the Tie2 pathway has been implicated in the triggering of a bevacizumab-mediated VEGF-independent angiogenesis that explains the long-term refractoriness of GBMs to anti-VEGF treatment.
- ***Immunosuppressive tumor microenvironment.*** GBM is characterized by an immunosuppressive microenvironment that is mediated by tumor associated myeloid cells (including TEMs) that prevent the immune system from recognizing and rejecting the tumor. Our treatment approach is designed to exploit TEMS to deliver IFN-α to the tumor so that the immune system recognizes the tumor and halts tumor cell proliferation and recurrence.

- ***Availability of a "competent" immune system.*** Our approach relies on a patient's immune system being capable of providing an immune response upon recognition of the tumor. Therefore, we believe newly diagnosed GBM patients who have relatively "competent" immune systems, not yet damaged by repeated cycles of chemotherapies, are strong candidates for our candidate.

- ***Compelling preclinical data.*** Our preclinical studies, published in peer-reviewed papers, suggest that TEMs play an active role in GBM, and when used as a "Trojan Horse," significantly shrink the tumor and to control disease progression. In more recent unpublished studies, we have also demonstrated, in a preclinical immunocompetent GBM mouse model, that treatment by Temferon resulted in a long-lasting immune response in surviving mice, even after repeated tumor challenge intended to replicate possible tumor recurrences.

- ***Market Opportunity.*** Based on currently available treatments, the global market size for GBM is projected to grow to over $1.5 billion by 2026. We believe a novel therapeutic which demonstrates improvement over existing therapies would greatly increase the market size.

We are discussing a second study using Temferon in a second solid tumor indication. Locally advanced HCC and ICC are the leading indications under consideration and, as with GBM, these liver cancer indications have been selected for similar reasons as described above.

Temferon for GBM

Disease Overview

GBM is the most common malignant primary brain tumor accounting for more than half of all central nervous system (CNS) cancers and for which there is a high unmet medical need. The incidence rate is 3.20 per 100,000 persons with over 13,000 deaths per year in the United States. This disease is lethal and left untreated, the median survival is three (3) months. The current standard of care includes using a combination of surgery, radiation therapy, and chemotherapy for treatment. Although these treatments may improve survival, the prognosis for GBM patients remains poor with a median overall survival (mOS) of approximately 15 months and only 5.5% of patients estimated to be alive 5 years after diagnosis. GBM may occur at any age, but 70% of cases are seen in patients between 45 and 70 years of age (median 64 years). The disease often progresses rapidly (over 2 to 3 months). Neurological signs are nonspecific as they result from intracranial hypertension and include headaches and vomiting, often associated with behavioral changes or focal neurological deficits. Variants of GBM include secondary glioblastoma (20% of total diagnosed GBM), gliosarcoma (2%) and giant cell glioblastoma (1%). We are not including these variants in our studies because they do not fully meet our selection criteria discussed above.

Current Treatment Landscape and Limitations

The current standard of care for GBM includes surgery to remove the accessible tumor followed by radiation therapy (RTx), chemotherapy with temozolomide (TMZ) and/or tumor treating fields (TTFields).

- ***Surgery*** remains the mainstay of initial treatment. If the tumor is located in a resectable region of the brain, it is used to histologically confirm the diagnosis and level of tumor burden. For many patients, removal of the tumor also results in a decrease of tumor mass-associated symptoms. Although the extent of the surgical removal of the tumor is linked to longer survival, due to the invariably infiltrative nature of the disease, even the complete removal of the accessible tumor is not curative and most people with GBM later develop recurrent tumors either near the original site or at more distant locations within the brain. Additionally, as a possible consequence of surgical procedures, permanent brain damage may occur.

- ***Radiation therapy*** improves survival and is typically started approximately 3 to 4 weeks after surgery. RTx is performed daily for approximately 6 weeks. RTx induces the formation of neo-antigens and a pro-inflammatory response that are key aspects for immune system mediated disease control. However, the efficacy of RTx is impaired by hypoxia and by the negative effects of RTx on tumor infiltrating immune cells.

- ***Chemotherapy.*** Temozolomide, the current chemotherapeutic standard of care, is a DNA-alkylating agent that can cross the blood-brain barrier to reach therapeutic concentrations in the brain. The drug is administered every day during radiation therapy and then for six to 12 cycles after radiation as a maintenance therapy. Each cycle lasts 28 days, with TMZ given the first five days of each cycle, followed by 23 days of rest. TMZ adds a methyl group to DNA that, if unrepaired, leads to DNA strand breaks and cytotoxicity. More than one-third of glioblastomas are deficient in methylguanine methyltransferase (MGMT), a repair protein that removes the methyl group. This MGMT deficiency occurs through the methylation (silencing) of the MGMT gene promoter. Glioblastoma patients with a silenced MGMT gene who are treated with TMZ have a longer survival than those with an unmethylated MGMT. TMZ has several adverse side effects, including a cumulative bone marrow toxicity.

- ***Tumor-Treating Fields (TTFields)***. The use of TTFields to extend temozolomide maintenance chemotherapy for newly diagnosed glioblastoma patients has recently been incorporated as a new standard of care. TTFields are applied via multiple electrodes that are directly fixed to the scalp. These low-intensity, alternating electrical fields interfere with cell division ultimately leading to cell cycle arrest, aneuploidy, and apoptosis. The most common TTFields-associated adverse events (AEs) are mild-to-moderate array-associated contact dermatitis.

- **Experimental Treatments.** Along with the above-mentioned treatments, the addition of the antiangiogenic agent bevacizumab (BEV) to RTx and TMZ has been explored with mixed clinical results BEV was tested both a first-line treatment together with RTx and concomitant TMZ administration in newly diagnosed glioblastoma patients, as well as in combination with RTx in recurrent GBM patients. BEV was approved by the FDA as monotherapy for recurrent glioblastoma in 2009 under the name Avastin®. The EMA declined to approve BEV for recurrent glioblastoma due to the absence of a non-bevacizumab control arm, a modest overall survival increment versus historic controls, inadequate elucidation of true antitumor effect, and challenges with radiographic response assessment. More recently, an immune-checkpoint blocker nivolumab was tested in combination with TMZ and RTx in a Phase 3 trial in recurrent glioblastoma patients but showed minimal activity and no benefit in terms of mOS, resulting in failure to meet one of its primary endpoints, progression free survival (PFS).

Currently available GBM surgical treatments have not been able to prevent GBM recurrence because of the infiltrative nature of this disease and the absence of an effective immune system. A therapeutic able to cross the blood-brain barrier and selectively impact proliferation of cancer cells independently from the region of the brain where the tumor resides would be a significant advancement.

Our Solution

We believe that our investigational product, Temferon, has the potential to address the world recognized unmet need. Through a single administration, we believe Temferon may be able to provide a long-lasting immune response, minimize systemic toxicity, counteract cancer progression and prevent tumor relapse.

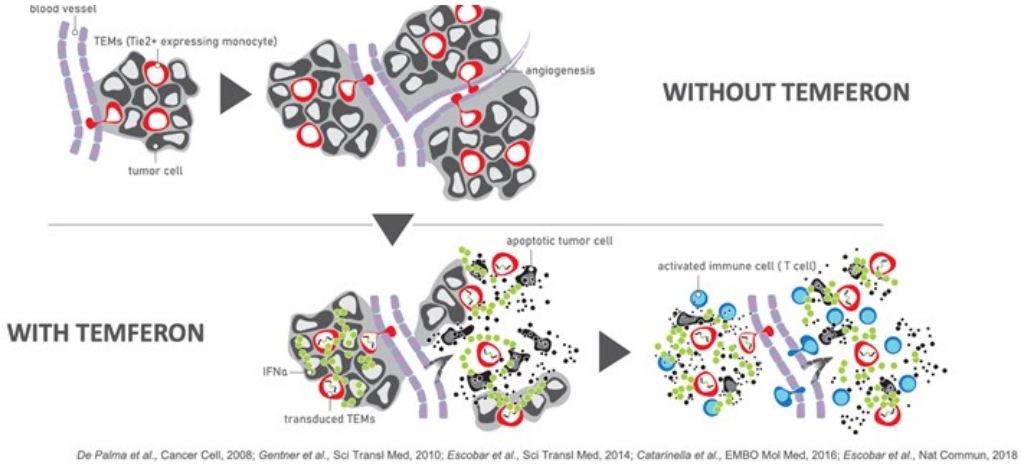
Temferon utilizes our platform and *ex-vivo* gene therapy approach to introduce a functional copy of IFN-α which is Temferon's transgene payload, into the patient's autologous HSPCs, resulting in a drug product that can then be reintroduced into the patient as outlined above (*see "Our Leading Product Candidate: Temferon" and "Our Platform"*). Temferon is designed to colonize the patient's bone marrow with the genetically modified HSPCs to continuously generate TEMs containing the IFN-α payload. Since TEMs are recruited within the tumor microenvironment, IFN-α is released solely at the targeted tumor, which may result in clinical activity without inducing systemic toxicity.

Once within the tumor microenvironment, IFN-α is expected to act both *directly* by promoting cancer cell apoptosis and inhibiting vascularization and *indirectly* by restoring the body's anti-tumor immune response, as follows:

- ***Direct Effects.*** IFN-α suppresses tumor cell proliferation and promotes the apoptosis of tumor and stromal cells by induction of proapoptotic genes or repression of anti-apoptotic genes. Moreover, IFN-α inhibits angiogenesis by downregulating the expression of proangiogenic factors.

- ***Indirect Effects.*** IFN-α stimulates early innate immune responses and the subsequent adaptive immune response via multiple pathways and mechanisms, including: maturation and cross-priming capacity of dendritic cells (DCs); upregulation of the expression of tumor-associated surface antigens and MHC class I molecules on tumor cells and of MHC class I and II molecules on DCs; enhanced priming and survival of T cells; enhanced humoral immunity; increased cytotoxic activity of NK cells and macrophages; control of helper T cell population balance (Th1=Th2); immunoglobulin class switching of B cells; and the regulation of CD8+ cytotoxic T-lymphocyte (CTL) responses.

We believe that through these immunomodulatory functions and based on our preclinical data, IFN-α increases tumor immunogenicity, recruits and activates immune cells within the tumor milieu, breaks established tumor-induced immunotolerance and may induce tumor rejection.



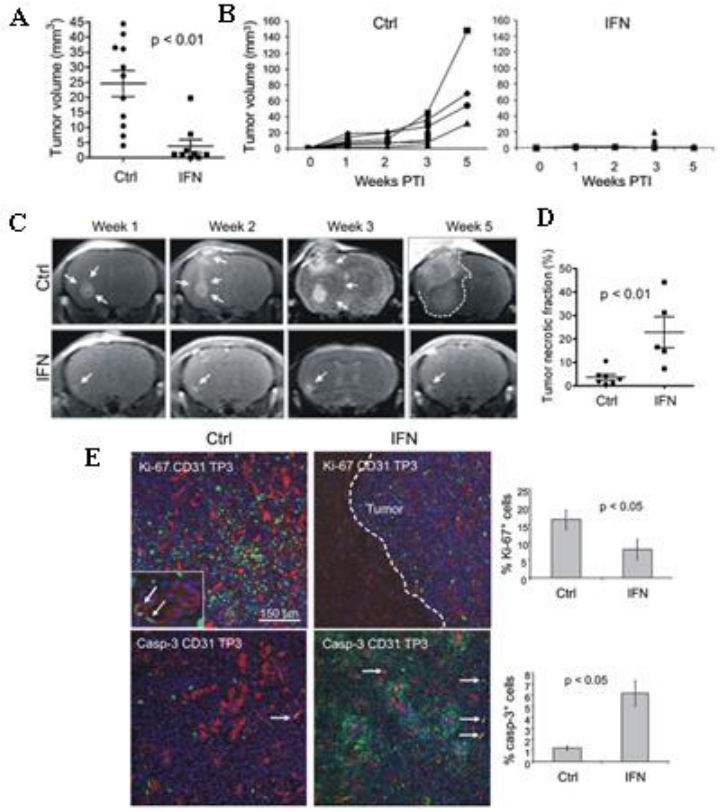
Overview of Temferon antitumor activity

Once recruited at the tumor site, instead of fostering tumor growth and inhibiting the immune systems, TEMs start to release IFN-α that triggers cancer cell apoptosis and arms the immune cells to fight the cancer.

Clinical Development of Temferon in GBM

Preclinical Data

We have preclinical data, published in 2018, suggesting that TEMs play an active role in GBM disease. Further studies published in 2008 showed that when TEMs were used as a "Trojan Horse," as utilized by Temferon, the GBM tumor volume decreased and the disease progression was controlled. In more recent, unpublished preclinical studies, we have also demonstrated, in an immunocompetent GBM mouse model, that treatment with Temferon resulted in a long-term immune response in surviving mice, even after repeated tumor challenge intended to replicate possible tumor recurrences.



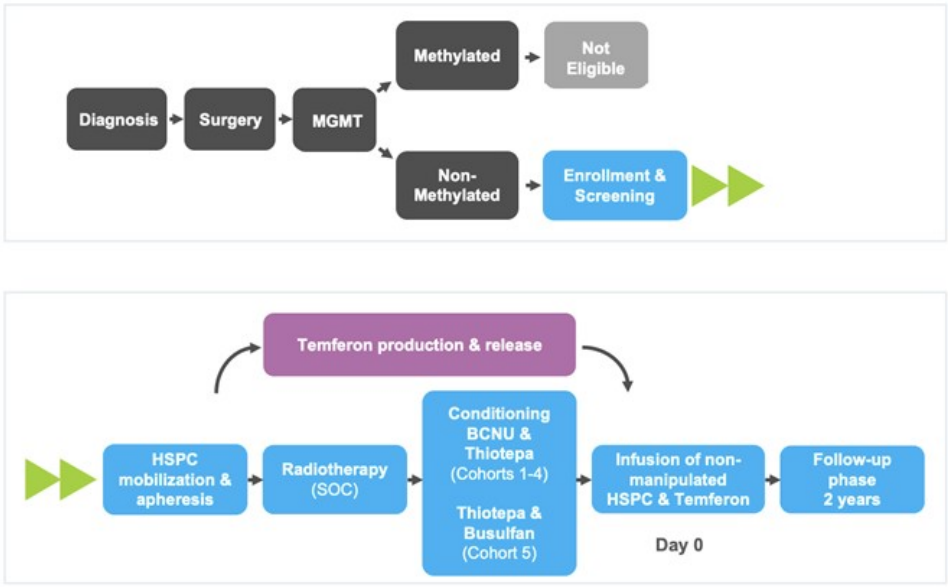
Inhibition of Human Gliomas in IFN-α Gene Therapy Treated Athymic Mice (De Palma et al., 2008).

A-B) *Glioma growth (mean tumor volume ± SEM, measured by MRI) in individual control and IFN-α gene therapy treated mice (Tie2-IFN) at 3 weeks post tumor injection (PTI). Tumor volume and progression decreased in IFN-α gene therapy treated mice.* ***C)*** *MRI images showing brain tumor growth at the indicated time points PTI in representative control (Ctrl) and Tie2-IFN mice. Intracranial gliomas are indicated by arrows and dashed line. The tumor did not progress in Tie2-IFN mice.* ***D)*** *Measurement of tumor necrotic fraction (mean necrotic fraction, % ± SEM) by MRI in individual Ctrl and Tie2-IFN mice at 3 weeks PTI, evidencing cancer cell death.* ***E)*** *The Tie2-IFN tumors that grew sufficiently to be analyzed displayed decreased cell proliferation and greater apoptosis (assessed by Ki-67 and cleaved caspase-3 immunostaining, respectively a proliferation and an apoptosis marker) as compared to the control tumors. (Caspase-3 = Casp-3; green) and CD31 (marker of blood vessels; red) TO-PRO-3 (TP3; nuclear staining, blue). Arrows show Ki-67+CD31+ or caspase-3+CD31+ (ECs; dashed line indicates tumor margin).*

Phase 1/2a Clinical Trial

In the second quarter of 2019, we initiated a single-arm, open label, dose escalation, Phase 1/2a clinical trial, in adult patients aged 18 to 70 years ("TEM-GBM 001 study"). The trial is being conducted at two clinical centers of excellence located in Milan, Italy: (i) Istituto Nazionale Neurologico "*Carlo Besta*", an internationally recognized leading center in neuroscience, specializing in the diagnosis and treatment of neurological diseases in adults and children, and (ii) OSR, which has a recognized expertise in complex and innovative diagnostic and therapeutic approaches in onco-hematological patients and in gene therapy treatments.

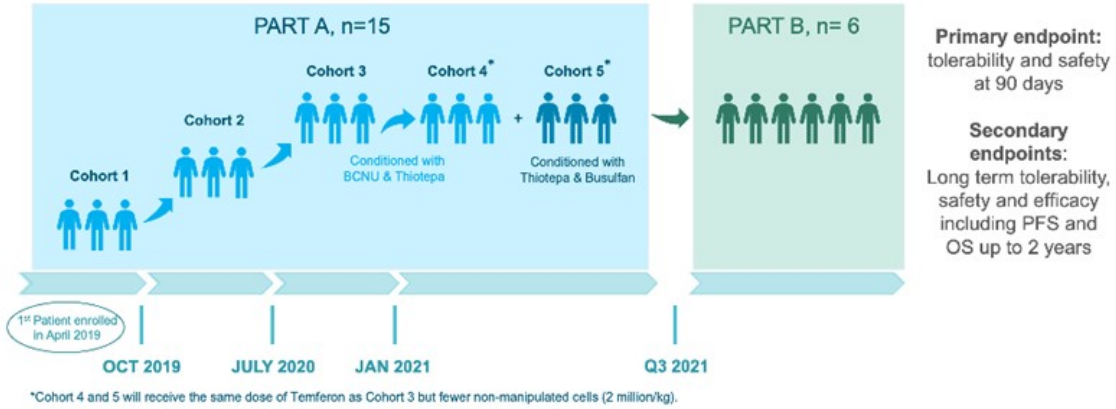
The primary objective of the TEM-GBM 001 study is to evaluate the safety, feasibility and biological activity of Temferon in GBM patients with an unmethylated MGMT gene, who as a result of the gene, have a poor prognosis and are expected to not respond to TMZ treatment. These patients are identified immediately after surgery, upon confirmation of the diagnosis and MGMT methylation status. After enrollment, each patient is screened for eligibility, and if eligible subjected to the mobilization procedure to induce HSPCs to exit from the bone marrow niche and to migrate into the peripheral blood where they are collected by leukapheresis. Immediately after collection, each patient's HSPCs are sent to our CMO to be genetically modified and become Temferon. After Temferon administration, each patient will be followed for two years. The figure below depicts the different stages of TEM-GBM 001 study enrollment and treatment.



TEM-GBM 001 Study Design.

Our study is split into two parts, Part A and Part B. Part A evaluates the tolerability and safety of three escalating doses of Temferon in 15 patients at 90 days. Part B evaluates the safety and tolerability of a single dose, as identified from Part A, in 6 patients with GBM at 90 days. The secondary objective of this study is to evaluate the long-term tolerability and safety of Temferon for up to 2 years following Temferon administration.

Patients in Part A of our study will be split into five cohorts, each containing three patients. Each cohort will be administered one of three escalating Temferon doses (Dose I to III, with Dose III also administered to patients from cohorts 4 to 5) following the infusion of supporter HSPCs ($3x10^6$ of non-manipulated CD34+ cells/kg or $2x10^6$ non-manipulated CD34+ cells/kg). We will also test two sub-myelosuppressive conditioning regimens required for the engraftment of Temferon (i) carmustine (BCNU) and thiotepa in patients of cohorts 1-4, and (ii) busulfan and thiotepa in patients of cohort 5. We are evaluating the two conditioning regimens to determine which regimen results in better engraftment of Temferon to the bone marrow with fewer side effects. Upon completion of Part A of our study, we will enroll an additional six patients into Part B of the study to evaluate the safety and tolerability of the single dose of Temferon identified from Part A. The conditioning regimen we use in Part B will also be selected based on the results of Part A. Once Part B starts, we will add another stand-alone site, the Policlinico Gemelli in Rome (Italy). The figure below represents the TEM-GBM 001 study scheme with interim and anticipated milestones. The study EudraCT Number is 2018-001404-11 and can be found at clinicaltrialsregister.eu/ctr-search/trial/2018-001404-11/IT.



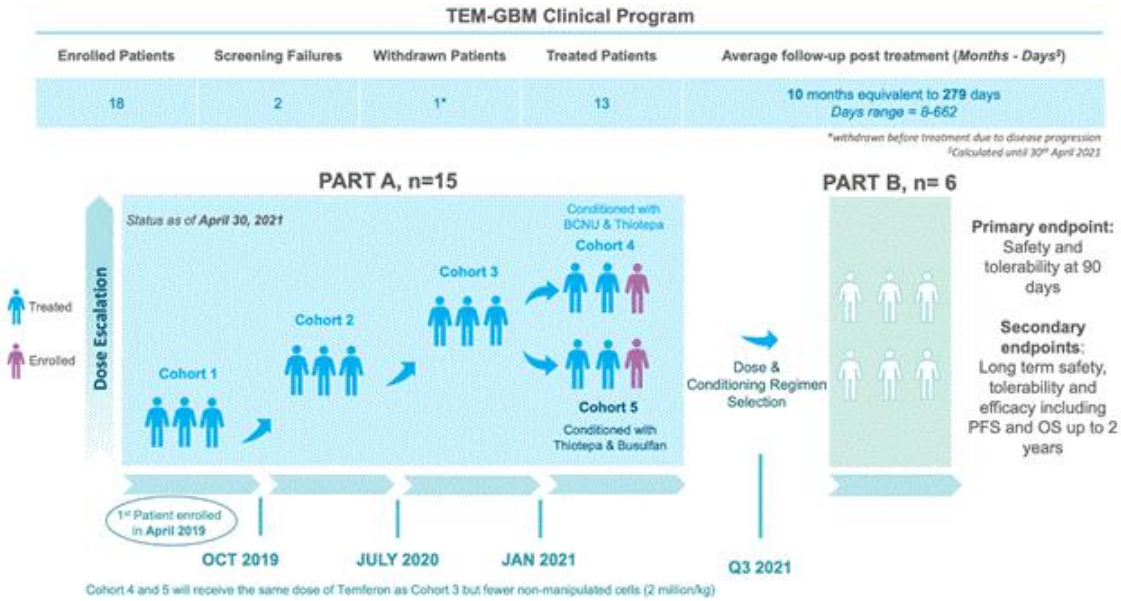
TEM-GBM Study Design.

Preliminary Interim Results.

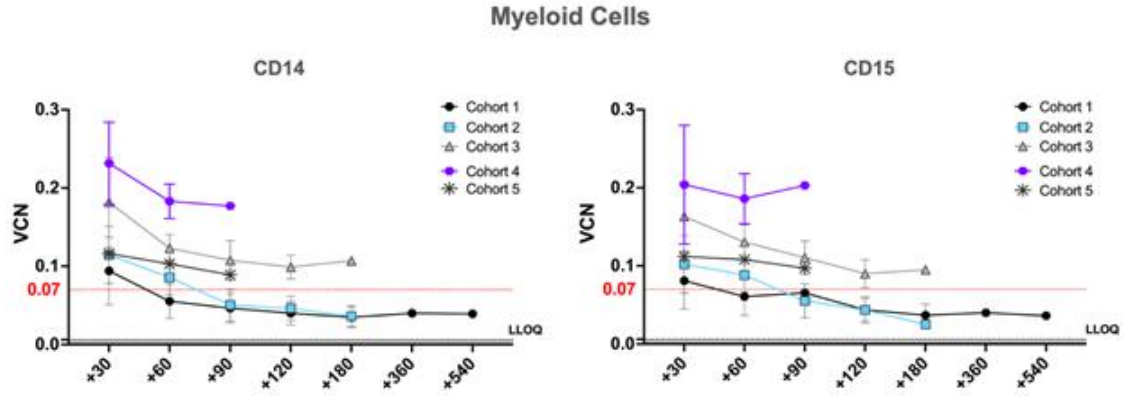
We designed the TEM-GBM 001 study to: (i) obtain rapid accrual of patients (ii) assess the safety profile of Temferon, (iii) identify the optimal dose, and (iv) measure the biological activity of Temferon on those patients who progress to the point of requiring a second surgery. Although our studies to date have not been statistically powered, meaning that drawing determinative conclusions from studied datasets regarding causality is not supported by statistical theory, this approach is typical for early stage cancer studies and biological evidence provided by such studies may lend support to theories of MOA and indicate safety and tolerability of the agent being studied.

We designed our study anticipating that patients receiving lower doses of Temferon could progress to the point of needing a second surgery. A second surgery provides the only source of GBM specimens post treatment to evaluate the biological activity of Temferon, and to evaluate its mechanism of action in patients. We enrolled our first patient in April 2019 and as of April 30, 2021, we have dosed thirteen patients, nine of them belonging to the first three dose escalating cohorts, two belonging to cohort 4 and two belonging to cohort 5. Two additional patients are also enrolled, one which is assigned to cohort 4 and one which is assigned to cohort 5. We expect to complete dosing of patients assigned to cohorts 4 and 5 by the end of the second quarter of 2021 and progress to Part B of our study in the third quarter of 2021.

Overview of the current TEM-GBM clinical development program



There have been no dose limiting toxicities identified in our clinical study to date. All patients showed rapid engraftment and hematological recovery after administering the sub-myeloablative conditioning regimens (BCNU and Thiotepa or Busulfan and Thiotepa). Evidence of presence and persistence of Temferon-derived differentiated cells is assessed by measuring the vector genomes in the DNA of peripheral blood and bone marrow cells (absolute number quantified by ddPCR). The vector copy number (VCN) positive cells were present within 14 days post treatment and were detectable, albeit at lower levels, in the long-term (up to 18 months, the last measured timepoint to date).



Engineered myeloid cells persist in peripheral blood for up to 18 months

We also detected very low concentrations of IFN-α in the plasma and cerebrospinal fluid, suggesting effectiveness of the transgene expression control mechanism may be working as intended.

Serious adverse events have mainly been attributed by the Investigator to the effects of the conditioning regimen (pneumonia, pulmonary embolism, febrile neutropenia, fatigue, C.diff infection, CMV reactivation, sepsis, anemia due to CMV reactivation) or disease progression (worsening left hemiparesis, seizure, brain abscess, sudden death). Three instances of elevated gamma glutamyl transferase (GGT) have been observed: two mild cases attributed to chemotherapy and HSPC harvesting, each of which has resolved; and one case occurring at D+78 following Temferon administration, which was classified as a suspected unexpected serious adverse reaction (SUSAR) possibly related to Temferon, and which has also resolved. Four deaths have been reported to date: three at +322, +340 and +402 days after Temferon administration due to disease progression, and the fourth at +60 days due to complications following the conditioning regimen.

The last evaluable disease status as assessed by immunotherapy response assessment for neuro-oncology (iRANO) criteria as of April 30, 2021, the last evaluable time point for all 13 treated patients, was as follows: four patients had shown stable disease (SD), two patients had demonstrated partial response, six patients had shown progressive disease (PD) and one patient had shown pseudoprogression. For reference, The iRANO guidelines specifically address interpretation of initial progressive imaging findings in the context of neuro-oncology patients with a goal of decreasing the likelihood of premature discontinuation of potentially beneficial therapies while ensuring maximum patient safety. iRANO empirically stipulates a three month window for confirmation of progression on follow-up imaging, and further advises that progressive imaging changes beyond six months after immunotherapy initiation are more likely true tumor progression.

All patients from the first two, lower dose, cohorts progressed. The PD occurred after a median of + 124 days (range 83–239 days) following administration of Temferon. Two patients of cohort 3 progressed before Temferon administration. Preliminary analyses performed on the tumor specimens belonging to patients with PD who underwent a second surgery (4 patients) confirmed the presence of TEMs within the tumor, as assessed by flow cytometry, and an increased expression of IFN-responsive gene signatures compared to diagnosis, as assessed by quantitative polymerase chain reaction (PCR) tests. We believe that these findings suggest intra-tumor IFN-α release.

Of the four patients who underwent the second surgery, one patient had a prior lesion, which was not removed during the first surgery. When this patient underwent the second surgery following treatment with Temferon, it was observed that this lesion was stable and had not grown. In addition, this patient presented a relapsing progressing lesion that had developed at the first surgery site. Both lesions were removed and biopsied at the second surgery. Notably, as assessed by flow cytometry, the stable lesion had a higher proportion of T cells and TEMs within the myeloid infiltrate and as detected by quantitative PCR a markedly increased IFN-response signature as compared to the relapse-progressing lesion.

We also analyzed the peripheral blood of the patients from cohorts 1 and 2. In these patients, the peripheral blood showed, on two of the three subjects with samples at the first and second surgery, a change in the T cell immune repertoire post treatment, revealing expansion of tumor-associated clones, which suggested that changes in the immune system are occurring.

We believe these results align with our preclinical data and suggest the immune activation effects of Temferon. Specifically, the preliminary interim results, including the tumor analysis conducted after second surgery described above, provide biological evidence to support the hypothesis that cellular and molecular changes were triggered by Temferon in GBM patients despite the low dose administered. We have yet to reach the maximum tolerated dose of Temferon and as outlined in our study protocol, we will be increasing the dose in cohorts 4 and 5.

United States TEM-GBM Clinical Development Plan

We plan to use the results of our TEM-GBM Phase 1/2a study (NCT03866109) to support our submission of an IND to the FDA. In advance of our submission, we intend to have a Pre-IND meeting with the FDA by the end of the second quarter of 2021 to discuss our clinical trial design and endpoints, proposed commercial manufacturing process, including analytical methods and corresponding qualification, and validation plans for Temferon. We anticipate submitting an IND for a Temferon Phase 1/2b study for GBM patients by the fourth quarter of 2021. The Phase 1/2b study will evaluate the safety, tolerability, biological reprogramming of the tumor microenvironment in Temferon treated patients compared to the current standard of care, with primary endpoints, of PFS and mOS. Additionally, we intend to identify and select a CMO to manufacture and to supply Temferon in the U.S. for our larger trials to be conducted after the completion of our Phase 1/2b study.

Key components of the anticipated clinical trial are as follows:

- Multicenter study evaluating Temferon for safety, tolerability and efficacy compared to the current standard of care;
- Enrollment and treatment of up to 30 patients with newly diagnosed GBM and unmethylated MGMT promoter; and

- Co-primary study endpoints to include PFS and mOS.

The study design will be discussed with FDA at the Pre-IND meeting and may be subjected to modifications.

Second Solid Tumor Indication

We are also evaluating liver cancers as a potential second solid tumor to be investigated. HCC and ICC are gastrointestinal cancers affecting the digestive system. We chose to pursue these indications for similar reasons as the GBM indication, namely:

- ***High unmet medical need and market opportunity*.** The prognosis for patients with locally advanced HCC and ICC remains poor with few therapeutic options having limited clinical benefits.
- ***TEMs have an active role in HCC and ICC pathology.***
    - Several third-party studies have shown that tumor infiltration by tumor associated myeloid cells, including TEMs, is a negative prognostic factor in HCC and ICC.
    - In HCC, TEMs are the most abundant proportion of tumor associated myeloid cells.
    - Hepatitis B (HBV) infections and hepatitis C (HCV) infections, both of which predispose individuals to the development of chronic liver disease and the subsequent liver cancers, upregulate Ang-2 expression, further contributing to tumor angiogenesis and TEMs migration.
    - In HCC, Ang-2 mRNA expression is significantly increased when compared to adjacent liver tissue and angiopoietins and tumor infiltrating TEMs appear to be associated with metastasis and recurrent disease.

  All the above evidence highlights the role of TEMs in fostering liver cancer growth, by promoting angiogenesis.
- ***Pro-inflammatory and immunosuppressive tumor microenvironment.*** Both locally advanced HCC and ICC are characterized by a pro-inflammatory and immunosuppressive tumor microenvironment with TEMs playing a key role.
- ***IFN-α and liver tumors.*** Chronic inflammation resulting from HBV and HCV infection are key contributors for the development of HCC or ICC. Before the introduction of antiviral agents in 2011, parenterally administered interferons, including IFN-α, were utilized as the standard of care in order to achieve viral clearance and/or suppression. The use of IFN-based regimens for HCV and HBV infections has been associated with a reduction in HCC risk. Evidence suggests that use of IFN-α as an adjuvant therapy in HCC patients after curative therapy may reduce the recurrence rates for up to 5 years, particularly in patients with concurrent HCV infection.
- ***Available preclinical data.*** We have preclinical data, published in peer reviewed papers suggesting that TEMs used as a “Trojan Horse” for cancer that has metastasized to the liver were able to induce a statistically significant tumor shrinkage and control disease progression.
- ***Market Opportunity.*** Based on currently available treatments, the HCC and ICC combined global market value is projected to grow to over $2.6 billion by 2026. We believe a novel therapeutic which demonstrates improvement over existing therapies would greatly grow the market size.

Disease Overview

Liver and intrahepatic bile duct cancers are upper gastrointestinal (GI) cancers that affect the digestive system. They are the fifth most common cause of cancer deaths in men in the U.S., and the seventh most common cause of death in women. The American Cancer Society (ACS) estimates that 42,230 new cases of liver cancer (including intrahepatic bile duct cancers) will be diagnosed in 2021. Of these cases, approximately three-quarters were HCC, while less than one-quarter were bile duct cancers (both intrahepatic and extrahepatic). We are developing Temferon to treat the two tumor types listed below.

- ***Hepatocellular carcinoma*** (HCC) is a primary malignancy of the liver that occurs predominantly in patients with underlying chronic liver disease and cirrhosis. The incidence of HCC has been rising worldwide over the last 20 years, with about eight new cases per 100,000 adults per year. The highest incidence of HCC occurs in Asia and Africa, where the endemically high prevalence of hepatitis B (HBV) and hepatitis C (HCV) strongly predisposes individuals to the development of chronic liver disease and the subsequent development of HCC. Patients with HCC have, when treated with the current standard of care, an expected median OS of only 11 months with approximately 10-40% of patients surviving 3 years. Up to 25% of HCC patients have no history of cirrhosis and do not present any risk factors for chronic liver disease, such as HBV and HCV.

- ***Cholangiocarcinoma*** is a biliary tract cancer and represents approximately 3% of all GI malignancies. Of this 3%, ICC accounts for 5% to 10% of those cases. The incidence is 2.1 per 100,000 person years. Despite surgery, the prognosis remains poor with disease recurrence and progression occurring in approximately two-thirds of patients and a 5-year survival rate of only 30%.

HCC Current Treatment Landscape and Limitations

In general, HCC patients are asymptomatic in the early stages of the disease, and as a result, the diagnosis is usually obtained in later stages of the disease when there are no curative therapies available. The implementation of surveillance, and the improvements in imaging techniques, have enabled the diagnosis at earlier stages of HCC. In terms of first line treatment approaches, patients with very early HCC are optimal candidates for surgical resection and liver transplantation but when these options are not suitable due to tumor localization or the absence of a matched liver donor, local ablation through percutaneous ethanol injection or radiofrequency are the available alternative treatments. For late-stage HCC, the transcatheter arterial chemoembolization (TACE) is the standard of care.

- ***Surgical Resection*** is the recommended first line therapy for patients with a single HCC nodule, achieving the highest effectiveness in terms of disease control and overall survival. However, despite the accurate selection of patients with early tumors and the complete tumor removal, HCC patients are at high risk of tumor recurrence.

- ***Percutaneous ethanol injection*** (PEI) is an effective technique used for early-stage HCC with a low complication rate that induces the complete necrosis of small HCC lesions. However, PEI has limitations including the need for multiple treatment sessions (4-6) and a prolonged treatment time. Although generally well tolerated, PEI can result in death and rare instances of tumor seeding. PEI-treated lesions have a high rate of local recurrence (33% - 43%).

- ***Radiofrequency ablation*** (RFA) has advantages compared to PEI including ease of performance, effectiveness similar to that of surgical resection, high safety, and low invasiveness. RFA is the first-choice post-surgery procedure for patients with early-stage HCC. However, despite the advantages of RFA, complete tumor ablation remains difficult to achieve in some specific liver sites. Many patients treated with RFA develop atrial fibrillation on long-term follow-up.

- ***Transarterial chemoembolization*** (TACE) is the current standard of care for patients with intermediate/late-stage HCC and who have relatively preserved liver function. TACE combines the “tumor embolization”, meaning the treatment blocks the vascular supply to a tumor accompanied by a local administration of chemotherapy. This permits high concentration of drugs in the tumor area, while simultaneously reducing systemic exposure. However, the technique is not standardized and there is no universal consensus as to TACE application in the clinical setting thereby limiting reliable comparison of results.

- ***Sorafenib*** has been the first line chemotherapy standard of care for patients with advanced unresectable hepatocellular carcinoma (HCC) since 2007 and has also been found to be useful in association with TACE as an effective chemotherapeutic agent to prolong survival in inoperable HCCs. However, Sorafenib is associated with adverse events (AEs) such as hand-foot skin reaction, rash, upper and lower gastrointestinal distress (i.e. diarrhea), fatigue, and hypertension. Furthermore, a proportion of treated patients show no response to the drug.

ICC Current Treatment Landscape and Limitations

Surgery (radical excision) is the only treatment available for ICC. However, the disease will recur in 40–85% of patients who have a median survival of 36 months. Neo-adjuvant approaches have largely been unsuccessful and adjuvant therapy (radiotherapy, chemoradiotherapy or chemotherapy alone) is offered to patients only as a palliative solution. Based on a single, positive Phase 3 study, chemotherapy with gemcitabine and cisplatin is considered the standard of care and plays an established role as a palliative care solution.

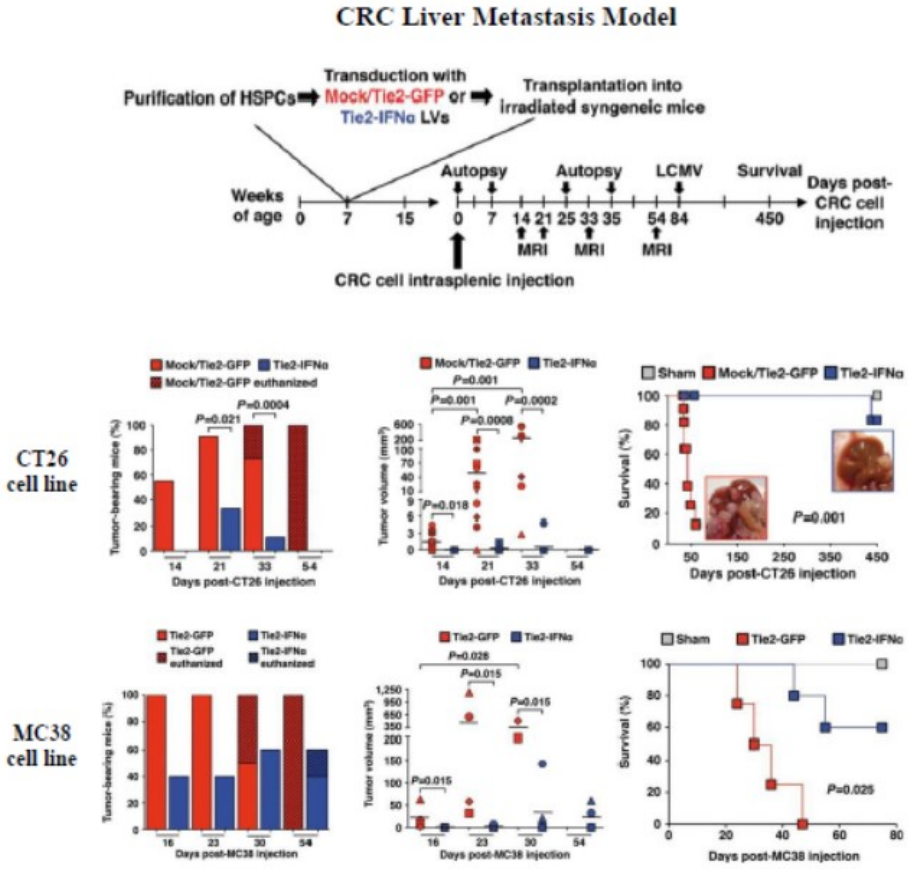
Our Solution

Similar to Temferon for GBM, we believe that Temferon may overcome the current treatment limitations of HCC and ICC that are not curative/resolutive by stopping/delaying disease progression.

Clinical Development of Temferon in HCC and ICC

Preclinical Data

As described in the study published by Giovanni Sitia's research group at OSR in collaboration with Luigi Naldini, our IFN-α gene delivery platform was tested in a mouse model of liver metastases from colorectal cancer (CRC) resulting in a substantially delayed or complete prevention of tumor growth with prolonged long-term survival. Our approach was also effective on pre-established liver metastases that more closely mimics tumor treatment in human.



In vivo data on Tie2-IFN gene therapy platform in a mouse model of colorectal cancer (CRC) liver metastasis (Catarinella et al.; 2016)

IFN-α gene therapy treatment impairs the metastatic growth in the liver CRC liver metastasis.

CT26 and MC38 cell line panels: Percentage and tumor volume quantification measured by MRI analysis of mice injected with CT26 cells bearing at least one CRC liver metastasis estimated by MRI analysis and Kaplan–Meier survival curves of the indicated groups. The inset images show representative macroscopic photographs of the metastatic progression in the liver. Sham i.e., mice transplanted with non-transduced HSPCs and intrasplenically injected with saline thereafter.

TEM-HC Study Design

We are currently developing the TEM-HC study design. As with the TEM-GBM 001 study, we plan to propose to the Italian regulatory bodies a non-randomized, open label, single center, Phase 1/2a, therapeutic-exploratory, prospective study, involving a single injection of Temferon administration

in up to 9 patients affected by either HCC or ICC. The study will recruit and track patients at OSR. We intend to initiate this Phase 1/2a study within the first quarter of 2022, subject to feedback from regulatory authorities.

Patients will be administered Temferon following the same process as our TEM-GBM trial, namely: (i) HSPCs harvesting, (ii) standard of care chemotherapy concomitant to Temferon manufacturing, (iii) administration of the conditioning regimen followed by Temferon infusion, and (iv) 2-years of follow-up.

Additional Pipeline Pre-Clinical Programs

Our platform technology was designed to be flexible so that it can be potentially adapted to treat a variety of cancers. We believe that Temferon lends itself to be used in combination with a variety of current existing therapeutics to potentially enhance overall efficacy because its mechanism of action is intended to abrogate tumor induced tolerance. Additionally, we are developing a second-generation platform which is designed to release our therapeutic payload “on demand”. Finally, our proprietary platform is designed to control the expression of a potentially wide variety of therapeutic payloads we may choose for different targets.

Combination Treatment

While therapies to treat several types of cancers, such as ICI, CAR-T and TCR, are rapidly transforming the practice of medical oncology, clinical data point to the risk of late relapses after treatment with these therapeutics. Thus, the data suggest that the durability of the response to these therapies remains a significant challenge. We believe that due the agnostic nature of Temferon, its potential activity, which includes the abrogation of tumor induced tolerance, and its potentially synergistic mechanism of action, makes it an ideal candidate to be considered for combination treatments. Specifically, Temferon may be a good candidate to be used in combination, for very aggressive tumors, with other immune-oncology drugs, such as CAR-T and ICI, to extend the durability of the response in very aggressive tumors. We believe that this additional Temferon application is supported by the promising results coming from the combination studies performed using Temferon with CAR-T, TCR and ICI in our pre-clinical programs as discussed below.

In preclinical studies conducted in the laboratories of our founders, Professor Luigi Naldini and Dr. Bernhard Gentner, Temferon was evaluated in combination with CAR T, TCR-edited T cells directed against tumor-associated antigens and immune checkpoint blockers. The results showed promising additive-to-synergistic anti-tumor activity in leukemia experimental models (Escobar et al., Nature Communication 2018), glioblastoma models, and multiple myeloma mouse models (manuscripts in preparation). These results lead us to believe that IFN gene therapy might also boost the efficacy of other immunotherapies.

Specifically, in a leukemia mouse model, a CD19 CAR-T approach had detectable, but not significant effect on the tumor burden. However, when used in combination with Temferon, the combination treatment resulted in a significant inhibition of the hematological malignancy with a significant fraction of CAR-T/Temferon treated mice surviving at the latest timepoint of analysis. Similarly, the combination of IFN gene therapy to α-CTLA4, an immune check point blocker, or adoptive T cell therapy, significantly improved the survival of the mice (Escobar et al., Nature Communication 2018).

In a multiple myeloma mouse model, Temferon was administered in combination with human TCR-edited T cells directed against NY-ESO1 and anti-myeloma drugs. The combination approach showed promising additive-to-synergistic effects leading to more pronounced disease control compared to most single-agent regimens, and without exacerbating hematologic or systemic toxicities (manuscript in preparation).

Switchable Platform

Our founders are developing a second-generation platform designed to release the therapeutic payload “on demand” to allow in vivo control of its potential efficacy. Potential advantages of this application include (i) broadening the clinical application to patient populations with more favorable pre-treatment prognoses; (ii) control of long-term side effects that may arise from the chronic exposure to immunostimulatory molecules and (iii) the ability to activate the immune system on demand to recognize tumors based on clinical need.

An inducible version of the IFN-a payload has been generated by fusing the protein with a destabilizing domain (DD), which targets the protein to proteasomal degradation, unless a small molecule ligand binding to the DD and stabilizing it, is administered. The optimized fusion construct is delivered by the TEM platform and the exogenous administration of the ligand switches on its secretion within the tumor. The results from experiments performed in the laboratory of Professor Naldini with a glioblastoma mouse model showed similar anti-tumor activity of the inducible and wild-type IFN payload. Moreover, the inducible construct allows switching of IFN release upon tumor clearance (manuscript to be submitted for publication). We plan to use our second generation platform carrying an IFN-a payload in combination with CAR T cells to target glioblastoma-associated antigens or immune checkpoint blockers in an experimental tumor model in mice.

Other Payloads

Our platform is designed to allow the control of the expression of any payload we use. Similar to IFN-a, there are several alternative payloads with immunotherapeutic properties that were previously systemically delivered to patients, but were discontinued due to significant toxicity that prevented the drug from reaching therapeutic dosages (e.g. TNF-a). Because we believe that our first- and second-generation platforms may overcome the limitations associated with systemic administration, we are testing them with additional payloads such as IFN-g, IL-12 and TNF-a. Because each payload triggers a unique biological response, we believe our platform may enable a personalized treatment approach unique amongst the current treatment paradigms.

Additional immune activating cytokines have been tested for TEM-mediated gene-based delivery to tumor models in mice. Current pre-clinical results suggest the feasibility and specificity of tumor-targeted delivery of IFN-g and TNF-a and further support our hypothesis that the specific transcriptional and microRNA regulated expression of the payload prevents toxicity. Data generated in the laboratory of our founders in a leukemia model showed that IFN-g but not TNF-a mediate anti-tumor activity when delivered *ex vivo*. Further *ex vivo* studies showed enhanced anti-tumor activity upon combined delivery of two cytokines by the TEM-based platform.

Moreover, experiments conducted with our second-generation inducible platform expressing IL-12 supported the hypothesis that our proprietary transcriptional and microRNA regulated expression of the payload to may prevent toxicity. Indeed, IL-12 is a potent cytokine that must be kept within a therapeutic dose range to prevent toxicity. Targeted delivery and anti-tumor activity of the new inducible payload are being investigated (abstracts to be presented at EACR in June 2021; at ASGCT 2021 in May 2021; and manuscript to be submitted). The laboratory of Professor Naldini plans to test the combination of TEM-mediated gene-based delivery of inducible Il-12 or additional inducible payloads with CAR-T, TCR and ICI in experimental murine tumor models.

Competition

Biotechnology and pharmaceutical industries put significant resources in developing novel and proprietary therapies for the treatment of cancer. For the cell therapy field in particular, this results in rapidly advancing and changing technologies, intense competition and a strong emphasis on intellectual property. While we believe that our leading product candidate, Temferon and our scientific expertise in the field of cell and gene therapy provide us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

Manufacturing

The manufacturing process for our autologous cell and gene therapy approach requires the following steps:

1. HSPCs harvesting in a specialized clinical center (leukapheresis)
2. Shipping of apheresis bag/s to the selected contract manufacturing organization (CMO)
3. CD34+ cells enrichment
4. *Ex-vivo* transduction of CD34+ cells with our LVV,
5. Cryopreservation, characterization and release by a Qualified Person of the obtained drug product.

The LVV manufacturing needed for the *ex-vivo* transduction process, as well as steps from 3 to 5, are conducted by the CMO. The figure below delineates the steps and the timeline for manufacturing Temferon.

Overview of Temferon manufacturing Process

We have entered into agreements with AGC Biologics to manufacture our LVV and drug product for our ongoing clinical programs in Italy. AGC Biologics is a leading global contract development and manufacturing organization (CDMO), providing world-class development and manufacture of mammalian and microbial-based therapeutic proteins of plasmid DNA (pDNA) and recently with the acquisition of Molecular Medicine S.p.A. ("MolMed"), of viral vectors and genetically engineered cells. MolMed S.p.A. is recognized as the leading cell and gene therapy CDMO focused on research, development, production and clinical validation of cell and gene therapies for the treatment of cancer and rare diseases. Indeed, Strimvelis, the first ever market approved *ex-vivo* gene therapy for children, was developed and is still currently manufactured by MolMed. Accordingly, Orchard Therapeutics (NasdaqGS: ORTX) in July 2020 renewed their collaboration agreement with MolMed which will continue to support activities related to the development and manufacturing of vectors and drug products for several of Orchard's investigational *ex-vivo* hematopoietic stem cell (HSC) gene therapies in the upcoming years, including the recent EU market authorized gene therapy drug *Libmeldy.*

AGC Biologics Headquarters and Capabilities

Our agreement with MolMed establishes agreed-upon timelines for purchase order submissions and manufacturing date changes/cancellation. The supply agreement also sets milestones both during the clinical phase and any future commercial phase of our product candidates and for technology transfer if required, as well as customary termination provisions, allowing for termination by a party upon the other party's uncured material breach or upon the other party's insolvency. For our planned US clinical program, AGC Biologics will manufacture LVV and a US-based CMO whom we will engage with will manufacture Temferon. The LVV is a cryopreserved raw material stable in vapor liquid nitrogen up to 48 months under current approvals, and will be shipped to the US-based CMO for drug product manufacturing.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Temferon

Temferon is protected by the following patents families that contain both issued and/or pending patent applications. While the following patent families are jointly owned by OSR and Fondazione Telethon (Telethon), as set forth in our December 15, 2014 license agreement with OSR (described below), Telethon granted OSR a worldwide exclusive license, with the right to sublicense, its rights in the patent families pursuant to a separate cooperation agreement between OSR and Telethon. As described below, we have a worldwide exclusive license, from OSR, to the following patent families (including the U.S. and European family members indicated) in the fields of: GBM, solid liver cancer (LC) and any lympho-hematopoietic indication:

Focus / Family	U.S.	E.U.	Expiration
Gene Vector comprising mi-RNA (composition and method of treatment claims) PCT/IB2010/001166 (WO / 2010/125471)	USP 10,287,579 USP 9,951,328 USSN 16/384,571 (pending)	EP 2424571 B1 EP 20167404.1 (pending)	4/30/2030
Gene Vector comprising mi-RNA (composition and method of treatment claims) PCT/IB2006/002266 (WO 2007/000668).	USP 10,000,757* USP 9,556,438 USSN 16/004,394 (pending)	EP 2002003 B1	5/26/2026*
Monocyte Cell (Tie-2) activation process (composition claims) USP 7,833,789	USP 7,833,789	-	10/5/2027
Methods for Genetic Modification of Stem Cells (method of treatment claims) PCT/IB2014/065594 (WO 2015/059674)	USP 10,617,721* USSN 16/827,708 (pending)	EP 3060670 B1 EP 19185334 (pending)	10/24/2034*
Vector Production (composition and method of treatment claims) PCT/IB2015/055286 (WO 2016/009326)	USP 10,912,824	EP 3169788 (pending)	7/13/2035
Type 1 Interferon Gene Therapy (method of treatment claims) PCT/EP2018/060238 (WO 2018/193119)	USSN 16/604,484 (pending)	EP 18724470.2 (pending)	4/20/2038**

* Later expiration for certain U.S. patents pursuant to patent term adjustment (35 U.S.C. §154(b)).
** Application pending, anticipated expiration based on 20 year patent term.

Our technology incorporates the use of a lentiviral vector (LVV) that combines a therapeutic transgene sequence, or payload, with our proprietary platform. Our proprietary platform consists of (i) the Tie-2 promoter, that drives transgene sequence transcription specifically in TEMs, and (ii) miRNA-126 target sequences to downregulate transgene expression post-transcription in those cells where the Tie-2 promoter is active and the miRNA-126 is present. Intellectual property protection for our proprietary platform includes an exclusive license to all issued patents and pending applications (if any) in the PCT/IB2006/002266 (WO 2007/000668) and PCT/IB2010/001166 (WO / 2010/125471) families, as well as trade secrets. As discussed below, we have the option to license exclusively USP 7,833,789 and issued patents and pending applications (in the PCT/IB2014/065594 and PCT/IB2015/055286 patent families we have not yet exercised the option rights), and improvements, for other indications (fields of use) and other product candidates.

In addition to patents and patent applications that we have been granted licenses to, we may also rely on unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We seek to protect know-how and trade secrets through an active program of legal mechanism including invention assignments, confidentiality agreements, material transfer agreements, research collaborations and licenses to protect our product candidates. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For a more comprehensive discussion of the risks related to our intellectual property, please see “Risk Factors — Risks Related to Our Intellectual Property.”

Collaboration / Licensing

License Agreement with Ospedale San Raffaele

Effective December 15, 2014, we entered into a license agreement with OSR (OSR License Agreement) pursuant to which OSR granted us an exclusive, royalty-bearing, non-transferrable (except with the prior written consent of OSR) worldwide license, subject to certain retained rights, to certain patents, patent applications and existing know-how for (1) the use in the field(s) of IFN gene therapy by lentiviral based-HSPC gene transfer with respect to (a) any Lympho-Hematopoietic Indication and/or (b) any Solid Cancer Indication that we exercise a future option (discussed below); and (2) certain products developed during the license term for use in the aforementioned field(s) consisting of any lentivirals vector regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter. Lympho-Hematopoietic Indications mean any indication related to lympho-hematopoietic malignancies and Solid Cancer Indication means any solid cancer indication (e.g., without limitation, breast, pancreas, colon cancer), wherein each affected human organ being considered as a specific Solid Cancer Indication.

The rights retained by OSR, and extending to its affiliates, include the right to use the licensed technology for internal research within the field(s) of use, and the right to use the licensed technology for any use outside the field(s) of use, but subject to the options described below. In addition, we granted OSR a perpetual, worldwide, royalty-free, non-exclusive license to any improvement generated by us with respect to the licensed technology, to conduct internal research within the field of use directly, or in or with the collaboration third parties; and, for any use outside the field of use, in which case the license is sublicenseable by OSR. Finally, the world-wide rights for the field of use granted to us regarding the Lentigen know-how are non-exclusive and cannot be sublicensed due to a pre-existing nonexclusive sublicense to these rights between OSR and GlaxoSmithKline Intellectual Property Development Limited.

As stated, we have an exclusive option to (i) certain additional patents and patent applications, and OSR improvements at no additional cost, which could be useful for the development and/or commercialization of licensed products in the field of use; and (ii) any Solid Cancer Indication to be included as part of the field of use, on an indication-by-indication basis, subject to the payment of specified option fees and milestone payments.

As consideration, we paid OSR an upfront fee of €250,000, and we agreed to pay OSR royalties on a single digit percentage of the net sales of each licensed product. The royalty may be reduced upon the introduction of generic competition or patent stacking, but in no event would the royalty be less than half of what it would have otherwise been, but for the generic competition or patent stacking. We also agreed to pay OSR a royalty of our net sublicensing income for each licensed product and to pay OSR certain milestone payments upon the achievement of certain milestone events, such as the initiation of different phases of clinical trials of a licensed product, MAA approval by a major EU country, BLA acceptance by the FDA, the first commercial sale of a licensed product in the United States and certain EU countries, and achievement of certain net sales levels.

As part of the license, we agreed to use OSR as the primary site in any preclinical study or clinical trial (including all phases thereof) relating to any licensed products in the field of use, subject to OSR maintaining any required quality standards and providing its services on customary and reasonable terms and consistent with then-applicable market standards. We are also obligated to carry out our development activities using highly skilled professionals and sufficient level of resources and, specifically, to invest (a) at least €5,425,000 with respect to the development of the licensed products, and (b) at least €2,420,000 with respect to the manufacturing of such licensed products (subject to certain adjustments).

OSR maintains control of the preparation, prosecution and maintenance of the patents licensed. We are obligated to pay those costs unless additional licensees benefit from these rights, in which case the cost will be shared *pro rata*. OSR controls enforcement of the patents and know-how rights, at its own expense. In the event that OSR fails to file suit to enforce such rights after notice from Genenta, we have the right to enforce the licensed technology within the field of use. Both us and OSR must consent to settlement of any such litigation, and all monies recovered will be shared equally between the parties after reimbursement for costs, or failing a bona fide agreement between us and OSR, on a 50% - 50% basis.

The OSR License expires upon the expiry of the “Royalty Term” for all licensed products in all countries, unless terminated earlier. The Royalty Term begins on the first commercial sale of a licensed product and ends upon the later of the (a) expiration of the commercial exclusivity for such product (wherein the commercial exclusivity refers to any remaining valid licensed patent claims covering such licensed product, or any remaining regulatory data exclusivity for such licensed product), and (b) 10 years from the first commercial sale of such licensed product. The parties may terminate the agreement in the event the other party breaches its obligations therein, which termination shall become effective 60 business days following written notice thereof to the breaching party. The breaching party shall have the right to cure such breach or default during such 60 business days. OSR may terminate the agreement for failure to pay in the event that we fail to pay any of the upfront payment, sublicensing income or milestone payments within 30 days of due dates for each. In addition, OSR may terminate our rights as to certain fields of use for our failure to develop (a) with respect to a solid cancer indication, upon third anniversary of the date we exercised such option, if we have not filed an IND with respect to such optioned solid cancer indication specifically, as to GBM, we are required to file an IND regarding Temferon for GBM prior to February 2022, or (b) with respect to a lympho-hematopoietic indication, on the earlier of (i) the fifth anniversary of the initiation (first patient dosed) of the first human clinical trial for a licensed product in any lympho hematopoietic indication or solid cancer indication if a patient has not been dosed with a licensed product in a Phase 3 clinical trial and (ii) September 1, 2025.

In March 2017, the OSR License Agreement was amended to provide us with additional exclusive option to expand the license to include the use of lentiviral based-HSPC gene therapy platform to use tumor necrosis factor (TNF) as an alternative payload (rather than IFN) and for the use of that product alone or in combination with other products and committed to spend €500,000 on such product should the option be exercised. We have until September 30, 2021 to exercise this option, upon the payment of specified option fees.

In February 2019, we entered into a second amendment to the OSR License Agreement, whereby we exercised an option with respect to GBM as the first solid cancer indication. We agreed to pay OSR a GBM option fee of €1.0 million upon the dosing of the tenth patient in a specified clinical trial of GBM. We also agreed to extend the period to exercise the option rights set forth by the license agreement until September 30, 2021.

In December 2020, we entered into a third amendment to the OSR License Agreement, whereby the GBM option fee included in the second amendment was reduced to €500,000 pursuant to an agreement to enter into a sponsored research agreement (SRA) within forty-five (45) days (and later amended to seventy (70) days) from the effective date of the third amendment (discussed below) in relation to research programs aimed at further studies regarding Temferon, with all intellectual property generated by such SRA being owned by OSR/Telethon subject to the grant by OSR to us of exclusive option rights with respect to such intellectual property. With the third amendment we also exercised an option with respect to a second solid cancer indication, namely solid liver cancer (LC). We agreed to pay OSR an LC option fee of €500,000 upon the earlier of (i) June 30, 2021 and (ii) the enrollment of the first patient within the Phase I clinical study for an LC licensed product. Under the terms of the third amendment, if we are unable to obtain regulatory approval to initiate human clinical trial with respect to solid liver cancer within nine (9) months from the third amendment effective date, we have the right, at no additional cost, to convert the option exercise for the second solid liver cancer indication to an alternative indication. In addition, pursuant to the third amendment, the option period for us to exercise an option with respect to any other solid cancer indication is extended until the second anniversary of the third amendment effective date, or December 23, 2022. The aggregate amount paid to date under the OSR License Agreement is €0.75 million. In addition, €0.5 million is currently due under the OSR License Agreement. Future potential payments that are not yet considered probable under this agreement include €53 million relating to GBM, €47.5 million relating to LC and €0.3 million relating to the license fee option for the third indication, if exercised.

In February 2021, we entered into a Sponsored Research Agreement ("SRA") with OSR to conduct certain research projects related to Temferon. Unless terminated earlier or extended by mutual agreement, the SRA ends upon the earlier of (a) the date of completion of all activities relating to the sponsored research and (b) December 31, 2022. The total consideration to be paid by the Company under the SRA will be €1.0 million with payments scheduled quarterly over 2021 and 2022. The aggregate amount paid in 2021 to date under the SRA is €0.25 million.

Know-How License Agreement with Fondazione Telethon

In February 2016, we entered into a Know-How License Agreement with Telethon (Telethon License Agreement). Telethon granted us a non-exclusive, perpetual, sublicensable (through multiple tiers), royalty-bearing, worldwide license to use its manufacturing know-how in the research and development, sale and export of any product, which is defined therein as any lentiviral vector regulated by miRNA 126 and/or miRNA 130 and/or other miRNAs with the same expression pattern as miRNA 126 and/or miRNA 130 in hematopoietic cells for the expression of any anticancer protein under the control of a Tie2 promoter or INF under the control of any promoter other than Tie2 for any cancer indication. As consideration for the license, we agreed to pay Telethon a royalty equal to a low single digit percentage of any actual payments (excluding taxes) to any CMO for the manufacturing of any product using the licensed know-how. The royalty payments must be made for eight (8) years from the effective date, or until February 2, 2024. The parties may terminate the agreement in the event the other party breaches its obligations therein, which termination shall become effective sixty (60) business days following written notice thereof to the breaching party.

Government Regulation; Coverage, Reimbursement, Pricing

Government authorities in the United States, at the federal, state and local levels, and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, sales, pricing, reimbursement, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of biopharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Approval and Regulation of Drugs in the United States

In the United States, drug products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and other laws, including, in the case of biologics, the Public Health Service Act ("PHSA"). Drug products are also subject to other federal, state and local statutes and regulations. A failure to comply with any applicable requirements during the product development, approval, or post-approval periods may lead to administrative or judicial sanctions, including, among other things, the imposition by the FDA or an institutional review board ("IRB") of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, or administrative, civil and/or criminal investigation, penalties or prosecution.

In the United States, all of our product candidates are regulated by the FDA as biologics. Biologics require the submission of a BLA and approval by the FDA prior to being marketed in the United States. Manufacturers of biologics may also be subject to state and local regulation.

The steps required before a biologic may be marketed in the United States generally include:

- completion of preclinical studies, animal studies and formulation studies, performed in accordance with the FDA's good laboratory practices ("GLP") requirements, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an investigational new drug application ("IND"), which must become effective before human clinical trials may commence;
- approval of the protocol and related documentation by an independent IRB or ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials under protocols submitted to the FDA and reviewed and approved by each IRB, conducted in accordance with the FDA's good clinical practices ("GCPs") requirements and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity and potency of the biologic for each targeted indication;
- preparation of and submission to FDA of a biologics license application ("BLA") for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to accept and file the application;
- satisfactory completion of an FDA pre-license inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current good manufacturing practices ("cGMPs") to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- potential FDA audit of the preclinical study and clinical trial sites that generated the data in support of the BLA in accordance with any applicable expedited programs or designations;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies);
- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for particular indications for use in the U.S.;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the biologic is produced to assess compliance with current Good Manufacturing Practices ("cGMP") and to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the BLA.

Preclinical Studies and the IND Process

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of a product's biological characteristics, chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of the preclinical studies must comply with federal regulations and requirements, including, as applicable, GLP and the Animal Welfare Act.

Prior to commencing an initial clinical trial in humans with a product candidate in the U.S., an IND must be submitted to the FDA and the FDA must allow the IND to proceed. An IND is an exemption from the FD&C Act that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, the clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND must become effective before human clinical trials may begin. Once submitted, the IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a full or partial clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial or part of the study can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. The FDA also may impose clinical holds on a sponsor's IND at any time before or during clinical trials due to, among other considerations, unreasonable or significant safety concerns, inability to assess safety concerns, lack of qualified investigators, a misleading or materially incomplete investigator brochure, study design deficiencies, interference with the conduct or completion of a study designed to be adequate and well-controlled for the same or another investigational product, insufficient quantities of investigational product, lack of effectiveness, or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical Trials

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators. Clinical trials are subject to extensive regulation and must be conducted in compliance with (i) federal regulations, (ii) GCP standards, which set safeguards to protect the rights and health of patients and establish standards for conducting, recording data from, and reporting results of clinical trials, and (iii) protocols detailing, among other things, the objectives of the trial, subject selection and exclusion criteria, the parameters and criteria to be used in monitoring safety, and the effectiveness criteria to be evaluated, if any. Foreign studies conducted under an IND generally must meet the same requirements that apply to studies being conducted in the United States. The informed written consent of each study patient must be obtained before the patient may begin participation in the clinical trial. The study protocol, study plan, and informed consent forms for each clinical trial must be reviewed and approved by an IRB for each clinical site, and the study must be conducted under the auspices of an IRB for each trial site. Investigators and IRBs must also comply with FDA regulations and guidelines, including those regarding oversight of study patient informed consent, complying with the study protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

The clinical trial program for a product candidate is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases are as follows:

- *Phase 1*. Phase 1 involves the initial introduction of a product candidate into humans. Phase 1 clinical trials are typically conducted in healthy human subjects, but in some situations are conducted in patients with the target disease or condition. These clinical trials are generally designed to evaluate the safety, metabolism, pharmacokinetic ("PK") properties and pharmacologic actions of the product candidate in humans, the side effects associated with increasing doses and, if possible, to gain early evidence of effectiveness. During Phase 1 clinical trials, sufficient information about the product candidate's PK properties and pharmacological effects may be obtained to inform and support the design of Phase 2 clinical trials.

- *Phase 2*. Phase 2 includes the controlled clinical trials conducted to obtain initial evidence of effectiveness of the product candidate for a particular indication(s) in patients with the target disease or condition, to determine dosage tolerance and optimal dosage, and to gather additional information on possible adverse side effects and safety risks associated with the product candidate. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population; and

- *Phase 3*. Phase 3 clinical trials are clinical trials conducted in an expanded patient population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product candidate has been obtained and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for regulatory approval. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the product candidate, although a single Phase 3 clinical trial with other confirmatory evidence may be sufficient in certain instances.

In August 2018, the FDA released a draft guidance entitled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to biological product development and reduce developmental costs and time.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may also be made a condition to approval of the BLA. Failure to exhibit due diligence regarding conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA, emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information.

The decision to suspend or terminate development of a product candidate may be made by either a health authority body, such as the FDA, by an IRB, or by a company for various reasons and during any phase of clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by a data safety monitoring board ("DSMB"), which is an independent group of qualified experts organized by the trial sponsor to evaluate at designated points in time whether or not a trial may move forward and/or should be modified. These decisions are based on unblinded access to data from the ongoing trial and generally involve determinations regarding the benefit-risk ratio for study patients and the scientific integrity and validity of the clinical trial.

In addition, there are requirements for the registration of certain clinical trials of product candidates on public registries, such as www.clinicaltrials.gov, and the submission of certain information pertaining to these trials, including clinical trial results, after trial completion.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, a sponsor submits extensive information about the product candidate to the FDA in the form of a BLA to request marketing approval for the product candidate in specified indications.

Biologics License Applications

In order to obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The BLA includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product candidate, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the product candidate to the satisfaction of the FDA.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, the fees payable to the FDA for reviewing an original BLA, as well as annual program fees for approved products, can be substantial, subject to certain limited deferrals, waivers and reductions that may be available. The FDA has 60 days from receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may refuse to accept for filing any BLA that it deems incomplete or not properly reviewable at the time of submission, in which case the BLA will have to be updated and resubmitted. The FDA's PDUFA review goal (which is not a legal requirement) is to review 90% of priority BLA applications within six months of filing and 90% of standard applications within 10 months of filing, but the FDA can and frequently does extend this review timeline to consider certain later-submitted information or information intended to clarify or supplement information provided in the initial submission. The FDA may not complete its review or approve a BLA within these established goal review times. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure, and potent for its intended use, and whether the product is being manufactured in compliance with cGMP to ensure its continued safety, purity and potency. The FDA may also refer applications for novel product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured or the facilities that are significantly involved in the product development and distribution process, and will not approve the product candidate unless cGMP compliance is satisfactory and the manufacturing processes and facilities are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements.

Under the Pediatric Research Equity Act, certain BLAs must include an assessment, generally based on clinical trial data, of the safety and effectiveness of the biological product in relevant pediatric populations. The FDA may waive or defer the requirement for a pediatric assessment, either at a company's request or by its own initiative, including waivers for certain products not likely to be used in a substantial number of pediatric patients. Unless otherwise required by regulation, products with orphan drug designation are exempt from these requirements for orphan-designated indications with no formal waiver process required.

After the FDA evaluates the BLA and the manufacturing facilities, the FDA may issue either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA may issue an approval letter. The FDA's PDUFA review goal is to review such resubmissions within two or six months of receipt, depending on the type of information included. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and deny approval of a resubmitted BLA. FDA approval of any application may include many delays or never be granted. An approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the product outweigh the potential risks. REMS can include Medication Guides, communication plans for healthcare professionals, and also may include elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the biologic. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the biologic's safety, purity, or potency, which can be costly.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or a supplemental BLA before the change can be implemented. A supplemental BLA for a new indication typically requires clinical data similar to that in the original application, and the FDA generally uses the same procedures and actions in reviewing a supplemental BLA as it does in reviewing a new BLA.

Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance. In addition, new or modified government requirements, including from new legislation, may be established that could delay or prevent regulatory approval of our product candidates under development or affect our ability to maintain product approvals we have obtained.

Orphan Drug Designation

The FDA may grant orphan drug designation to biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or a disease or condition that affects 200,000 or more individuals in the United States but there is no reasonable expectation that the cost of developing and making the biologic would be recovered from sales in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. In addition, if a company receives the first FDA approval of a drug or biologic for the indication for which it has orphan drug designation, the product is entitled to seven years of orphan exclusivity, which means the FDA may not approve any other application for the "same" drug or biologic for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition.

In the EEA, the criteria for designating an "orphan medicinal product" are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (a) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating conditions; (b) either such condition that affects no more than five in 10,000 people in the E.U.; or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the E.U. to justify the investment needed for its development; and, (c) there exists no satisfactory method of diagnosis, prevention or treatment of the condition concerned, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition. The application for orphan designation must be submitted to the EMA and approved by the European Commission before an application is made for marketing authorization for the product. Once designated, orphan medicinal product designation also entitles a party to financial incentives such as reduction of fees or fee waivers. Moreover, ten years of market exclusivity is granted, if the product continues to be designated as an orphan medicinal product upon grant of the marketing authorization. During this ten-year period, with a limited number of exceptions, neither the competent authorities of the E.U. Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is demonstrated to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. This period of market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it can be demonstrated on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Expedited Programs in the United States and Other Jurisdictions

In the United States, the FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions. A product may be granted fast track designation if it is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. With fast track designation, the sponsor may be eligible for more frequent opportunities to obtain the FDA's feedback. Another benefit of fast track designation, for example, is that the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. Even if a product candidate receives fast track designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast-track designation. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program. Even if one or more of our product candidates receives breakthrough therapy designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

A product candidate may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity or mortality, that is reasonably likely to predict irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

The FDA may grant priority review designation to a product candidate, which sets the user fee target date for FDA action on the application at six months from FDA filing. Priority review may be granted where a product is intended to treat a serious or life-threatening disease or condition and, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in safety or efficacy compared to available therapy. If criteria are not met for priority review, the standard FDA review period is ten months from FDA filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the 21st Century Cures Act, a drug is eligible for regenerative medicine advanced therapy ("RMAT") designation if (i) the drug is a regenerative medicine therapy, which is defined by FDA to include cell therapy, therapeutic tissue engineering product, human cell and tissue product, any combination product using such therapies or products, and certain human gene therapies and xenogeneic cell products, except for human cells, tissues, and cellular and tissue-based products ("HCT/P's") that are regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations; (ii) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. An RMAT designation include all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with FDA, and the potential to support accelerated approval and address post-approval requirements. An RMAT designation request should be submitted with the IND or after and, ideally, no later than the end-of-phase 2 meeting. Even if a product candidate receives RMAT designation, the designation can be rescinded and provides no assurance that a product will be reviewed or approved more expeditiously than would otherwise have been the case, or that the product will be approved at all.

Under the centralized procedure in the EEA, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding ''clock stops,'' when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Accelerated evaluation might be granted by CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, which should be justified and assessed on a case-by-case basis. In this circumstance, EMA ensures that the opinion of CHMP is given within 150 days (excluding clock stops).

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, also called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The FDA regulations allow access to investigational drugs under an IND by the sponsor or the treating physician for treatment purposes on a case-by-case basis for individual patients, intermediate-size patient populations, and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

The suitability of treating a patient or a group of patients under expanded access is determined by the following: if patient(s) have a serious or immediately life-threatening disease or condition, there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition, the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated, and the expanded use of the investigational drug for the requested treatment will not interfere with the initiation, conduct or completion of clinical investigations that could support marketing approval of the product candidate or otherwise compromise the potential development of the product candidate.

Sponsors of one or more investigational drugs for the treatment of a serious disease(s) or condition(s) make publicly available their policies for evaluating and responding to requests for expanded access for individual patients. This provision requires drug companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study or 15 days after the drug receives breakthrough therapy, fast track, or regenerative medicine advanced therapy designation. Additionally, in 2018 the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

U.S. market exclusivity

A biological product can obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until 12 years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

Post-approval requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as requirements relating to record keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. Manufacturers of products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer’s tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

As a condition of BLA approval, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the product. In addition, as a holder of an approved BLA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products.

Manufacturers must comply with the FDA’s advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product’s approved labeling (known as “off-label use”), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems with a product or failure to comply with applicable regulatory requirements after approval may result in serious and extensive restrictions on a product or the manufacturer or holder of an approved BLA, as well as lead to potential market disruptions. These restrictions may include suspension of product manufacturing until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a ‘‘consent decree,’’ which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. Other potential consequences include interruption of production, issuance of warning letters or other enforcement letters, refusal to approve pending BLAs or supplements to approved BLAs, product seizure or detention, product recalls, fines, and injunctions or imposition of civil and/or criminal penalties.

In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation, correction, and reporting of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Newly discovered or developed safety or effectiveness data may require changes to a product’s approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, such as additional post-market clinical trials to assess new safety risks or distribution-related or other restrictions under a REMS. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Patent Term Restoration and Extension

Depending upon the timing, duration and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension. The provisions of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Many other countries also provide for patent term extensions or similar extensions of patent protection for biologic products. For example, in Japan, it may be possible to extend the patent term for up to five years and in Europe, it may be possible to obtain a supplementary patent certificate that would effectively extend patent protection for up to five years.

Health Care Laws and Regulations

Health care providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state health care laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, directly or indirectly, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

- the FCPA which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to health care items or services that are reimbursed by non-government third-party payors, including private insurers.

Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pharmaceutical Insurance Coverage and Health Care Reform

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated health care costs. Significant uncertainty exists as to the coverage and reimbursement status of drug products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of such product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product candidate that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product candidate is approved. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drug products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved drug products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the health care system in the United States.

In March 2010, the United States Congress enacted the PPACA, which, among other things, included changes to the coverage and payment for drug products under government health care programs. The PPACA effected the following changes of importance to our potential product candidates:

- established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price" for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 70% point-of-sale discount off of the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since enactment of the PPACA, there have been numerous legal challenges and congressional actions to repeal and replace provisions of the law. For example, with enactment of the TCJA, which was signed by the President on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, the President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amended the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress will likely consider other legislation to replace elements of the PPACA during the next congressional session.

The current presidential administration has also taken executive actions to undermine or delay implementation of the PPACA. In January 2017, the President signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the PPACA exchanges. At the same time, the current presidential administration announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. In addition, the Centers for Medicare & Medicaid Services has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces.

Further, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the current presidential administration's budget proposal for fiscal year 2019 contained further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the current presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs.

Review and Approval of Medicinal Products in Europe

In order to market any medicinal product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of medicinal products. Whether or not it obtains FDA approval for a product candidate, an applicant will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Some countries outside of the United States have a similar process that requires the submission of a CTA much like the IND prior to the commencement of human clinical trials. In the E.U., for example, a CTA must be submitted to the national competent authorities of the E.U. Member States where the clinical trial is conducted and to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

In April 2014, the E.U. adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the E.U. Specifically, the new regulation, which will be directly applicable in all Member States (meaning that no national implementing legislation in each E.U. Member State is required), aims at simplifying and streamlining the approval of clinical trials in the E.U. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications. It is expected that the new Clinical Trials Regulation will come into effect following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the new Clinical Trials regulation, through an independent audit, which is currently expected to occur in December 2021.

Clinical Trial Regulations in Italy

Under the E.U. and EU-member country legislation, any application for marketing authorization must be accompanied by the results of clinical trials conducted in accordance with applicable regulations. A unified regulation on clinical trial procedures has been approved (EU Reg. 536/2014), but is not yet effective. The currently applicable rule is EU Directive 2001/20, as implemented in the various EU member countries from time to time through national laws and regulations.

We are currently conducting or planning Phase I/II clinical trials on Temferon in Italy, in accordance with the specific regulations applicable to such early-phase trials. As discussed elsewhere in this prospectus, we are currently conducting our TEM-GBM 001 study on GBM patients and plan to start new ones on hepatic tumor (HCC and IHC) in the near future by means of appropriate application to the Italian Regulatory Authority ("AIFA").

The applicable Italian regulation is the Decree of April 27, 2015 of the Ministry of Health, providing a precise sequence of approvals for the start of Phase I studies and subsequent amendments to the related protocols. According to such Decree, an initial request must be submitted to AIFA seeking a technical-scientific opinion of Istituto Superiore di Sanità (ISS), acting on behalf of AIFA, on the admissibility of the request. Upon the favorable opinion of ISS, AIFA issues an authorization to proceed with the planned study, and the rules generally governing the conduct of clinical trials (Legislative Decree 211 of June 24, 2003, implementing in Italy EU Directive 2001/20, Decree of December 17, 2004 of the Ministry of Health for non-profit studies, plus procedural rules such as the Decree of December 21, 2007, so called "CTA decree", for the prescribed formats), are of application.

Based on the AIFA approval, the Independent Ethics Committees ("IECs") of the research centers participating in the trial issue their opinions on the conduct of the study, having evaluated the study protocol and all other relevant documentation such as the informed consent form ("ICF"), the insurance policy underwritten by the sponsor, the information and consent form for data protection purposes. The IEC of the Coordinating Center issues first its opinion – the so-called *Parere Unico*, lit. "sole opinion" ("PU") - and then the IECs of the other participating centers accept or refuse the PU in its entirety (they may seek amendment to the ICF on the basis of local operating circumstances).

All documents pertaining to each specific step of the procedure, in the right sequence, must be loaded on the online database of Aifa ("Osservatorio sulle Sperimentazioni Cliniche", or OsSC); the OsSC system provides certain controls to make sure that e.g. no IEC opinion can be loaded before the pertinent AIFA approval, or that the opinions of the participating sites cannot be loaded before the PU is loaded. It may occur however that, due to calendar mismatches in the calendars of IEC meeting (usually held on a monthly basis), an approval may precede by a few days a "prior" one (typically, the PU or the AIFA approval): in such cases the IEC approval is issued under reservation ("*con riserva*") and can be loaded in advance accordingly, under the assumption that the documents subjected to evaluation - protocol (updated) version, ICF and the rest – coincide exactly.

Marketing Authorization Application for Biologic Medicinal Products

To obtain regulatory approval to commercialize a new drug in the EEA (comprising the E.U. Member States plus Iceland, Liechtenstein and Norway, we must submit a marketing authorization application.

In the E.U., a marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or national procedure (single country). The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products, those produced by biotechnology, advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue-engineered products) and those with a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, autoimmune and other immune dysfunctions, viral diseases or diabetes, and is optional for certain other products, including medicinal products with a new active substance for other indications, and products that are a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health.

Under the centralized procedure, the applicant can submit a single application for marketing authorization to the EMA which will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Based on the opinion of the EMA, the European Commission takes a final decision to grant a centralized marketing authorization which permits the marketing of a product throughout the EEA. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA Committee for Medicinal Products for Human Use ("CHMP")). Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a marketing authorization application under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the E.U., Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January, 1 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the United Kingdom medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

For other countries outside of the E.U., such as the United Kingdom and countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with cGCPs, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Advertising, Promotion and Compliance

In the E.U., the advertising and promotion of our products will also be subject to E.U. laws and E.U. Member States' national laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. The SmPC forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion and is prohibited in the E.U. The applicable laws at the E.U. level and in the individual E.U. Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the E.U. could be penalized by administrative measures, fines and imprisonment. As the United Kingdom medicinal products legislation is still largely based on EU legislation, the promotion of prescription-only medicines to the public and promotion of medicinal products not in compliance with the SmPC are both also prohibited under United Kingdom law.

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These penalties could include the imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Regulatory Data Protection in the EEA

In the EEA, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator's data when applying for a generic or biosimilar marketing authorization for a period of eight years from the date on which the innovator's product was first authorized in the EEA. During an additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted and authorized, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on a marketing authorization application with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the relevant Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EEA Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year period of marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EEA market (in case of centralized procedure) or on the market of the authorizing EEA Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Pediatric Studies and Exclusivity

Prior to obtaining a marketing authorization in the EEA, applicants must demonstrate compliance with all measures included in an EMA-approved PIP covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, commonly referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect an adult population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA must determine that a company actually complied with the agreed studies and measures listed in each relevant PIP, unless the EMA has granted: (i) a product-specific waiver, (ii) a class waiver or (iii) a deferral for one or more of the measures included in the PIP. If an applicant obtains a marketing authorization in all EEA Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results of the pediatric clinical trials conducted in accordance with the PIP are included in the drug product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Regulatory Requirements after a Marketing Authorization has been Obtained

In case an authorization for a medicinal product in the EEA is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice, or EU cGMP. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and APIs, including the manufacture of API outside of the EU with the intention to import the API into the EU.
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU notably under Directive 2001/83EC, as amended, and E. Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of Brexit. Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the EU took effect on January 31, 2020, however, there was a transition period until December 31, 2020 during which EU laws, including in respect of medicinal products, continued to be applicable in the United Kingdom. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to drug products and the approval of product candidates in the United Kingdom, now that the United Kingdom legislation has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and approved drug products in the United Kingdom in the long term. The MHRA, the United Kingdom's medicines and medical devices regulator, has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products evolves over time.

General Data Protection Regulation

The collection, use, disclosure, transfer or other processing of personal data of individuals in the EU, including personal health data, is governed by the GDPR, which became effective on May 25, 2018. After effectiveness of GDPR, the European data protection law background has been constantly implemented through the activity of the European Data Protection Board (EDPB) concerning the correct interpretation and application of GDPR, as well as through the ruling of the Court of Justice of the European Union (CJEU). The GDPR and EU Member States national data protection legislation, including Italy, are wide-ranging in scope and impose numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing notice to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States and now – after Brexit – the United Kingdom, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. Concerning the transfer of (pseudonymized) personal data to the United States, the recent CJEU case C-3111/18, also known as Schremes II, invalidated the European Commission's adequacy decision for the EU-U.S. Privacy Shield Framework, on which the majority of U.S. companies relied to conduct trans-Atlantic trade in compliance with EU data protection rules. The decision reinforced the importance of data protection to global commerce and imposed EU companies trading with US companies or organizations to rely the transfer of personal data on other legal basis or appropriate safeguards provided for in the GDPR, such as Standard Contractual Clauses (SCC), Binding Corporate Rules (BCR) or derogations for specific situations. Regarding the transfer of personal data to United Kingdom, the EU / UK agreement regulating the transition period after Brexit ("Statement on the end of the Brexit transition period") provides that, until June 2021, "all data flows of personal data between stakeholders subject to GDPR and UK organizations will not be considered as transfers to a third country", thus implying the adoption of appropriate legal basis and safeguards provided for in the GDPR for any communication of personal data to a third party, such as Data Processing Agreement containing Standard Contractual Clauses.

The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages.

Compliance with the GDPR and all relevant EU data protection rules will be a rigorous and time-intensive process that may increase our cost of doing business.

Pricing Decisions for Approved Drug Products

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU provides options for the EU Member States to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly with respect to prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new drug products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any drug products, if approved in those countries.

Employees and consultants

As of April 20, 2021, we had three full-time employees, all located in Milan, Italy and we rely on consultants and a large number of collaborators at SR-TIGET and OSR. Our full-time employees and consultants are engaged in clinical, research and development, product development and quality assurance activities. We consider our relationship with our employees to be good.

Property and Facilities

Our corporate headquarters is located in Milan, Via Olgettina 58 within San Raffaele Hospital, Italy, where we lease approximately 51 square meters of office space (3 offices). The lease commenced in January 2020 and has a 6-year initial term. It will expire on December 1, 2025 and may be renewed for additional 6 years. We also have a representative office in a co-working space located in New York, NY. We believe that our existing facilities are adequate for our near-term needs, and we believe that suitable additional or alternative office will be available as required in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business and have not been notified of any claims in respect thereof, other than as set forth below:

By letter dated February 25, 2019, Theravectys notified the Company of the possible infringement by Genenta of Theravectys' exclusive license to patents no. EP 1071804 (and of the corresponding US patent US 6,682,907), EP 1224314, and EP 1222300 (and of the corresponding US patent US 7,968,332) granted from the owner of the patents Institut Pasteur. Theravectys requested Genenta engage in discussions as to possible contractual arrangements including the opportunity to either enter into (i) a manufacturing and supply agreement; or (ii) a non-exclusive license for Genenta's use of the technologies allegedly protected under the patent(s). Each of these patents is now expired, having each reached the end of it its patent term on April 23, 2019 for EP1071804 and October 10, 2020 for EP 1224314, and EP 1222300.

To date, Genenta has not engaged in any such discussions with Theravectys nor has Genenta received any further claim/request from Theravectys in relation to the above.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age as of the date of this prospectus, and position of the individuals who will serve as directors and executive officers of Genenta Science S.p.A. following the Corporate Conversion and the closing of this offering. The following also includes certain information regarding the individual experience, qualifications, attributes and skills of our directors and executive officers as well as brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors:

Name	Age	Position	Year elected or appointed
Stephen Squinto, Ph.D.	64	Chairman of the Board of Directors(1)(2)	2021*
Pierluigi Paracchi	47	Chief Executive Officer, Director and General Manager	2014 (with reference to General Manager position: 2021*)
Richard B. Slansky	63	Chief Financial Officer	2021*
Carlo Russo, M.D.	67	Chief Medical Officer, Head of Development	2021*
Roger Abravanel	74	Director(1)(2)	2017
Daniela Bellomo, Ph.D.	53	Director	2019
Guido Guidi	67	Director(1)(2)	2017
Luca Guidotti	59	Director	2018
Anthony Marucci	59	Director(1)	2021*
Stefania Mazzoleni, Ph.D.	39	Scientific Project Manager and Communications Officer	2016

* Effective upon consummation of the Corporate Conversion.

(1) Independent Director (as defined under Nasdaq Stock Market rules)

(2) Member of the Compensation, Nomination and Governance Committee

The directors above were elected at the Company's general shareholders' meeting held on May 20, 2021, for a three-year term. The board of directors consists of 7 (seven) members.

The board of directors' term will expire with the Shareholders' Meeting called to approve the financial statements for the year ending December 31, 2023.

Following the expiration of the above board of directors, future members will be appointed by means of a slate voting mechanism: slates may be submitted by the shareholders representing, individually or collectively with other shareholders joining in the submission of the slate, at least 6% of share capital eligible to vote at the shareholders' meeting at which directors are to be elected, such eligibility to be established by filing an appropriate certification to that effect. The board of directors will be appointed as follows: (a) candidates for election as directors equal to the number of seats on the board of directors minus 1 (one) will be drawn from the slate that has obtained the highest number of votes cast on the shareholders' meeting (the Majority Slate), based on the progressive order in which they are listed on the slate, while (b) the first candidate listed on the slate that receives the second greatest number of votes cast (the Minority Slate) will be elected as director so long as the Minority Slate has no connection in any way, whether directly or indirectly, with the shareholders who have submitted or voted the Majority Slate.

Each shareholder and shareholders belonging to the same group shall not submit, or contribute to submit, or cast their vote for more than one slate, including through a nominee. Each candidate may only be listed on a single slate or, otherwise, will be ineligible for election if named on multiple slates.

For additional information concerning the slate voting mechanism, see “Description of Share Capital and Governing Documents” – “Board of Directors”.

Management

Pierluigi Paracchi, Chief Executive Officer, Director and General Manager

Mr. Paracchi has over 15 years of combined experience as an investor and director of life science companies, including as Founder and CEO of Quantica SGR and in senior roles at Axòn Capital, Sofinnova Partners and AurorA Science. He was also a board member and investor in Ethical Oncology Science, which was acquired in 2013 for $470 million. Pierluigi Paracchi is a member of the Assobiotec Steering Committee, the Italian Association for the development of biotechnology. He also serves on the Board of Directors of the autoimmune disease and cancer company Altheia Science, as non-executive Chairman at medical device company Lipogems International and is a venture partner with AurorA Science, an independent biotech investment vehicle.

Richard B. Slansky, Chief Financial Officer

Mr. Slansky is a senior financial executive with more than 30 years of experience as Chief Financial Officer in various biopharmaceutical, diagnostic and life science companies, including OncoSec Medical, Biological Dynamics and GenMark Diagnostics. His experience spans across public and private healthcare and technology companies at various stages of growth, pre-revenue to commercial. He has been responsible for strategic vision and oversight of financial and operational teams, organizational leadership and creating maximum stakeholder value. He also serves on the Board of Directors of several private companies, including Nuclear RNA Networks, an early-stage RNA gene transcription therapeutics company.

Carlo Russo, M.D., Chief Medical Officer & Head of Development

Dr. Russo has extensive experience as a biotech executive focused on medical affairs and research and development. He has served as Head of Development of GSK’s R&D Biopharm and Rare Disease Units and the Cardiovascular Metabolic Center. Previously, Dr. Russo served as an Executive VP and CMO of Adverum, CMO & Head of Research & Development of Annapurna and President and CEO of VaxInnate Corporation, among other senior roles. Dr Russo holds a number of senior positions at research institutions, including Cornell University Medical College, Columbia University and Scripps Research Institute. He holds his MD and Board Certification in Hematology from the University of Genoa Medical School and is the author of more than 70 scientific publications.

Stefania Mazzoleni, Ph.D., Scientific Project Manager and Communications Officer

Dr. Mazzoleni manages and oversees the scientific development of parallel immuno-gene therapy studies in oncology indications and provides scientific support for investor interactions. Dr. Mazzoleni has more than 15 years’ experience in life science research and development, oncology and project management, including over 4 years of drug development and cell and gene therapy experience acquired while working at various academic institutions (San Raffaele Hospital, National Institute of Molecular Genetics) and pharmaceutics (Nerviano Medical Sciences). Dr. Mazzoleni received a MSc in Medical Biotechnology in 2005, holds a PhD in Molecular and Cellular Biology from San Raffaele Vita-Salute University, has a second level vocational Master’s in Pharmacy and Pharmaceutical Oncology and is a member of the European Academy of Tumor Immunology.

Board of Directors

Stephen Squinto, Ph.D., Chairman of the Board of Directors

Dr. Squinto has more than 25 years' experience in the biotech industry and is an Executive Partner of the healthcare investment company OrbiMed Advisors. He was previously CEO of the gene therapy company, Passage Bio, and co-founded Alexion Pharmaceuticals, where he served as Chief Global Operations Officer and Global Head of Research, and held several senior leadership positions at Regeneron Pharmaceuticals. Dr. Squinto currently serves on the Board of Directors of several biotech and healthcare companies and has received numerous honors and awards from academic and professional organizations for his scientific work. Dr. Squinto has agreed to assume the role of Chairman of the Board upon the consummation of the offering.

Roger Abravanel, Director

Mr. Abravanel worked at McKinsey & Company for 34 years as a consultant for Italian and multinational corporations in Europe, the United States and the Far East, and is now an emeritus director. He is a former board member of Luxottica, COFIDE, Teva and Admiral, is currently Chairman of the INSEAD's advisory group in Italy and is the author of several best-selling business books.

Daniela Bellomo, Ph.D., Director

Dr. Bellomo is Head of Business Development at San Raffaele Hospital, where she oversees technology transfer, development and value generation of research in biotech, medical technology and digital health. Dr. Bellomo is a board member of San Raffaele's spin off Genespire and has previously been on the boards of Parco Tecnologico Padano and BiovelocITA, as well as an advisor to several life science start-ups, venture capital and incubators in the biotech and medical technology field.

Guido Guidi, Director

Mr. Guidi has 35 years of experience in top global roles in large pharmaceuticals companies, managing up to 7,000 employees and a turnover of more than €7 billion. He was previously Head of Pharma EU at Novartis, Head of Oncology at Novartis EU, overseeing major products including Cosentyx, Entresto, Lucentis, Gilenya, Xolair, Ultibro, Seebri, Galvus and Exforge and founded and is currently Chairman of AurorA Science.

Luca Guidotti, MD, PhD., Director

Dr. Guidotti is an experimental pathologist renowned internationally in the field of viral hepatitis. Dr. Guidotti spent more than 20 years as a Faculty of the Scripps Research Institute in La Jolla, California and he currently serves as Deputy Scientific Director of San Raffaele Hospital, Milan. He has published works in prestigious scientific journals including Cell, Nature, Science, Nature Medicine, Journal of Clinical Investigation and Journal of Experimental Medicine.

Anthony Marucci, Director

Mr. Marucci is a seasoned life sciences and public company leader who has raised $1.7 billion in capital in multiple organizations over his 30 years' experience. He is currently President and CEO of Celldex Therapeutics, the company he co-founded in 2004 and which develops targeted therapeutics, including immunotherapies and other targeted biologics. Prior to founding Celldex, he was Treasurer at Medarex, from which Celldex was spun out, and he holds an MBA from Columbia University and a MHL from Brown University. The appointment of Mr. Marucci will be effective upon consummation of the Corporate Conversion.

Executive Scientific Board

Luigi Naldini, M.D., Ph.D., Chairman of the Executive Scientific Board

Professor Naldini is a deeply experienced scientist and academic, considered by many to be the father of lentiviral gene therapy. Dr. Naldini is Professor of Cell and Tissue Biology and Cell and Gene Therapy at the Vita-Salute San Raffaele University School of Medicine in Milan, and Director of the San Raffaele-Telethon Institute for Gene Therapy and of the Division of Regenerative Medicine, Stem Cells & Gene Therapy at the San Raffaele Scientific Institute. He has previously served as President of the European Society of Gene and Cell Therapy and a member of the Board of Directors and Advisory Council of the American Society of Gene and Cell Therapy. Dr. Naldini is also a scientific advisor on EMEA and WHO committees for the evaluation of novel gene transfer medicines and has authored more than 250 scientific publications.

Bernhard Gentner, M.D., Member of the Executive Scientific Board

Dr. Gentner is a physician scientist, serving as Group Leader of the Translational Stem Cell and Leukemia Research Unit at the San Raffaele-Telethon Institute for Gene Therapy in Milan and Staff Hematologist in the Hematology and Bone Marrow Transplantation Unit of San Raffaele Hospital. Dr. Gentner completed his MD studies at the University of Heidelberg, Germany, the MD Anderson Cancer Center and Baylor College of Medicine, Houston, USA. He completed his internal medicine training at Erlangen University Hospital, Germany and his hematology training at San Raffaele Vita-Salute University and has authored more than 30 scientific publications.

Senior Advisor

Andrew Zambanini, Translational Medicine Advisor

Mr. Zambanini, through his company, Zambanini Consulting provides clinical and scientific support to the development of clinical trials in oncology indications for Temferon. Mr. Zambanini previously held various leadership positions with increasing responsibility at GSK from 2003 through 2009, including head of the European Cardiovascular Clinic Group and Vice President and Medicine Development Leader for late-stage diabetes agents. He graduated with a Bachelor of Medicine in 1991 from St George's Medical School in London and completed a specialty in clinical pharmacology and therapy from Imperial College London's Chelsea and Westminster Hospital. He is an accredited UK specialist in pharmaceutical medicine. In 1998 he received a one-year research fellowship in cardiology in Auckland, New Zealand and continued his research interests in vascular imaging and hemodynamics upon his return to the UK at St Mary's Hospital, London.

Family Relationships

There are no family relationships among our executive officers and directors.

Arrangements Concerning Election of Directors and Members of Management

There are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our directors or members of senior management were selected as such.

Compensation

The following table presents in the aggregate all compensation we paid to all of our directors and senior management as a group for the year ended December 31, 2020. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period. We are not required to provide the compensation, on an individual basis, of our executive officers and directors under Italian law. As a matter of Italian law, the compensation of directors is established at the time of their appointment or by the shareholders' meeting. The compensation of the managing directors shall be established by the board of directors, with the opinion of the board of statutory auditors. Our bylaws provides that the shareholders' meeting may determine a total amount for the compensation of the directors, including managing directors.

All amounts reported in the table below reflect the cost to the Company, in thousands of Euros, for the year ended December 31, 2020.

	Salary, Bonuses and Related Benefits	Pension, Retirement and Other Similar Benefits	Share Based Compensation
All directors and senior management as a group, consisting of persons	€	€	€

Differences between Italian Laws and Nasdaq Requirements

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, such as us, to comply with various corporate governance practices. In addition, following the listing of the ADSs on Nasdaq, we will be required to comply with the Nasdaq Stock Market Rules. Under those rules, we may elect to follow certain corporate governance practices permitted under Italian law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Nasdaq Stock Market Rules for U.S. domestic registrants.

In accordance with Italian law and practice and subject to the exemption set forth in Rule 5615 of the Nasdaq Stock Market Rules, as a foreign private issuer, we have elected to rely on home country governance requirements and certain exemptions thereunder rather than the Nasdaq Stock Market Rules, with respect to the following requirements:

- *Composition of the board of directors*. Italian law does not require that the majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we will not be subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present.

- Quorum. In accordance with Italian law quorum requirements generally applicable to general meetings of shareholders are set forth in the Italian Civil Code (see "Description of Share Capital and Governing Documents"—"Meeting of shareholders") therefore our bylaws may not provide a specific regulation of them. Our practice thus varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

  According to Italian law, the management report and the annual financial statements shall be communicated to Company's auditor and to the board of statutory auditors at least 30 days prior to the general meeting of shareholders convened for its approval. The board of statutory auditors must report to the shareholders' meeting on the results of the financial year and on the activities carried out in the performance of its duties, and make observations and proposals regarding the financial statements and their approval. The financial statements, together with the reports of the directors, statutory auditors and Company's auditors, must remain deposited at the Company's registered office for the 15 days preceding the shareholders' meeting called to approve them.

- *Proxy Solicitations*. Under Italian law shareholders may appoint attorneys-in-fact by delivering in writing appropriate power of attorney to represent them in an ordinary or extraordinary shareholders' meeting of the Company. Our directors, auditors and employees may not be proxies. Italian law does not have a specific regulatory regime for the solicitation of proxies in private companies; thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies.

- *Share Issuances*. Pursuant to Italian law, prior to this offering, we will opt out of shareholder approval requirements by way of including authorized and conditional share capital (see "Description of Share Capital and Governing Documents—General —Authorization of shares") for the issuance of securities in connection with certain events such as the acquisition of stock, assets or convertible notes, certain private placements and/or public offering. To this extent, our practice varies from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

- *Audit Committee*. US companies listed on Nasdaq are required to have an audit committee that satisfies the requirements of Rule 10A-3 under the Exchange Act and certain additional requirements set by the Nasdaq. In particular, all members of this committee must be independent and the committee must adopt a written charter. The committee's prescribed responsibilities include (i) the appointment, compensation, retention and oversight of the external auditors; (ii) establishing procedures for handling "whistle blower" complaints regarding accounting, internal accounting controls, or auditing matters; (iii) engaging independent counsel and other advisers, as it determines necessary to carry out its duties and (iv) determine appropriate funding for payments to the external auditor, advisors employed by the audit committee and other necessary administrative expenses of the audit committee. A company must also have an internal audit function, which may be outsourced, except to the independent auditor. We follow the "traditional" model of corporate governance for Italian companies and accordingly have established (and following the Corporate Conversion, will continue to have) a board of statutory auditors established in accordance with Italian law which performs substantially the same functions, (see "Description of Share Capital and Governing Documents" – Statutory auditors") and is accordingly exempt from the audit committee requirements established by Rule 10A-3 and Nasdaq rules. The Company's reliance on such exemption is based on the circumstance that the Company's board of statutory auditors meets the following requirements set forth in Exchange Act Rule 10A-3(c)(3):

(i) the board of statutory auditors is established and selected pursuant to Italian law expressly permitting such a board;

(ii) the board of statutory auditors is required under Italian law to be separate from the Company's board of directors;

(iii) the board of statutory auditors is not elected by management of the Company and no executive officer of the Company is a member of the board of statutory auditors;

(iv) Italian law provides for standards for the independence of the board of statutory auditors from the Company and its management;

(v) the board of statutory auditors, in accordance with applicable Italian law and the Company's governing documents, is responsible, to the extent permitted by Italian law, for the appointment, retention and oversight of the work (including, to the extent permitted by law, the resolution of disagreements between management and the auditor regarding financial reporting) of any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company.

Our reliance on Rule 10A-3(c)(3) does not, in our opinion, materially adversely affect the ability of its board of statutory auditors to act independently and to satisfy the other requirements of Rule 10A-3.

- *Compensation, Nomination and Governance Committee*. Italian law does not require the appointment of a Compensation, Nomination and Governance Committee as required by the Nasdaq Listing Rules. As a matter of Italian law applicable to Italian stock corporations whose shares are not listed on a regulated market in the European Union and under our bylaws, the compensation of executive directors, including the CEO, is determined by the board of directors, after consultation with the board of statutory auditors, while the Company's shareholders, according to Italian law and our bylaws, may determine a total amount for the compensation of the directors, including managing directors. Compensation of the Company's executive officers is determined by board of directors or by the CEO, if duly empowered. Nevertheless, although not required under Italian law, the Company intend to establish a Compensation, Nomination and Governance Committee.

- *Code of Business*. Conduct and Ethics. Pursuant to Italian law, prior to this offering, we will adopt an "Organization and Operational Model" as required by Italian Legislative Decree of June 8, 2001, No. 231 (relating to administrative responsibility) that we expect will consist of: (i) a Code of Etichs; (ii) operating procedures and reporting systems applicable to all of our directors, officers and employees, which may not comply with the requirements of Nasdaq Listing Rule 5610.

Committees of the Board of Directors

We currently follow the historical Italian corporate governance system, with a board of directors (*consiglio di amministrazione*) and a separate board of statutory auditors (*collegio sindacale*) with supervisory functions. The two boards are separate and no individual may be a member of both corporate bodies. Both the members of the board of directors and the members of the board of statutory auditors owe duties of loyalty and care to the Company.

Statutory Auditors

During 2020, the Company's statutory auditors received approximately € in compensation in the aggregate for their services to the Company.

At the Company's annual general shareholders' meeting held on May 20, 2021, the following individuals were elected to the Company's board of statutory auditors for a three-year term. The board consists of three members, one of which is the chairman, and two alternates. The board of statutory auditors' term will therefore expire with the Shareholders' Meeting called to approve the financial statements for the year ending December 31, 2023.

Name	Age	Position	Year elected or appointed
Carlo-Alberto Nicchio	46	Chairman of the Board of Statutory Auditors	2021*
Cesare Lazzaroni	70	Statutory auditor	2021*
Jacopo Doveri	48	Statutory auditor	2021*
Roberto Lorusso Caputi	60	Alternate auditor	2021*
Edda Specchio	83	Alternate auditor	2021*

* Effective upon consummation of the Corporate Conversion.

Following the expiration of the above board of statutory auditors, future members will be appointed by means of a slate voting mechanism: slates may be submitted by the shareholders representing, individually or collectively with other shareholders joining in the submission of the slate, at least 6% of share capital eligible to vote at the shareholders' meeting at which auditors are to be elected, such eligibility to be established by filing an appropriate certification to that effect. According to the Company's bylaws, the board of statutory auditors will be appointed as follows: (a) candidates for election as auditors equal to two statutory auditors and one alternate auditor will be drawn from the slate that has obtained the highest number of votes on the shareholders meeting (the Majority Slate), based on the progressive order in which they are listed, while (b) the remaining statutory auditor (who will act as President of the board of statutory auditors) and alternate auditor will be drawn from the slate that has obtained the second greatest number of votes cast (the Minority Slate) so long as the Minority Slate has no connection in any way, whether directly or indirectly, with the shareholders who have submitted or voted the Majority Slate.

Each shareholder and shareholders belonging to the same group shall not submit, or contribute to submit, or to cast their vote for more than one slate, including through a nominee. Each candidate may only be listed on a single slate or, otherwise, will be ineligible for election if named in multiple slates.

For additional information concerning the slate voting mechanism, see "Description of Share Capital and Governing Documents" – "Board of Statutory auditors".

The Company relies on an exemption from the Rule 10A-3 requirements provided by Rule 10A-3(c)(3) of the Exchange Act for foreign private issuers with a board of statutory auditors established in accordance with local law or listing requirements and subject to independence requirements under local law or listing requirements. See "— *Differences between Italian Laws and Nasdaq Requirements*" for more information.

Additional Board Committees

Although Italian law does not require that we adopt a Compensation, Nomination and Governance Committee, in connection with the Corporate Conversion, we plan to establish a Compensation, Nomination and Governance Committee according to Nasdaq Listing Rule 5615(a)(3). The members of our compensation, nomination and governance committee are expected to include Stephen Squinto, Roger Abravanel and Guido Guidi. The compensation, nomination and governance committee will assist our board of directors in overseeing our cash compensation and equity award recommendations for our executive officers along with the rationale for such recommendations, as well as summary information regarding the aggregate compensation provided to our executive officers.

Equity Incentive Plan

2021 – 2025 Equity Incentive Plan

On May 20, 2021, our shareholders meeting approved a capital increase to allow for issuance of up to 2,700,000 ordinary shares (*i.e.* the 10% of the share capital of the Company upon this offering on a fully diluted basis) to the service of a four-year employees' share option plan (the "2021-2025 Plan") to be adopted by the board of directors. The purpose of the 2021-2025 Plan is to motivate and reward performance of our employees, directors, non-employee directors and consultants, and in the best interests of the Company and our shareholders.

On 2021 our board of directors approved the specific terms (e.g., regulation) of our 2021 – 2025 Plan which will become effective upon the effectiveness of the registration statement of which this prospectus is part. Under Italian law, we do not need to obtain the approval of the specific terms of our equity incentive plans by our shareholders. Except where the context indicates otherwise, reference hereunder to our ordinary shares shall be deemed to include a number of ADSs equal to the number of ordinary shares.

Plan Administration. Our 2021 – 2025 Plan is administered by our board of directors in consultation with the Compensation, Nomination and Governance Committee, unless and until the board delegates administration to this latter. The board of directors has the authority to take all actions and make all determinations under the 2021 – 2025 Plan, to interpret the 2021 – 2025 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2021 – 2025 Plan as it deems advisable, subject to certain limitations imposed under the 2021 – 2025 Plan, and other applicable laws and stock exchange rules.

Eligible Participants. The board of directors jointly with the Compensation, Nomination and Governance Committee will be able to offer equity awards at its discretion under the 2021 – 2025 Plan to:

- any employees of us, of our parent company, or any of our subsidiaries;
- any non-employee directors serving on our board of directors;
- any consultants to us, our parent company to us or any of our subsidiaries (the "Eligible Participants").

Grant of Awards; Shares Available for Awards. The 2021 – 2025 Plan provides for the grant of options to purchase up to a maximum of ordinary shares (*i.e.* the of the share capital of the Company upon this offering on a fully diluted basis) in the future upon written exercise notice. This number is subject to adjustment in the event of a split-up, share dividend or other change in our capitalization. If any award expires, is cancelled, or is terminated, unexercised or is forfeited, the number of shares subject thereto is again available for grant under the 2021 – 2025 Plan.

The number of stock options to be granted to executives and directors cannot be determined at this time as the grant of stock options and/or restricted shares is dependent upon various factors such as hiring requirements and job performance.

Terms of exercise – Stock Options. Options may be granted to selected Eligible Participants (the "Optionee") on such terms and conditions as the board of directors may determine; provided, however, that the exercise price of an option may not be less than the fair market value of a Company share as of the grant date as determine by the board of directors, or the Compensation, Nomination and Governance Committee, in its reasonable discretion and the term of the option my not exceed three years from the grant date.

Vesting. The vesting conditions for stock options granted under the 2021 – 2025 Plan are set forth in the applicable award documentation.

Termination of Service and Change in Control. In the event of termination of an Optionee's employment or service without cause or an Optionee's resignation for just cause (as defined in the 2021 – 2025 Plan) following a change in control of the company (as defined in the 2021 – 2025 Plan), any awards outstanding to the Optionee (unless otherwise provided in the award agreement) will immediately vest and settle, and options will become fully exercisable by twelve (12) months following the Change in Control of the Company or by the shorter term. In the event of a change in control that involves a merger, acquisition or other corporate transaction, any outstanding award not assumed, substituted, replaced or continued in connection with the transaction will immediately vest and settle, and options will become fully exercisable and upon the effectiveness of such corporate transaction, the 2021 – 2025 Plan and all awards will automatically terminate.

Amendment and Termination. Within the limitations of the 2021 – 2025 Plan, the board of directors or the Compensation, Nomination and Governance Committee may amend, suspend or terminate the 2021 – 2025 Plan at any time and for any reason. The suspension or termination of the 2021 – 2025 Plan, or any amendment thereof, shall not affect any option previously granted under the 2021 – 2025 Plan. No option shall be granted under the 2021 – 2025 Plan after its suspension or termination. An amendment of the 2021 – 2025 Plan shall be subject to the approval of the Company's shareholders only to the extent required by applicable laws or regulations.

Right to amend options. The board of directors at any time, and from time to time, may amend the terms of any one or more options; provided, however, that the rights under any option shall not be impaired by any such amendment unless (i) the Company requests the consent of the optionee and (ii) the optionee consents in writing.

2021- 2025 Chairman Sub-Plan

The 2021 – 2025 Chairman Sub-Plan allows for the grant of options to our chairman of the board of directors, Mr. Squinto. Except for the following , all provisions of the 2021 – 2025 Plan are incorporated into the 2021 – 2025 Chairman Sub-Plan and provides for identical terms and conditions under our 2021 – 2025 Plan.

Accelerated Vesting of Existing Options Represented by Class B Quotas

The following table summarizes, as of the date of this prospectus, existing outstanding options subject to accelerated vesting upon the occurrence of a liquidity event. Upon the consummation of this offering, several of our executive officers and board members will fully vest their remaining options. All of the options described below are currently represented by class B quotas and will be converted into our Ordinary Shares as part of the Corporation Conversion.

Name	Class B quotas Underlying Options Awarded	Exercise Price (€/Share)
Roger Abravanel[(1)]	82	
Guido Guidi[(1)]	82	
Luca Guidotti[(1)]	82	
Carlo Russo	300	
Total		

(1) Includes 41 class B quotas such holder will be entitled to upon the consummation of the offering.

BENEFICIAL OWNERSHIP OF PRINCIPAL SHAREHOLDERS AND MANAGEMENT

The following table sets forth information regarding beneficial ownership of our ordinary shares as of , 2021 after giving pro forma effect to the Corporate Conversion by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our outstanding ordinary shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and includes voting or investment power with respect to ordinary shares. Percentage of shares beneficially owned before this offering is based on 15,000,000 shares outstanding on , 2021. The number of ordinary shares deemed outstanding after this offering includes the ordinary shares being offered for sale in this offering but assumes no exercise by the representative of the underwriters of the over-allotment option.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise noted below, each beneficial owner's address is: c/o Genenta Science S.r.l., Via Olgettina no. 58, 20132 Milan, Italy.

	No. of Shares Beneficially Owned Prior to this Offering	Percentage Owned Before this Offering[(1)]	Percentage Owned After this Offering
Directors and executive officers			
Stephen Squinto	—	%	%
Pierluigi Paracchi	2,275,516	[15.17]%	%
Roger Abravanel	73,729	[*]%	%
Daniela Bellomo	16,357	[*]%	%
Guido Guidi	61,553	[*]%	%
Luca Guidotti	49,469	[*]%	%
Anthony Marucci	—	—	
Richard B. Slansky	19,947	[*]%	%
Carlo-Russo	598,417	[3.99]%	
Luigi Naldini	1,386,145	[9.24]%	
Bernard Gentner	692,871	[4.62]%	
All directors and executive officers as a group (11 persons)	5,174,004	[34.49]%	%
5% Shareholders			
Ospedale San Raffaele	1,896,730	[12.64]%	%
Spafid	3,431,482	[22.88]%	

* Less than 1%.

(1) The percentages shown are based on 15,000,000 ordinary shares issued and outstanding as of , 2021.

Record Holders

As of , 2021, there was a total of holders of record of our ordinary shares, none of which had, to the best of our knowledge, a registered address in the United States.

We are not controlled by another corporation, by any foreign government or by any natural or legal persons except as set forth herein, and there are no arrangements known to us which would result in a change in control of the Company at a subsequent date.

RELATED PARTY TRANSACTIONS

Agreements with OSR

We have a longstanding relationship with OSR. Dr. Guidotti, a member of our Board of Directors, currently serves as Deputy Scientific Director of OSR. On June 4, 2015, we entered into a service agreement with OSR to provide certain services (accounting/bookkeeping and rent of spaces, the latter with an addendum effective from January 1, 2016) free of charge. Beginning in January 2020, we engaged a third-party provider to perform these services. We determined that the value of these services provided in 2019 and in prior years were not material to our financial statements. Beginning January 1, 2020, we entered into a six-year lease agreement for the use of office space in the OSR building. We paid OSR annual rent of €13,400 in 2020 with a security deposit of €3,350.

We entered into a license agreement with OSR effective December 15, 2014, pursuant to which OSR granted us an exclusive, royalty-bearing, non-transferable, worldwide license, subject to certain retained rights, to certain patents, patent applications and existing know-how in exchange for certain ongoing payment obligations. See "Business — Collaboration/Licensing." In February 2021, we entered into a Sponsored Research Agreement ("SRA") with OSR to conduct certain research projects related to Temferon. The total consideration to be paid by the Company under the SRA will be €1.0 million with payments scheduled quarterly during 2021 and 2022.

Employment, Consulting and Services Agreements

Mr. Russo is currently a party to a Service Agreement dated July 2017 through an affiliated company, XDG BioMed LLC, which, as amended, provides for fixed annual fees of €300,000 gross and a discretionary annual variable gross remuneration up to a minimum amount of €50,000, tax included. We entered into consulting agreements in October 2015 and April 2016 with Prof. Naldini and Dr. Gentner, which, as amended, provided for gross annual fees of €50,000 and €30,000, respectively. These agreements renew automatically each year.

We entered into a directorship agreement with Mr. Paracchi in December 2019, which provides for a gross annual salary of €250,000 and a discretionary €50,000 gross performance bonus payment to be approved by the Board of Directors. Such agreement will be terminated by the parties for mutual consent upon signature of the below employment agreement.

Proposed New Employment Agreements

We intend to enter into new employment agreements with each of Messrs. Paracchi, Russo and Slansky effective upon the consummation of this offering. The forms of such proposed employment agreements have been filed as exhibits to the registration statement of which this prospectus forms a part. Pursuant to such proposed employment agreements, Messrs. Paracchi, Russo and Slansky are entitled to gross annual base salaries of € 420,000, $500,000 and $240,000, respectively, each of which is subject to annual review by and at the sole discretion of the Compensation, Nomination and Governance Committee of our board of directors. Each of Messrs. Paracchi, Russo and Slansky are also eligible to receive an annual cash bonus equal to or exceeding 20% of base salary, provided that such individual achieves performance targets determined by the Compensation, Nomination and Governance Committee of the board of directors.

With specific reference to the proposed employment agreements of Messrs. Russo and Slansky, please note that such agreements are regulated by US Law and, therefore:

each proposed employment agreement has a term commencing on the date of consummation of this offering and continuing until terminated (i) upon death of the employee, (ii) upon disability, (iii) for cause or good reason, (iv) without cause, or (v) voluntarily. The employment agreement also contains, among other things, the following material provisions: (i) reimbursement for all reasonable travel and other out-of-pocket expenses incurred in connection with such individual's employment; (ii) paid vacation leave; (iii) health benefits; and (iv) a severance payment equal to twelve (12) months of base salary and a prorated portion of the applicable cash bonus upon termination by such individual for just cause or by the Company without cause (each as defined in the relevant agreement), with restrictive covenants applicable for a corresponding period after termination.

(a) in the event such individual is terminated six months prior to or two years after a Change of Control (as defined in the agreement) by the Company for any reason other than cause or by such individual for good reason, then the executive shall be entitled to receive a cash payment equal to times such individual's then-current annual base salary, plus 1.0 times his cash bonus for the year in which the termination occurs. Such payment shall be in lieu of the severance payment described above.

The proposed employment agreement of Mr. Paracchi is regulated by Italian Law and provides for, *inter alia*:

the duties of general manager (*direttore generale*) with direct report to the Board of Directors of the Company;

reimbursement of reasonable expenses incurred in the performance of work duties, health benefits and, subject to the approval of the Board of Directors of the Company, the executive will be granted an equity award under an equity incentive plan to be adopted after the offering;

even in case of Change of Control (as defined in the relevant agreement), in the event of termination not for "cause" by the Company or of resignation for "cause" by the executive (thus according to the Article 2119 of the Italian Civil Code), the executive shall be entitled to receive a cash payment equal to three times such individual's then-current annual base salary (such indemnity will replace any indemnity provided for by the applicable NCLA in case of termination);

non-competition and non-solicitation obligations of the executive for a 12 months period after the termination of the employment, with a specific compensation equal to 12 months his individual's then-current monthly base salary for each obligation;

Such agreement has a term commencing on the date of consummation of this offering and continuing until terminated, among other things, (a) upon death of the executive, (b) for just cause, (c) with objective or subjective reason, (d) by resignation of the executive, or (e) voluntarily by mutual agreement between the parties.

Proposed New Consultancy Agreements

We intend to enter into new consultancy agreements with each of Messrs. Squinto and Marucci effective upon the consummation of this offering. Such agreements contain the appointment of Messrs. Squinto and Marucci as consultants of the Company in order to support the development and the growth of the Company in the US market and provide for gross compensations of USD 25,000 (Mr. Squinto) and USD 11,875 (Mr. Marucci) per quarter, to be calculated on a *pro-rata temporis* basis. Consultants will be fully and exclusively responsible for the payment of all tax and/or social security charges. No expenses reimbursement is provided. These agreements will be for a fixed and definite term of 3 (three) years (with possibility for the parties to withdraw through a 15-days prior notice during the last month of each year of duration of the agreement).

Issuances of Share Capital

Since our founding, we have obtained equity financing in an aggregate amount of approximately €33.6 million in four separate rounds based on the credentials and reputation of our founders and management team and our relationship with SR-TIGET, OSR, and Telethon Institute for Gene Therapy.

Upon its organization in July 2014, the Company was capitalized with €11,650 through the issuance of the following quotas:

Name	Quotas (€)	Aggregate Purchase Price (€)
Ospedale San Raffaele	4,754.37	1,500
Pierluigi Paracchi	5,703.84	10,000
Luigi Naldini	794.53	100
Bernhard Gentner	397.26	50

The quotas held by Mr. Paracchi and OSR, on the one hand, and by Prof. Naldini and Dr. Gentner, on the other hand, were converted into class A and B quotas, respectively, in connection with our first round of equity financing approved by shareholders on December 23, 2014 (which resolution has been subsequently amended and restated), as follows:

- issuance of a maximum of €6,237.50 of class B quotas to Prof. Naldini and Dr. Gentner, directors, employees and other individuals in recognition of their contributions to the Company's growth; and
- issuance of class C quotas (including class C quotas issuable upon conversion of convertible notes) for an aggregate amount equal to €10.0 million.

The class C quotas were offered on the basis of a pre-money valuation of the Company of €20.0 million with assistance from Banca Esperia, the formerly Private Bank of Mediobanca, and purchased by accredited investors, including entrepreneurs, managers, and family offices, including affiliates of the Ferrari family, which controls FIS Holding, one of the leading manufacturers of pharmaceuticals in Europe, and an early investor in Advanced Accelerator Application (NASDAQ: AAAP) ("AAAP"), a biotech company later acquired by Novartis (NYSE: NVS) for $3.9 billion.

In connection with the class C quota offering, Roger Abravanel (former McKinsey & Company director and board member of TEVA) joined the Company's board of directors.

On June 27, 2017, our shareholders approved the issuance of class D quotas for an aggregate amount equal to €7.0 million on the basis of a pre-money valuation of the Company of €45.0 million. The class D quotas were purchased by Italian, British, and Swiss private investors, family offices, and angel investors, including FIDIM S.r.l., the holding company for the Rovati family, former owner of Rottapharm, which was acquired in 2014 by Meda/Mylan for $2.2 billion) ("FIDIM"), some other early investors in AAAP, and Mr. Giuseppe Vita, former Chairman of Schering-Plough.

In connection with the class D quota offering, Guido Guidi, then Head of Novartis in Europe joined the Company's board of directors. During his tenure as Head of Novartis' Oncology Europe division, Mr. Guidi led the development and launch of a number of highly successful products, such as Cosentyx, Entresto, Lucentis, Gilenya, Xolair, Ultibro, Seebri, Galvus, Exforge, Zometa, Femara and Glivec. At that time, Kenneth C. Anderson, Kraft Family Professor of Medicine at Harvard Medical School, past President of the American Society of Hematology, and Director of the Lebow Institute for Myeloma Therapeutics and the Jerome Lipper Myeloma Center at DanaFaber Cancer Institute, joined the Company's Scientific Advisory Board.

In August 2019, our shareholders approved the issuance of class E quotas for an aggregate amount equal €17.1 million, subscribed for €15.1 million, on the basis of a pre-money valuation of the Company of €70.0 million. The lead investor in the class E quota offering was Qianzhan Investment Management, a Shanghai based private company active in private equity and venture capital investments, and FIDIM. Qianzhan was an early investor in Tencent Music (NASDAQ: TME) and in pharmaceutical and biotech companies in China and in the U.S.

In July 2020, our shareholders approved the issuance of an additional of class E quotas for an aggregate amount equal to € 1.5 million on the basis of a pre-money valuation of the Company of €90.0 million. The lead investor was GM Investimenti, a private company controlled by Giuseppe Miroglio, former CEO and current Chairman of Miroglio Group.

The tables below set forth the aggregate number of class B and D quotas issued and subscribed by related parties as part of the offerings described above. No related parties purchased class C or E quotas.

Name	Class B Quotas (€)	Aggregate Purchase Price (€)
Luigi Naldini	2,795	2,795
Bernhard Gentner	1,396.5	1,396.5
Carlo Russo	1,200	1,200
Roger Abravanel	74	74
Guido Guidi	55	55
Luca Guidotti	42	42
Stefania Mazzoleni	30	30

Name	Class D Quotas (€)	Aggregate Purchase Price (€)
Roger Abravanel	28.81	50,000
Guido Guidi	17.29	30,000

DESCRIPTION OF SHARE CAPITAL AND GOVERNING DOCUMENTS

General

The following description summarizes important terms of our capital stock and certain provisions of our articles of association and by-laws, each of which will be in effect upon the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The description of our capital stock reflects the completion of the Corporate Conversion that will occur immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

As of the date of filing of this prospectus, and following the Corporate Conversion, our authorized capital stock consists of 15,000,000 ordinary shares.

Following the closing of this offering, there will be ordinary shares outstanding, held by approximately shareholders of record. No preference shares are designated, issued or outstanding.

The following is a summary of certain information concerning our ordinary shares and bylaws (*Statuto*), as well as Italian law provisions applicable to companies like ours whose shares are not listed in a "regulated market" within the European Union, as in effect at the date of this prospectus. The summary contains such information as we consider material regarding the ordinary shares but does not purport to be complete and is qualified in its entirety by reference to our bylaws or Italian law, as the case may be.

Under Italian law, most of the procedures regulating our Company, including certain rights of shareholders, are contained in our bylaws. Amendments to our bylaws must be approved at an extraordinary meeting of shareholders, as described below.

Authorization of shares

Our shareholders may authorize the issuance of additional shares at any time at an extraordinary shareholders' meeting. However, the newly issued shares may not be purchased before all the outstanding shares (i.e., the shares already subscribed) are entirely paid for. Moreover, although Italian law generally provides shareholders with preemptive rights when new shares are issued for cash, it is possible, in certain case, for general meeting to exclude or limit preemptive rights. Such an exclusion of preemptive rights must be illustrated by the directors with a specific report which sets out the reasons for the exclusion or limitation of the pre-emptive right, or, if the exclusion derives from a contribution in kind, the reasons for such contribution in kind, and in any case the criteria adopted for determining the issue price. On , 2021 following a recommendation by our board of directors, our shareholders approved several capital increases. In particular the shareholders' meeting [unanimously] resolved, *inter alia*:

- to increase the share capital, with effect from the implementation of the corporate conversion of the Company into a joint stock company, against payment in one or more instalments on a divisible basis, with the exclusion of the pre-emptive rights under Article 2441, paragraph 5, of Italian Civil Code, up to a maximum amount of EUR [115,000,000] (including share premium), with allocation to capital of EUR 0.10 per share, by issuance of a maximum of [11,500,000] new ordinary shares with no par value and with regular dividend entitlement, to the service of our initial public offering, granting authority to the board of directors to implement the proposed capital increase in one or more tranches, in the amounts quoted above, within the time limit of December 31, 2021, of which a maximum number of [10,000,000] ordinary shares against a countervalue of EUR [100,000,000] (including share premium), shall be issued to the service of the initial public offering; while a maximum number of [1,500,000] ordinary shares (subject to the maximum limit of 15% of the number of shares actually used to the service of our initial public offering) against a countervalue of EUR [15,000,000] (including share premium), shall be issued to the service of potential exercise of the over-allotment option (greenshoe);
- with effect from the implementation of the corporate conversion of the Company into a joint stock company, to approve the issuance of a maximum number of 500,000 warrants to be granted [free of charge] to the Underwriters;
- to further increase the share capital, with effect from the implementation of the corporate conversion of the Company into a joint stock company, on a divisible basis, to the service of warrants exercise by the Underwriters, by further maximum par values of EUR [5,000,000] (including share premium), with allocation to capital of EUR 0.10 per share, by issuance of a further maximum number of [500,000] ordinary shares (subject to the maximum limit of 4% of the ADSs to service our initial public offering as well as criteria set forth in agreements executed by the Company in relation to our initial public offering), all represented by ADSs, to be issued by no later than [●], being it specified that, if such increase is not fully subscribed within that time limit, the increase shall remain valid within the limits of the subscriptions collected; being it further specified that such capital increase shall be implemented, pursuant to the warrants regulation, by the board of directors duly authorized to set the issue price and the portions to be allocated to capital and to share premium;
- to increase the share capital, with effect from the implementation of the corporate conversion of the Company into a joint stock company, against payment in one or more instalments on a divisible basis, without pre-emption right under Article 2441, paragraph 5, of Italian Civil Code, up to a maximum amount of EUR [27,000,000] (including share premium), with allocation to capital of EUR 0.10 per share, by issuance of a maximum number of [2,700,000] new ordinary shares with no par value and with regular dividend entitlement (subject to the maximum limit of 10% of the number of shares in circulation at the time of issue, plus those which may be issued under the Warrants in circulation),to the service of the 2021 – 2025 Plan to be adopted by the board of directors, duly authorized to implement the proposed capital increase in one or more tranches, within the deadline of [●], and to set the issue price and the portions to be allocated to capital and to share premium; and
- to grant to the board of directors the authority, with effect from the implementation of the corporate conversion of the Company into a joint stock company, in accordance with Article 2443 of Italian Civil Code, to increase the share capital against payment, in one or more instalments on a divisible basis, up to a maximum amount of EUR [300,000,000] (including share premium), by issuance of a maximum number of [30,000,000] new ordinary shares with no par value and with regular dividend entitlement, also with the exclusion of pre-emptive rights or free of charge, in accordance with Article 2441, paragraphs 4, 5 and 8, of Italian Civil Code for a five-year period, also in support of third-party grants of participating interests and/or industrial and intellectual property rights and similar intangible assets (such as patents, marks and know-how) which can be granted and held by the board of directors itself in accordance to the scope of the corporate purpose, in addition to the authority, pursuant to Article 2420-*ter* of Italian Civil Code, to issue convertible debentures in one or more instalments, convertible into ordinary shares, within the same aggregate maximum amount of EUR [300,000,000] (including share premium), with consequent capital increase to the service of the conversion,

also with the exclusion of pre-emptive rights in accordance with Article 2441, paragraphs 4, 5 and 8 of Italian Civil Code, likewise for a period of five years.

Form and transfer of shares

Our ordinary shares are not represented by share certificates (*certificati azionari) as they are dematerialised (azioni dematerializzate*). The ownership of the shares, their transfer, the related rights and restrictions on the shares (if any) results from the electronical register managed by an intermediary (banks and other financial institutions). The entitlement to exercise the rights attached to the shares is then proven by the exhibition of certifications or communications to the issuer made by the intermediary, pursuant to its own accounting records, in favor of the subject entitled to the right.

There are no limitations on the right to own or vote our ordinary shares, which applies to non-Italian residents and foreign residents except for Golden Power's rules and Antitrust rule (see Section "Notification of Acquisition of Shares"). There are no provisions in our articles of association or bylaws that would have the effect of delaying, deferring or preventing a change of control of our Company and that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company. There are no provisions in our bylaws governing the ownership threshold which shareholder ownership must be disclosed. There are no provisions discriminating against any existing or prospective holder of our ordinary shares as a result of such shareholder owning a substantial number of our shares. There are no sinking fund provisions or provisions providing for liability for further capital calls by our Company.

Dividend rights

Our payment of any annual dividend must be proposed by our board of directors to the shareholders and is subject to the approval of our shareholders at the annual ordinary shareholders' meeting. Before dividends may be paid out of our unconsolidated net income in any year, we must allocate an amount equal to 5% of the Italian GAAP net income to our legal reserve until such reserve is at least equal to 20% of our corporate capital. If a loss in our corporate capital occurs, we may not pay dividends until the capital is reconstituted or reduced by the amount of such losses. We may pay dividends out of available retained earnings from prior years, provided that after such payment, we will have a legal reserve at least equal to the legally required minimum of 20% of the corporate capital. We may not approve or pay dividends until this minimum (i.e., 20% of the capital) is met. If the minimum is met, the board of directors could propose the issuance of a dividend to the shareholders and the shareholders' resolution might approve that issuance. The shareholders' resolution will specify the manner and the date for dividend payment. Any dividends which shareholders do not collect within five years of the date on which they become payable will be forfeited by those shareholders and come back to us. The board of directors may not approve interim dividends at times between our annual ordinary shareholders' meetings.

Governance

Under Nasdaq rules, the Company is permitted, as a listed foreign private issuer, to adhere to the corporate governance rules of our home country in lieu of certain Nasdaq corporate governance rules.

Corporate governance rules for Italian corporations (*società per azioni*) like the Company provide that the Company can be managed by a board of directors (*consiglio di amministrazione*) and a separate board of statutory auditors (*collegio sindacale*) with supervisory functions concerning the compliance of the by-laws and Italian laws. The two boards are separate and no individual may be a member of both boards. Both the members of the board of directors and the members of the board of statutory auditors owe duties of loyalty and care to the Company. As required by Italian law, an external auditing firm (*società di revisione*) is in charge of auditing the Company's financial statements. The members of the Company's board of directors and board of statutory auditors, as well as the external auditor, are directly and separately appointed by shareholders' resolution at the shareholders' meetings.

Board of directors

Our board of director consists of 7 (seven) members (see "Management" for additional information). Our board of directors is elected at an ordinary shareholders' meeting for the period established at the time of election but in any case, for no longer than three fiscal years. Our directors, who may but are not required to be shareholders, may be reappointed for successive terms.

Following the expiration of the above board of directors currently in force, future members will be appointed by means of a slates voting mechanism: slates may be submitted by the shareholders representing, individually or collectively with other shareholders joining in the submission of the slate, at least 6% of share capital eligible to vote at the shareholders' meeting at which directors are to be elected, such eligibility to be established by filing an appropriate certification to that effect. The board of directors shall be appointed as follows: (a) candidates for election as directors equal to the number of seats on the board of directors minus 1 (one) shall be drawn from the slate that has obtained the highest number of votes cast on the shareholders meeting (the Majority Slate), based on the progressive order in which they are listed on the slate, while (b) the first candidate listed on the slate that receives the second greatest number of votes cast (the Minority Slate) shall be elected as director so long as the Minority Slate has no connection in any way, whether directly or indirectly, with the shareholders who have submitted or voted the Majority Slate.

Each shareholder and shareholders belonging to the same group shall not submit, or contribute to submit, or cast their vote for more than one slate, including through a nominee. Each candidate may only be listed on a single slate or, otherwise, will be ineligible for election if named on multiple slates.

In the event that the Majority Slate does not contain a sufficient number of candidates to fill the number of vacancies on the board of directors to be filled as provided under paragraph (a) above, all candidates listed in the Majority Slate shall be elected directors and the remaining directors shall be elected from the Minority Slate according to the order in which they are listed in such slate. The voting procedure according to slates provided above shall be applicable only in case of election of the entire board of directors. In the event of a tie between slates, a new vote shall be taken and the candidates obtaining the largest number of votes shall be elected without regard to the slate on which they are listed or application of the slate voting mechanism. Should a single slate be submitted, the shareholders eligible to vote at the meeting shall cast their vote on such slate and, so long as more votes are cast for such slate than votes cast against such slate, all the members of the board of directors shall be elected from that slate in accordance with applicable law at the time. If no slates are submitted, or a single slate is submitted and such slate does not obtain the requisite number of votes, or the number of directors to be elected on the basis of the slates submitted is less than the full number of directors to be elected, or the entire board of directors is not to be entirely elected, or it is otherwise not possible for any reason to elect the board of directors in accordance with the provisions set out in our by-laws, the members of the board of directors shall be elected at the shareholders' meeting in accordance with generally applicable procedures and required majorities under applicable law, without application of the slate voting mechanism.

Our board of directors has all ordinary and extraordinary powers to manage our affairs as it deems advisable for the achievement of our corporate purposes, except for the actions reserved, by applicable law or the bylaws, to a vote of the shareholders at an ordinary or extraordinary shareholders' meeting.

If we cannot repay our creditors, and a court determines that our directors did not perform their duties regarding the preservation of our assets, the court may find our directors liable to our creditors. However, the judgement on the director's diligence in carrying out his or her mandate should never cover the management choices or the manner and circumstances of such choices, even if the same entail significant economic risks, but should cover only the diligence shown by the director in appreciating in advance the risk margins connected with the transaction to be undertaken, and therefore, the possible omission of those precautions, assessments and information normally required for a decision of that type, implemented in those circumstances and with those methods. Directors are liable to the company's creditors when their improper management conduct impairs the company's assets in such a way that the same may not be sufficient to satisfy creditors' claims.

If a chairman (president) is not already appointed by the shareholders, the board of directors must appoint one and may appoint a vice-chairman. The chairman of the board of directors is the legal representative of the Company. Our board of directors may delegate certain powers to one or more managing directors (*amministratori delegati*), determine the nature and scope of the powers delegated to each director and revoke such delegation at any time. The managing directors must report to the board of directors and the board of statutory auditors at least every 180 days on the Company's business and the main transactions carried out by the Company or by its subsidiaries. Our board of directors may also appoint one or more general managers (*direttori generali*) who must report directly to the board and confer powers for single acts or categories of acts to employees of the Company or persons unaffiliated with the Company. These general managers may be employees, and the board may delegate certain powers to general managers that the board has not already delegated to managing directors or an executive committee, subject to the limitations discussed below.

The board of directors may establish one or more committees with advisory, deliberative or oversight functions in accordance with applicable laws and regulations in whatsoever applicable jurisdiction, as well as with codes of conduct and corporate governance best practices. If one or more committees are established, their composition, powers and operation shall be as determined by the board of directors.

Under Italian law, the members of the board of directors must perform the duties imposed on them by law and company's bylaws with the degree of diligence that is required by the nature of their office and pursuant to their specific level of competence.

Under Italian law, our board of directors cannot delegate certain responsibilities, including the preparation and approval of draft financial statements, the approval of merger and de-merger plans to be presented to shareholders' meetings, increases in the amount of our share capital or the issuance of convertible debentures (if any of such powers has been delegated to our board of directors by our shareholders at an extraordinary shareholders' meeting).

Meetings of our board of directors are called no less than four days in advance or, in case of urgency, at least one day in advance by registered letter or e-mail sent by the chairman, the deputy chairman or by a managing director, at his/her own initiative. Statutory auditors are normally required to attend our board meetings, but if a meeting has been duly called, the board can validly take action at the meeting even if the board of statutory auditors does not attend. If the meeting has not been duly called, the meeting is nevertheless validly constituted if all of the directors in office and all of the statutory auditors are in attendance.

Meetings of our board of directors may be held in person, or by audio-conference or video-conference, in Italy and in any member state of the European Union or the United States. The quorum for meetings of our board of directors is the attendance of the majority of the directors in office. Resolutions are adopted by the vote of the majority of the directors in attendance at a meeting at which a quorum is met.

Our directors are not subject to the non -compete obligation provided for under Italian law. As a result, our directors may (i) hold shareholdings in competing companies, with unlimited liability, (ii) exercise in person or on behalf of third parties activities in competition with that of our Company, and (iii) be elected directors of, or act as general managers (*direttori generali*) in, competing companies.

Under Italian law, directors having any interest in a proposed transaction must disclose their interest to the board of directors and to the board of statutory auditors, even if such interest is not in conflict with the Company's interest in the same transaction. The interested director is not required to abstain from voting on the resolution approving the transaction, but the resolution must state explicitly the reasons for, and the benefit to us of, the approved transaction. If these provisions are not complied with, or if the transaction would not have been approved without the vote of the interested director, the resolution may be challenged by a director or by our board of statutory auditors if the approved transaction may be prejudicial to us. A director having any interest in a proposed transaction that he or she has authority to approve must solicit prior board approval of such transaction. The interested director may be held liable for damages to us resulting from a resolution adopted in breach of the above rules. Finally, directors may be held liable for damages to us if they illicitly profit from insider information or corporate opportunities.

Our board of directors may transfer the Company's registered office within Italy, set up and eliminate secondary offices and, if the company's bylaws (as in our case) so provide, approve mergers by absorption into the Company of any subsidiary in which the Company holds at least 90% of the issued share capital. Our board of directors may also approve the issuance of shares or convertible debentures and reductions of the Company's share capital in the case of withdrawal of a shareholder if so authorized by the Company's extraordinary shareholders' meeting.

Under Italian law, directors may be removed from office at any time by the vote of shareholders at an ordinary shareholders' meeting. Whilst the removal is immediately effective within the company, it is effective *vis-à-vis* third parties only upon entry of the relevant resolution in the companies register. The resolution of the shareholders' meeting in favor of a liability suit against the director and the occurrence of causes of ineligibility also constitute justified causes for removal. If the removal of a director occurs without just cause, such directors may have a claim for damages against us. These damages may include, but are not limited to, compensation that would otherwise have been paid to the director for the remainder of his or her term and damage to his or her reputation. Directors may resign at any time by written notice to our board of directors and to the chairman of our board of statutory auditors. Our board of directors must appoint substitute directors to fill vacancies arising from removals or resignations, subject to the approval of the board of statutory auditors, to serve until the next ordinary shareholders' meeting. If, at any time, more than half of the members of our board of directors appointed by the shareholders' meeting of the Company resign, such resignation is ineffective until the majority of the new board of directors has been appointed. In such a case, the remaining member of the board of directors (or the board of statutory auditors if all members of the board of directors have resigned or ceased to be directors) must promptly call an ordinary shareholders' meeting to appoint new directors.

Our Compensation, Nomination and Governance Committee will recommend the compensation of our directors to our board of directors, which in turn makes recommendations to our shareholders. Under Italian law, our shareholders determine the compensation of our directors relating to basic board service, such as annual fees for serving on the board and/or fees for attending board meetings. Our board of directors, after consultation with our board of statutory auditors, may determine the remuneration of directors that serve on the various board committees and/or perform management or other special services for us, such as managing directors. Our directors are entitled to reimbursement for expenses incurred in connection with their service as directors, such as expenses incurred in travel to attend board meetings. Our articles of association and bylaws do not contain any provisions with respect to borrowing powers exercisable by our directors.

Statutory auditors

The board of statutory auditors (*Collegio Sindacale*) is elected by the shareholders and must be comprised of individuals qualified to act in such capacity under Italian law. Statutory auditors are elected for a term of three fiscal years, they may be re-elected for successive terms and may be removed only for cause and with the approval of a competent court. Each member of our board of statutory auditors must provide evidence that such individual is qualified to act in such capacity under Italian law and meets certain professional standards.

Under Italian law, at least one standing statutory auditor and one substitute statutory auditor of a company shall be chosen among persons registered with the Register of Auditors established with the Italian Ministry of Justice. The other statutory auditors shall be chosen among those registered with any register established by decree of the Ministry of Justice or among University professors in economics or law, if they are not registered with the Register of Auditors. The following persons may not be appointed as statutory auditors:

- a person legally incapacitated, bankrupt, or disqualified from holding public or an executive office under Italian law;
- the spouse, parent or relative-in-law of a director of the company or an affiliate of the company; and
- one whose independence may be impaired due to an employment or consulting relationship or any other economic relationship with the company or an affiliate of the company.

Our bylaws currently provides that the board of statutory auditors shall consist of three standing statutory auditors and two alternate auditors (who will automatically replace a statutory auditor who resigns or is otherwise unable to serve).

Following the expiration of the above board of statutory auditors currently in force, future members will be appointed by means of a slate voting mechanism: slates may be submitted by the shareholders representing, individually or collectively with other shareholders joining in the submission of the slate, at least 6% of share capital eligible to vote at the shareholders' meeting at which auditors are to be elected, such eligibility to be established by filing an appropriate certification to that effect. The slates of candidates shall be split into two sections, one for the candidates for the position of statutory auditor and one for the candidates for the position of alternate auditor. According to the Company's bylaws, the board of statutory auditors will be appointed as follows: (a) candidates for election as auditors equal to two statutory auditors and one alternate auditor shall be drawn from the slate that has obtained the highest number of votes on the shareholders meeting (the Majority Slate), based on the progressive order in which they are listed, while (b) the remaining statutory auditor (who will act as President of the board of auditors) and alternate auditor shall be drawn from the slate that receives the second greatest number of votes cast (the Minority Slate) so long as the Minority Slate has no connection in any way, whether directly or indirectly, with the shareholders who have submitted or voted the Majority Slate.

Each shareholder and shareholders belonging to the same group shall not submit, or contribute to submit, or cast its/their vote for more than one slate, including through a nominee. Each candidate may only be listed on a single slate or, otherwise, will be ineligible for election if named in multiple slates.

In the event that the Majority Slate does not contain a sufficient number of candidates to fill the number of vacancies on the board of auditors to be filled as provided under paragraph (a) above, all candidates listed in the Majority Slate shall be elected statutory auditors and the remaining statutory auditors shall be drawn from the Minority Slate according to the order in which they are listed in such slate. The voting procedure according to slates provided above shall be applicable only in case of election of the entire board of auditors. In the event of a tie between slates, a new vote shall be taken and the candidates obtaining the largest number of votes shall be elected without regard to the slate on which they are listed or application of the slate voting mechanism. Should a single slate be submitted, the shareholders eligible to vote at the meeting shall cast their vote on such slate and, so long as more votes are cast for such slate than votes cast against such slate, all the members of the board of auditors shall be elected from that slate in accordance with applicable law at the time. If no slates are submitted, or a single slate is submitted and such slate does not obtain the requisite number of votes, or the number of statutory auditors to be elected on the basis of the slates submitted is less than the full number of statutory auditors to be elected, or the board of auditors is not to be entirely elected, or it is otherwise not possible for any reason to elect the board of auditors in accordance with the provisions of this title, the members of the board of auditors shall be elected at the shareholders' meeting in accordance with generally applicable procedures and required majorities under applicable law, without application of the slate voting mechanism.

In the event of the resignation or removal termination of a member of the board of auditors who was drawn from the Majority Slate or from the Minority Slate, as the case may be, alternate statutory auditors drawn from the same slate shall fill the vacancy in declining order of age, subject to compliance with the requirements of the corporate charter regarding the composition of the board of auditors

The board of statutory auditors is required, among other things, to verify that we:

- comply with applicable laws and our bylaws;
- respect principles of good governance; and
- maintain adequate organizational structure, internal controls and administrative and accounting system.

The board of statutory auditors is required to meet at least once every ninety days and is expected to attend meetings of our board of directors and our shareholders. In case a statutory auditor, without just cause, does not attend the shareholders' meetings or does not attend two consecutive meetings of the board of directors or of the board of statutory auditors during the same fiscal year, such statutory auditor shall automatically be removed from office. Our statutory auditors may decide to call a meeting of our shareholders, ask for information about our management from our directors, carry out inspections and verifications at our offices and exchange information with our external auditors. Any shareholder may submit a complaint to our board of statutory auditors regarding facts that the shareholder believes should be investigated and if shareholders collectively representing 5% of our corporate capital, or 2% of the corporate capital should our company be classified as an Open Company (see Section "Comparison Of Italian Law And Delaware Law") submit such a complaint, our board of statutory auditors must promptly undertake an investigation and present its findings and any recommendations to a shareholders' meeting (which must be convened immediately if the complaint appears to have a reasonable basis and there is an urgent need to take action). Our board of statutory auditors may report serious breaches of directors' duties to a competent court which then may take such actions as inspecting the company's operations, removing directors, appointing temporary administrators to manage the company or any other actions that the court feels is necessary to preserve the value of our company for our creditors and shareholders.

External auditor

Italian law requires us to appoint an external auditor or a firm of external auditors (*revisore legale dei conti*), each of them qualified to act in such capacity under Italian law, to verify during the fiscal year that our accounting records are correctly kept and accurately reflect our activities, and to audit our financial statements. The external auditor's opinion on the financial statements must be published.

The external auditor is appointed for a three-year term by the vote of our shareholders at an ordinary shareholders' meeting. Once appointed, the shareholders may remove the auditors only for cause and with the approval of the board of statutory auditors and of a competent court. Following revocation, the Company and the external auditor or auditing firm must timely inform the Italian Ministry of Economics and Finance, explaining the reasons justifying the revocation. In case we are considered an Open Company, such communication must be served to the Consob.

On May 20, 2021, our shareholders appointed Kreston GV Italy – Audit S.r.l., as our external auditors for three-year term expiring at the time of the annual shareholders meeting to approve the financial statement for the financial year ending on December 31, 2023.

Meetings of shareholders

Shareholders are entitled to attend and vote at ordinary and extraordinary shareholders' meetings. Votes may be cast personally or by proxy. Shareholders' meetings may be called by our board of directors (or by our board of statutory auditors) and must be called if requested by holders of at least 10% of the outstanding shares. Shareholders are not entitled to request that a meeting of shareholders be convened to vote on issues which as a matter of law is falling within the authority of the board of directors. If the shareholders' meeting is not called despite the shareholders' request and such refusal is unjustified, a competent court may call the meeting.

We may hold meetings of shareholders at our registered office, or elsewhere within Italy and any member state of the European Union or the United States. Our bylaws provides that our shareholders' meetings, both ordinary and extraordinary, shall be called by notice published in the Italian daily newspaper "Il Sole 24 Ore" at least fifteen days prior to the date of the meeting or otherwise given by our Company, provided that so long as the Company is allowed by applicable Italian law, by sending, either in the alternative to or in addition to the foregoing published notice, a notice to the shareholders, to the members of the board of directors and to the members of the board of auditors, by: (a) registered mail with return receipt requested; (b) e-mail with electronic acknowledgment of receipt; as long as the notice is received by the addressee at least eight (8) calendar days before the date set for the meeting with evidence thereof as provided above. The notice shall also be posted on our Company's web site. However, if the above procedures are not complied with, the shareholders' meeting will still be deemed validly held if all outstanding shares are represented, all other holders having the right to vote are present and a majority of the board of directors and the board of statutory auditors are in attendance; provided that in such event, any shareholder or other participant present may object to the discussion of items with respect to which he/she does not deem to have been adequately informed.

We must convene an ordinary shareholders' meeting at least once a year. Our annual stand-alone financial statements are prepared by the board of directors and submitted for approval to the ordinary shareholders' meeting, which must be convened within 120 days after the end of the fiscal year to which such financial statements relate. This term may be extended by up to 180 days after the end of the fiscal year, as long as the Company continues to be bound by law to draw up financial statements or if particular circumstances concerning our structure or our purposes so require. At ordinary shareholders' meetings, our shareholders also appoint the external auditors, approve any distribution of dividends that have been proposed by our board of directors, elect our board of directors and statutory auditors, determine their remuneration and vote on any business matter for which resolution or authorization is entrusted to the shareholders by law.

We may call extraordinary shareholders' meetings to vote upon split-ups, dissolutions, appointment of receivers and similar extraordinary actions. We may also call extraordinary shareholders' meetings to vote upon proposed amendments to our bylaws, issuance of convertible debentures, mergers and de-mergers and capital increases and reductions, if the actions may not be authorized by the board of directors. The board of directors has the authority to transfer our registered office within Italy, authorize, on a non-exclusive basis, amendments to our bylaws that are required by law, authorize mergers by absorption to our subsidiaries in which we hold all or at least 90% of the outstanding shares, if the company's bylaws (as in our case) so provide, authorize reductions of our share capital in case of withdrawal of a shareholder and indicate who among the directors is our legal representative. If the shareholders authorize the issuance of shares or other securities at an extraordinary meeting, they may delegate the power to make specific issuances to the board of directors.

Once our shareholders have authorized the issuance of securities, the securities that have been subscribed must be fully paid for before the shareholders may authorize the issuance of additional securities, unless the shareholders meet and vote to cancel those authorized but unsubscribed securities.

The notice of our shareholders' meeting may specify two or more meeting dates for an ordinary or extraordinary shareholders' meeting.

The quorum for an ordinary meeting of our shareholders on the first call, also in the event we are considered an Open Company, is at least 50% of the outstanding ordinary shares, while on second call there is no quorum requirement. In either case, resolutions are adopted by the majority of ordinary shares in attendance or represented at the meeting. The quorum for an extraordinary shareholders' meeting is more than half of the outstanding ordinary shares on the first call and more than one-third of the outstanding shares on second call. Resolutions are adopted by the majority of the outstanding ordinary shares on first call and at least two-thirds of the holders of shares in attendance or represented at the meeting on second call. In the event we are considered an Open Company, the quorum for an extraordinary shareholders' meeting is, on first call, the majority of at least two-thirds of the holders of shares present or represented at such meeting, provided that a quorum of at least half of the share capital is attending; on second call, the majority of at least two-thirds of the holders of shares present or represented at such meeting, provided that a quorum of more than one-third of the share capital is attending. In addition, certain matters (such as, for example, a change in our purpose, the transfer of our registered office outside Italy or our liquidation prior to the date set forth in our bylaws) must be adopted by shareholders representing more than one-third of the outstanding ordinary shares (not just the ordinary shares in attendance or represented at the meeting.

Shareholders are entitled to one vote per ordinary share. Neither Italian law nor our bylaws limit the right of non-resident or foreign owners to hold or vote their shares. Shareholders do not need to present their share certificates (due to the fact that our shares are not represented by share certificates) but the entitlement to attend the meetings is then proven by exhibition of the certificate or communication to the Company made by the intermediary (banks and other financial institutions) which manages the electronical register whereby ownership of the shares, their transfer, the related rights and restrictions on shares (if any) are recorded.

Shareholders may appoint attorneys-in-fact by delivering in writing the proxies to represent them in an ordinary or extraordinary shareholders' meeting. Our directors, auditors and employees may not be proxies. Italian law provides that no proxy may represent more than twenty shareholders prior to the company "seeking access to the risk capital market." It is unsettled whether listing shares on a stock exchange outside of the European Union constitutes "seeking access to the risk capital market for this purpose.

Preemptive rights

Pursuant to Italian law, holders of outstanding ordinary shares and convertible debentures are entitled to subscribe for issuance of ordinary shares or convertible debentures in proportion to their holdings at the time that the shareholders authorize the capital increase for those issuances, unless those issuances are for non-cash considerations. Those who exercise the preemptive right, provided they make such request simultaneously, have a pre-emption right on the purchase of shares and debentures convertible into shares that have not been subscribed. The preemptive rights may be excluded or limited by resolution of the shareholders at an extraordinary meeting of shareholders, or by a board of directors if the bylaws delegate such power to the board of directors (including the power to exclude or limit the preemptive right), and provided that such exclusion or limitation is in the interest of the company, or if the shares are to be paid by means of contributions in kind. According to Italian law proposals to increase share capital with exclusion or limitation of preemptive rights must be illustrated by the directors with a specific report which handles the reasons for the exclusion or limitation of the option right, or, if the exclusion derives from a contribution in kind, the reasons for such contribution in kind, and in any case the criteria adopted for determining the issue price. The report must be communicated by the directors to the board of statutory auditors and to the person appointed to audit the accounts at least thirty days prior to the date set for the shareholders' meeting. Within fifteen days, the board of statutory auditors must express its opinion on the fairness of the issue price of the shares. The opinion of the board of statutory auditors and, only in the case of contribution in kind, the sworn report of the expert appointed by the Court or the documentation provided by Italian law, must remain deposited at the company's registered office during the fifteen days prior to the shareholders' meeting and until the latter has passed a resolution. The resolution shall determine the issue price of the shares on the basis of the value of shareholders' equity, taking into account, in the case of shares listed on regulated markets, also the trend in prices over the last six months. The foregoing procedure shall apply also in case of capital increase delegated to the board of directors.

Preference shares; other securities

Italian law permits us to issue preference shares with limited voting rights, other classes of equity securities with different economic and voting rights, shares with economic rights related to the results of the corporate activity in a specific sector, to issue "participation instruments" with limited economic and voting rights against the contribution, by shareholders or third-parties, of work or services, as well as "participation instruments" in favor of employees.

Our bylaws allow us to issue shares without voting rights, with voting rights limited to particular subjects, with voting rights subject to the occurrence of particular conditions not merely arbitrary or with multiple voting rights (each multiple voting right share may have a maximum of three votes). According to Italian law, the total value of such shares may not exceed half of the share capital. Our bylaws also provides that, in relation to the quantity of shares held by the same party, the voting right may be limited to a maximum extent or may be staggered.

"Participation instruments", which may include, for example, convertible equity and/or "hybrid" instruments endow the right to vote on specific matters and/or grant economic rights, to be determined at the time of the issuance of such instruments, or administrative rights, such as the right to appoint, in accordance with the procedures established by the bylaws, an independent member of the board of directors or a statutory auditor.

Our bylaws currently allow us to issue these securities. We may also issue convertible and non-convertible debt securities. In order to issue convertible debt securities, our board of directors would need to recommend to our shareholders that they approve the issuance of particular securities in connection with a capital increase, and the shareholders would need to vote to approve such an issuance and capital increase at an extraordinary meeting. The board of directors would also need to recommend, and the shareholders would need to approve by vote at the extraordinary meeting, specific terms of the securities. The shareholders may vote at the extraordinary shareholders' meeting to delegate authority to the board of directors to issue those securities from time to time, but not for more than five years from the date of the extraordinary shareholders' meeting.

Debt-equity ratio

Italian law provides that we may not issue debt securities for an amount exceeding twice the value of the sum of our equity capital, our legal reserve and any other disposable reserves appearing on the latest balance sheet approved by our shareholders. The board of statutory auditors must certify compliance with such limitation. This limitation may be exceeded if the debt securities issued in excess are intended for subscription by professional investors subject to prudential supervision pursuant to special laws. In the event of subsequent circulation of the debt security, whoever transfers them is liable for the solvency of the company vis-à-vis buyers who are not professional investors. The rules indicated above do not apply in case we intend to issue debt securities to be listed on regulated markets or multilateral trading systems or which have attached the right to purchase or subscribe shares. The legal reserve is a reserve to which we are required to allocate 5% of our Italian GAAP net income each year until it equals at least 20% of our equity capital. One of the other reserves that we maintain on our balance sheet is a "share premium reserve", meaning amounts paid for our ordinary shares in excess of the amount of such ordinary shares that is allocated to stated capital (*valore nominale*). Until our outstanding debt securities are repaid in full, we may not voluntarily reduce our equity capital or distribute our reserves (such as by declaring dividends) in the event the aggregate of the capital plus reserves, after giving effect to such reduction, is less than half of the outstanding amount of the debt securities. If our equity capital is reduced by losses or otherwise such that the amount of the outstanding debt securities is more than twice the amount of our equity capital, we cannot distribute profits to our shareholders until the ratio between the amount of our debt securities and our equity capital plus reserves is restored. If our equity capital is reduced, we could recapitalize by means of issuing new shares or having our current shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital. The legal requirements regarding the ratio of debt securities to equity capital plus reserves do not apply to issuances of debt securities to professional investors (as defined by Italian law). However, in such a case, should the professional investors transfer such debt securities to third parties not qualified as professional investors, the former remains liable for the payment of such securities.

Reduction of equity by losses

Italian law requires us to reduce our shareholders' equity in certain situations. Our shareholders' equity has three main components: capital, legal reserves and other shareholders' equity (such as any share premium and any retained earnings). We first apply our losses from operations against our shareholders' equity other than legal reserves and capital. If additional losses remain and, after the legal reserves, our corporate capital is reduced by more than one-third, our board of directors must call a shareholders' meeting as soon as possible. The shareholders should take appropriate measures, which may include, inter alia, either reducing the legal reserves and capital by the amount of the remaining losses, or carrying the losses forward for up to one year. If the shareholders vote to elect to carry the losses forward up to one year, and the losses are still more than one-third of the amount of the capital at the end of the year, then we must reduce our capital by the amount of the losses.

We have no present intention to enter into any such transaction and no such transaction is currently in effect.

Liquidation rights

Pursuant to Italian law and subject to the satisfaction of the claims of all creditors, our shareholders are entitled to a distribution in liquidation that is equal to an amount resulting from the division of the positive liquidation balance by the number of shares (to the extent available out of our net assets). Preferred shareholders and holders of "participating certificates" typically do not participate in the distribution of assets of a dissolved corporation beyond their established contractual preferences. Once the rights of preferred shareholders and holders of participating certificates and the claims of all creditors have been fully satisfied, holders of ordinary shares are entitled to the distribution of any remaining assets.

Purchase of shares by us (Treasury Stocks)

We are permitted to purchase our outstanding shares, subject to certain conditions and limitations provided for by Italian law. We may only purchase the shares out of profits available for dividends or out of distributable reserves, in each case as appearing on the latest shareholder-approved financial statements; in lack, the shares in excess must be cancelled and the corporate capital must be reduced accordingly. Further, we may only repurchase fully paid-in shares. Such purchases and the conditions thereto must be authorized by our shareholders by vote at an ordinary shareholders' meeting and the authorization may be issued for a period not exceeding the term of eighteen (18) months.

A corresponding reserve equal to the purchase price of such shares must be created in the balance sheet, and such reserve is not available for distribution, unless such shares are sold or cancelled. Shares purchased and held by us may be resold only pursuant to a resolution of our shareholders adopted at an ordinary shareholders' meeting. The voting rights attaching to the shares held by us or our subsidiaries cannot be exercised, but the shares can be counted for quorum purposes in shareholders' meetings. Dividends and other rights, including pre-emptive rights, attaching to such shares will accrue to the benefit of other shareholders.

The foregoing limitations do not apply in case we purchase our shares: (i) by giving execution to shareholders' meeting resolution authorizing capital reduction through repurchase or cancellation; (ii) for free, to the extent they are fully paid-in; (iii) as a consequence of universal succession, merger or demerger; (iv) on occasion of foreclosures authorized to satisfy a credit of our company, to the extent they are fully paid-in.

As long as such shares remain the property of the company, the right to profits and the right of option are attributed proportionally to the other shares. The right to vote is suspended, but such shares are nevertheless taken into account for the purposes of calculating the majority and the quorum required for the constitution and for the resolutions of the shareholders' meetings.

The Company does not hold any of its ordinary shares.

Notification of the acquisition of shares

In accordance with Italian antitrust laws, the Italian Antitrust Authority could prohibit, if certain threshold requirements are met, the acquisition of control in a company which would thereby create or strengthen a dominant position in the domestic market or a significant part thereof and which would result in the elimination or substantial reduction, on a lasting basis, of competition, provided that certain turnover thresholds are exceeded. However, if the turnover of the acquiring party and the company to be acquired exceed certain other monetary thresholds, the antitrust review of the acquisition falls within the exclusive jurisdiction of the European Commission.

In addition, if we fall under the scope of the Law Decree No. 21 of March 15, 2012 (Italian Golden Power regulation), as subsequently amended and supplemented, (i) certain resolutions of the Company and, if specific thresholds requirements are met, (ii) certain third-party investors' purchases of our shares may be subject to *ad hoc* notifications to the Italian Government and this latter may object to the transaction thereof.

In particular, in such cases the Government would have, *inter alia*:

(i) the power to veto or to impose specific conditions with respect to the acquisition of certain shareholdings by any foreign entity outside the European Union, in companies having assets and relations in sectors of strategic importance; and

(ii) the power to veto or impose specific conditions with regard to the adoption of specific corporate resolutions, acts or transactions by the same companies.

Minority shareholders' rights; withdrawal rights

Shareholders' resolutions which are not adopted in conformity with applicable law or our bylaws may be challenged (with certain limitations and exceptions) within ninety days of such resolution (or, if such resolution is subject to registration or filing with the Italian Company Register, within ninety days of its registration or filing) by absent, dissenting or abstaining shareholders representing individually or in the aggregate at least 5% of our share capital (as well as by our board of directors or our board of statutory auditors). Shareholders not reaching this threshold or shareholders not entitled to vote at our meetings may only claim damages arising from the challenged resolution.

Dissenting or absent shareholders may withdraw from the company as a result of shareholders' resolutions approving, among other things, material modifications of our corporate purpose or of the voting rights of our ordinary shares, our transformation from a share corporation into a different legal entity or the transfer of our registered seat outside Italy. In such a case, our other shareholders would have a pre-emptive right to purchase the shares of the withdrawing shareholder. Should no shareholder exercise that pre-emptive right, the shares must be offered to third parties or, in the absence of any third party wishing to buy them, they will be purchased by us by using the available reserves. In the event that no reserve is available, our equity capital must be reduced accordingly. Any repurchase of such shares by us must be on terms authorized by our board of directors, upon consultation with our board of statutory auditors and our external auditor, having regard to our net asset value, our prospective earnings and the market value of our ordinary shares, if any. Under Italian law, we may set forth different criteria in our bylaws for the consideration to be paid to withdrawing shareholders. We have not done so as of the date of this registration statement.

Each shareholder may bring to the attention of the board of statutory auditors facts or acts which such shareholder deems wrongful. If such shareholders represent at least 5% of our share capital, or in case we are considered an Open Company 2% of the same, our board of statutory auditors must investigate without delay and report its findings and recommendations at our shareholders' meeting. Shareholders representing more than 10% of our share capital, or, in case we are considered an Open Company one-twentieth, have the right to report to the competent court serious breaches of the duties of the directors which may be prejudicial to us or to our subsidiaries. In addition, shareholders representing at least 20% of our share capital may commence derivative suits before the competent court against our directors, statutory auditors and general managers. We may waive or settle the suit unless shareholders holding at least 20% of the shares vote against such waiver or settlement. We will reimburse the legal costs of such action in the event that the claim of such shareholder is successful and the court does not award such costs against the relevant directors, statutory auditors or general managers.

Applicable Laws

As of the date of this prospectus and upon completion of the contemplated initial public offering of our ADS, our Company is and will be governed by the corporate laws of Italy, and is and will be legally considered and treated, according to the Italian Civil Code, as a private company being our shares not listed on a regulated market in Italy or within the European Union.

For the purpose of the present section, it is appropriate to specify that our Italian corporate legal framework, while regulating joint-stock companies as a unitary type, draws a distinction between those companies that do not have access to the capital markets (hereinafter referred to as the ***Private Companies***) and companies that instead do have it. This latter category comprises both companies listed on European regulated markets (***Public Companies***) and companies whose securities are not listed on such markets, insofar as they have a significant distribution of their securities among the public (so-called "*emittenti aventi strumenti finanziari diffusi tra il pubblico in maniera rilevante*"), according to the relevant provisions set forth in Italian Financials' Consolidated Act and its implementing provisions (hereinafter referred to as the ***Open Companies***).

Pursuant to Article 2-bis of the Issuer's Regulation implemented by Consob (*Regolamento emittenti*), Open Companies must meet the following requirements:

a) having shareholders other than the majority shareholders accounting for more than 500, and holding overall at least a 5% participation in the corporate capital; and

b) exceeding two out of three limits indicated under the first subsection of Article 2435-*bis* of the Italian Civil Code[2].

Based on the foregoing, in the event that, following completion of the initial public offering, our Company issues financial instruments widely distributed among the public, the regulation relating to Open Companies could apply to us.

Stock Exchange Listing

We have reserved the symbol "GNTA" for purposes of listing the ADSs on the Nasdaq Capital Market and plan to apply to list the ADSs on the Nasdaq Capital Market.

Transfer Agent and Registrar of Shares

Our share register is currently kept by , which acts as transfer agent and registrar. The share register reflects only record owners of our ordinary shares.

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[2]Article 2435-*bis* of the Italian Civil Code provides the following requirements:

- balance sheet total assets side: Eur 4,400,000;
- total revenues coming out from sales and services: Eur 8,800,000; and
- average number of employees during the accounting period: 50 units.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent one share (or a right to receive one share) deposited with The Bank of New York Mellon, as custodian, acting through an office located in the United Kingdom. Each ADS will also represent any other securities, cash or other property that may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Italian law governs shareholder rights. The depositary will be the holder of the shares underlying the ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Directions on how to obtain copies of those documents are provided under the heading "Where You Can Find More Information."

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares the ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See "Taxation." The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.

Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, you will receive no value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender the ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Italy and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you will not be able to exercise voting rights unless you surrender the ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to Deposited Securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 45 days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	***For:***
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property. Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement)Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates, or the custodian or we may convert currency and pay U.S. dollars to the depositary. Where the depositary converts currency itself or through any of its affiliates, the depositary acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation to act without negligence or bad faith. The methodology used to determine exchange rates used in currency conversions made by the depositary is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions from the us in U.S. dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on the ADSs or on the deposited securities represented by any of the ADSs. The depositary may refuse to register any transfer of the ADSs or allow you to withdraw the deposited securities represented by the ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by the ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do so by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold *the* ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
    - we delist the ADSs from an exchange in the United States on which they were listed and do not list the ADSs on another exchange in the United States or make arrangements for trading of ADSs on the U.S. over-the-counter market;
- we delist our shares from an exchange outside the United States on which they were listed and do not list the shares on another exchange outside the United States;
    - the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on Form F-6 under the Securities Act of 1933;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;

  are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and

- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying the ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Jury Trial Waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

You will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depositary's compliance with U.S. federal securities laws or the rules and regulations promulgated thereunder.

COMPARISON OF ITALIAN LAW AND DELAWARE LAW

The following comparison table summarizing the most significant differences in shareholder rights between the applicable provisions of the Delaware General Corporation Law and the corporate laws of Italy, also taking into account those main differences existing between the Private Companies and Open Companies.

It should be considered that this is only a general summary of certain provisions applicable to companies in Delaware and Italy. Certain Delaware and Italian companies may be permitted to exclude certain of the provisions summarized below in their charter documents.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Mergers and similar arrangements	
Under the Delaware General Corporation Law, with certain exceptions, a merger, consolidation, sale, lease or transfer of all or substantially all of the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. A shareholder of a Delaware corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights pursuant to which such shareholder may receive cash in the amount of the fair value of the shares held by such shareholder (as determined by a court) in lieu of the consideration such shareholder would otherwise receive in the transaction. The Delaware General Corporation Law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary of which it owns at least 90.0% of each class of capital stock without a vote by the shareholders of such subsidiary. Upon any such merger, dissenting shareholders of the subsidiary would have appraisal rights.	Under Italian law, a merger requires the approval of more than half of the share capital at an extraordinary shareholders' meeting of each company which is part to the merger. The merger may only be adopted after the expiry of a period of sixty (60) days from the filing of the merger decision and the related documents with the competent companies' register. This time limit, in particular, is intended to allow the company's creditors, subject to limited exceptions, to file an opposition to the merger, provided however that if such an opposition is deemed groundless and the company has given an adequate guarantee, the competent court may nevertheless decide that the merger shall take place notwithstanding the opposition. Italian law also provides for simplified forms of merger (with less documentation needed) in cases where the merger is carried out by embedding wholly-owned subsidiaries and subsidiaries which are at least 90% owned. In both cases the decision to merge is delegated to the administrative body, provided that the company's bylaws (as in our case) so provide. The delegation of powers to the administrative body does not, in any event, release the administrative body from the obligation to file and/or publish, as the case may be, the merger plan in order to make shareholders informed of the merger and to postpone, unless the shareholders waive their right thereof, 30 days from the filing/publication of the merger plan before passing the merger resolution. Shareholders of the "acquiring" company representing at least 5% of the share capital may in any event request the decision on the merger to be taken by the extraordinary shareholders' meeting. In such a case the jurisdiction of the extraordinary shareholders' meeting, as provided for the non-simplified procedure, shall apply.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Shareholders' suits	
Class actions and derivative actions generally are available to shareholders of a Delaware corporation for, among other things, breach of fiduciary duty, corporate waste and actions not taken in accordance with applicable law. In such actions, the court has discretion to permit the winning party to recover attorneys' fees incurred in connection with such action.	Shareholders may bring to the attention of the board of statutory auditors, facts or acts which such shareholder deems wrongful. If such shareholders represent 5% of our share capital, or 2% should our company be classified as an Open Company, our board of statutory auditors must investigate without delay and report its findings and recommendations at our shareholders' meeting. If there is a well-founded suspicion that the directors, in breach of their duties, have committed serious irregularities in the management that may cause damage to the company, the shareholders representing, in Private Companies, one-tenth of the share capital or, in Open Companies, one-twentieth can report the facts to the court. The court, having heard the directors and the statutory auditors, may order an audit of the company. The court does not order the audit and suspends the legal proceedings for a fixed period in the event the shareholders' meeting replaces the directors and the auditors with other subjects having adequate prerequisites, who take action without delay to ascertain whether the violations exist and, if so, to eliminate them, reporting to the court on the findings and the activities carried out. If the reported violations exist or if the above investigations are insufficient to eliminate them, the court may order the appropriate provisional measures and call the shareholders' meeting for the relevant resolutions. In the most serious cases, the court can revoke the directors and also the auditors, and appoint a receiver, determining his powers and duration of office. Liability claim against directors and general managers may be brought either by our shareholders' meeting, by our board of statutory auditors (following a resolution passed with the favorable vote of two thirds of its members) or directly by shareholders representing a certain percentage of the corporate capital. With reference to the shareholders' meeting, the resolution concerning the liability of the directors may be taken by the ordinary shareholders' meeting either at a meeting convened for that purpose or at the meeting called to approve the financial statements. Unless otherwise provided for in the bylaws, the shareholders' meeting shall pass the resolution by the majority normally prescribed for it. The liability claim is time-barred in five years from the date of termination of the director's office and can be waived or settled upon resolution of the shareholders' meeting, unless a minority of shareholders, in Private Companies such as ours, representing at least one-fifth of the share capital and, in Open Companies, one-twentieth of the share capital, vote against. The legal costs of such action in the event that the claim of such shareholders is successful and the court does not award such costs against the relevant directors, statutory auditors or general managers will be reimburse by us. As anticipated also shareholders representing a certain percentage of the share capital may bring claims against directors. Such percentages differ depending on whether the company is a Private Company or an Open Company. In case of a Private Company like our case, the percentage required is equal to at least one-fifth of our share capital, while for an Open Company the percentage amounts to one-fortieth of the share capital.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Dissenters' rights	
Any shareholder of a Delaware corporation has the right to dissent from any plan of merger or consolidation to which the corporation is a party, except that, unless the certificate of incorporation provides otherwise, a shareholder shall not have the right to dissent from any plan of merger or consolidation, with respect to shares of a class or series that are listed on a national securities exchange or held of record, by not less than 2,000 holders on the record date fixed to determine the shareholders entitled to vote upon the plan of merger or consolidation. A dissenting shareholder has a right to appraisal of its shares.	Under Italian law, shareholders' resolutions which are not adopted in conformity with applicable law or our bylaws may be challenged (with certain limitations and exceptions) within ninety days of such resolution (or, if such resolution is subject to registration or filing with the Italian Company Register, within ninety days of its registration or filing) by any absent, dissenting or abstaining shareholders representing, individually or in the aggregate, at least 5% of our share capital, or should the our company be considered an Open Company, at least one per thousand of the share capital (or by our board of directors or our board of statutory auditors). Shareholders who do not meet the threshold or are not otherwise entitled to vote at our meetings may only claim damages arising from the resolution. Alongside the challenge to the resolution, an urgent application may also be filed to suspend the implementation of the claimed resolution, in order to anticipate the effects of a possible winning award. Dissenting or absent shareholders may withdraw from the company as a result of shareholders' resolutions approving, among other things, material modifications to our corporate purpose, the rights attached to our ordinary shares (e.g., voting rights and/or economic rights related to ordinary shares), our conversion from a share corporation into a different legal entity or a transfer of our registered office outside of Italy. Under any such circumstances, our other shareholders would have pre-emptive rights to purchase the shares of the withdrawing shareholders. Should no shareholder exercise its pre-emptive right, the shares must be offered to third parties. If no third-party desires to purchase the shares, we will purchase them with our available reserves. In the event that there are no reserves available, we must reduce our capital accordingly. According to Italian law, the liquidation value of any such shares must be on terms determined by our board of directors, after consultation with our board of statutory auditors and our external auditor, and after careful consideration of our net asset value, our prospective earnings and the market value of our ordinary shares, if any. Under Italian law, we may include provisions in our bylaws governing the criteria for determining the liquidation value of shares in the event of withdrawal. We have not done so as of the date of this registration statement.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Shareholder vote on board and management compensation	
Under the Delaware General Corporation Law, the board of directors has the authority to fix the compensation of directors, unless otherwise restricted by the certificate of incorporation or bylaws.	Under Italian Law, the compensation of directors is established at the time of appointment or by the shareholders' meeting. The compensation of the chief executive officers shall be established by the board of directors, with the opinion of the board of statutory auditors. If the bylaws so provide, the shareholders' meeting may determine a total amount for the compensation of the directors, including that of the chief executive officers.
Annual vote on board renewal	
Unless otherwise specified in the certificate of incorporation or bylaws of the corporation, directors shall be elected by a plurality of votes of the shareholders on a date and at a time designated by or in the manner provided in the bylaws. Re-election is possible.	The board of directors is elected by the ordinary shareholders' meeting of the Company, for the period established at the time of election but in no case for longer than three fiscal years. A director, who may be, but is not required to be, a shareholder of the Company, may be reappointed for successive terms.
Indemnification of directors and executive management and limitation of liability	
The Delaware General Corporation Law provides that a certificate of incorporation may contain a provision eliminating or limiting the personal liability of directors, officers, employees or agents of the corporation for monetary damages for breach of a fiduciary duty as a director, except no provision in the certificate of incorporation may eliminate or limit the liability of a director for: • any breach of a director's duty of loyalty to the corporation or its shareholders; • acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; • statutory liability for unlawful payment of dividends or unlawful share purchase or redemption; or • any transaction from which the director derived an improper personal benefit. A Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any proceeding, other than an action by or on behalf of the corporation, because the person is or was a director or officer, against liability incurred in connection with the proceeding if the director or officer acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the corporation; and the director or officer, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Unless ordered by a court, any foregoing indemnification is subject to a determination that the director or officer has met the applicable standard of conduct: • by a majority vote of the directors who are not parties to the proceeding, even though less than a quorum; • by a committee of directors designated by a majority vote of the eligible directors, even though less than a quorum; • by independent legal counsel in a written opinion if there are no eligible directors, or if the eligible directors so direct; or • by the shareholders. Moreover, a Delaware corporation may not indemnify a director or officer in connection with any proceeding in which the director or officer has been adjudged to be liable to the corporation unless and only to the extent that the court determines that, despite the adjudication of liability but in view of all the circumstances of the case, the director or officer is fairly and reasonably entitled to indemnity for those expenses which the court deems proper.	Italian law requires directors and members of any committee designated by the board of directors to perform their duties with that degree of diligence that is required by the nature of their office and pursuant to their specific level of competence. The judgement on the director's diligence in carrying out his or her mandate should never cover the management choices or the manner and circumstances of such choices, even if the same entail significant economic risks, but should cover only the diligence shown by the director in appreciating in advance the risk margins connected with the transaction to be undertaken, and therefore, the possible omission of those precautions, assessments and information normally required for a decision of that type, implemented in those circumstances and with those methods. Directors are liable to the company's creditors when their improper management conduct impairs the company's assets and prevents creditors from meeting their claims. If we cannot repay our creditors, and a court determines that our directors did not adequately perform their duties relating to the preservation of our assets, the court may find our directors liable to our creditors. Liability, as mentioned above, does not arise when the damage to the assets is the result of correctly adopted management decisions.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Directors' fiduciary duties	
A director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.	Under Italian law, directors must perform the duties imposed on them by law and company's bylaws with the degree of diligence that is required by the nature of their office and pursuant to their specific level of competence.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Shareholder action by written consent	
A Delaware corporation may, in its certificate of incorporation, eliminate the right of shareholders to act by written consent.	Under Italian law, shareholders may not act without a meeting.
Special/extraordinary meetings of shareholders	
Under Delaware law, special meetings of shareholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or the bylaws.	Under Italian law, a shareholders' meeting, both ordinary and extraordinary, may be called by our board of directors and must be called if requested by holders of at least 10% of the issued shares, or should our Company be considered an Open Company, at least 5% of the share capital, or, in both cases, the lower threshold set out in in the bylaws. Shareholders are not entitled to request that a meeting of shareholders be convened to vote on issues which as a matter of law shall be resolved upon the basis of a proposal, plan or report by our board of directors. If a request by the shareholders for an extraordinary meeting, or even an ordinary meeting, is refused by the board of directors, and such refusal is unjustified, the meeting may be called by a competent court.
Shareholder proposals	
A shareholder of a Delaware corporation has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.	Registered holders of the Company's ordinary shares are entitled to attend and vote at ordinary and extraordinary shareholders' meetings. When shareholders who represent at least 10% of the share capital of an Italian corporation, or should our Company be considered an Open Company, at least 5% of the share capital, or, in both cases, the lower threshold set out in in the bylaws, request the board of directors to call a meeting of the company's shareholders, they must set out in their request the proposals to be discussed.
Cumulative voting	
Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation provides for it.	Under Italian law, shareholders are not entitled to elect directors through cumulative voting. The directors of a corporation are elected by a majority of the votes cast by the shareholders entitled to vote in person or by proxy at an ordinary meeting of shareholders at which the relevant quorum is met.
Board action by written consent	
Under Delaware law, any action required or permitted to be taken at any meeting of the board of directors may be taken without a meeting if all members of the board consent to the action in writing or by electronic transmission, and the writing or electronic transmission is filed with the minutes of proceedings of the board, unless otherwise restricted by the certificate of incorporation or bylaws.	Under Italian law, directors of a corporation may not act without a meeting.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Removal of directors	
Unless there is cumulative voting or there is a classified board, generally a director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors.	Under Italian law, a director may be removed from office at any time by the vote of shareholders at an ordinary shareholders' meeting. Whilst the removal is immediately effective within the company, it is effective vis-à-vis third parties only upon entry of the relevant resolution in the companies register. The resolution of the shareholders' meeting approved in favor of a liability suit against the director and the occurrence of causes of ineligibility also constitute justified causes for removal. If the removal of a director was without just cause, such director may have a claim for damages against us. These damages may include, but are not limited to, compensation that would otherwise have been paid to the director for the remainder of his or her term and damage to his or her reputation. Directors may resign at any time by written notice to the board of directors and to the chairman of the board of statutory auditors. The board of directors, subject to the approval of the board of statutory auditors, must appoint substitute directors to fill any vacancies caused by removal or resignation, who will serve until the next ordinary shareholders' meeting. If, at any time, more than half of the members of our board of directors appointed by the shareholders' meeting of the Company resign, such resignation is ineffective until the majority of the new board of directors has been appointed. In such a case, the remaining member of the board of directors (or the board of statutory auditors if all the members of the board of directors have resigned or ceased to be directors) must promptly call an ordinary shareholders' meeting to appoint new directors.
Transactions with interested shareholders or directors	
The Delaware General Corporation Law generally prohibits a Delaware corporation from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or group who or which owns or owned 15.0% or more of the corporation's outstanding voting shares within the past three years.	Italian law provides that the resolution of the shareholders' meeting approved with the decisive vote of our shareholders who have, on their own behalf or on behalf of third parties, an interest in conflict with that of the company may be challenged in case it could damage it. Furthermore, under Italian law, a director having any interest in a proposed transaction must disclose his or her interest to the board of directors and to the board of statutory auditors, even if such interest does not conflict with our interest in the transaction. The interested director is not required to abstain from voting on the resolution approving the transaction, but the resolution must explicitly state the reasons for the approved transaction, the terms thereto and the benefit of the transaction to us. If these provisions are not complied with, or if the transaction would not have been approved without the vote of the interested director, the resolution may be challenged within ninety days from the date of the resolution by any director or by our board of statutory auditors on grounds that the approved transaction would be prejudicial to us. An authorized representative of our company having any interest in a proposed transaction that he or she has authority to approve must solicit prior board approval before consenting to such transaction. The interested director may be held liable for damages to us resulting from a resolution adopted in breach of the above rules. Finally, a director may be held liable for illicitly profiting from insider information or a corporate opportunity.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Dissolution; winding up	
Unless the board of directors of a Delaware corporation approves the proposal to dissolve, dissolution must be approved by shareholders holding 100.0% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.	Under Italian law, and subject to the satisfaction of the claims of all creditors, upon liquidation our shareholders are entitled to a distribution that is equal to an amount resulting from the division of the positive liquidation balance by the number of shares or shareholders (to the extent available out of our net assets). Asset distribution to preferred shareholders and holders of "participating certificates" upon corporate dissolution is typically limited to established contractual preferences. Once the rights of preferred shareholders and holders of participating certificates have been fully satisfied, holders of ordinary shares are entitled to any remaining assets.
Variation of rights of shares	
A Delaware corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise.	Italian law allows the Company to issue preference shares with limited voting rights, to issue other classes of equity securities with different economic and voting rights, shares with economic rights related to the results of the corporate activity in a specific sector, to issue "participation instruments" (*strumenti finanziari partecipativi*) with limited economic and voting rights against the contribution, by shareholders or third parties, of work or services, as well as "participation instruments" in favor of employees.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Amendment of governing documents	
A Delaware corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise.	Under Italian law, the charter documents consist of articles of association and bylaws. An amendment to these documents requires the approval of the extraordinary shareholders' meeting. In this perspective, according to Italian law, resolutions at an extraordinary shareholders' meeting are adopted, on first call, by more than half of the share capital, on second call, by a majority of at least two-thirds of the holders of shares present or represented at such meeting, provided that a quorum of more than one-third of the issued shares is attending. In addition, certain matters (such as a change in business purpose or corporate form of the company, demergers, mergers, the transfer of its registered office outside Italy, its liquidation prior to the term set forth in its bylaws, the extension of the term, the revocation of liquidation and the issuance of special categories of shares) are approved by the extraordinary shareholders' meeting pursuant to the quora indicated above. Should our Company be considered an Open Company, according to Italian law, such resolutions are adopted, on first call, by a majority of at least two-thirds of the holders of shares present or represented at such meeting, provided that a quorum of at least half of the share capital is attending; on second call, by a majority of at least two-thirds of the holders of shares present or represented at such meeting, provided that a quorum of more than one-third of the share capital is attending; on third and subsequent calls, by a majority of at least two-thirds of the holders of shares present or represented at such meeting, provided that a quorum of at least one-fifth of the share capital is attending. Under Italian law, a shareholder who has not participated in a resolution amending the bylaws that involves a change in the rights attached to the shares has the right to withdraw from the company.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Inspection of Books and Records	
Shareholders of a Delaware corporation, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose, and to obtain copies of list(s) of shareholders and other books and records of the corporation and its subsidiaries, if any, to the extent the books and records of such subsidiaries are available to the corporation.	Under Italian law, our shareholders may review the report of the board of directors on the management of our company and the report of our statutory auditors and accounting firm on our financial statements during the fifteen days prior to the ordinary shareholders' meeting to approve those financial statements. The report remains on file at our offices and may be reviewed after the annual shareholders' meeting. The report is also filed with the Companies' Register of Milan and made publicly available. Moreover, any shareholder is entitled to examine the ledger of the minutes of the shareholders' meeting, at any time. Furthermore, since our Company is not a Private Company, the ownership of the participations to our corporate capital may vary on a daily basis and related transactions are electronically registered by intermediaries (banks and financial institutions) on specific accounting records. So, for each financial instruments account holder, the intermediary shall record in the register managed by the intermediary the financial instruments held, their transfer, the rights exercised and any restrictions, if any. After such registration, the account holder (basically the shareholder) shall legitimately have full and exclusive exercise of rights pertaining to the financial instruments registered on that account (such as voting, economic, administrative rights etc.). The entitlement to exercise such rights is then proven by the exhibition of certifications or communications to the issuer made by the intermediaries, pursuant to their own accounting records, in favor of the subject entitled to the right.
Payment of dividends	
The board of directors may approve a dividend without shareholder approval. Subject to any restrictions contained in its certificate of incorporation, the board may declare and pay dividends upon the shares of its capital stock either: ● out of its surplus, or ● in case there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year.	Under Italian law, our payment of any annual dividend must be proposed by our board of directors to the shareholders and is subject to the approval of our shareholders at the annual ordinary shareholders' meeting. Before dividends may be paid out of our profits in any year, we must allocate an amount equal to 5% of the net profit to our legal reserve until such reserve is at least equal to 20% of our corporate capital. If our capital is reduced as a result of accumulated losses, we may not pay dividends until the capital is reconstituted or reduced by the amount of such losses. We may distribute reserves derived from available earnings retained from prior years, provided that after such payment we will have a legal reserve at least equal to the legally required minimum of 20% of the capital. We may not approve or pay dividends until this minimum (i.e., 20% of the capital) is met. If the minimum is met, the board of directors could propose the issuance of a dividend and the shareholders' resolution might approve that issuance. The shareholders' resolution will specify the manner and the date of dividend payment. Any dividends which shareholders do not collect within five years of the date on which they become payable will be forfeited by those shareholders and the money will return to us. The board of directors may not approve interim dividends at times between our annual ordinary shareholders' meetings.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Return of Capital	
Delaware law provides that corporations may return capital by dividend, redemption or repurchase subject to certain solvency tests. Shareholder approval is not required for these transactions so long as the corporation meets the solvency tests.	Under Italian law, we are permitted to purchase our outstanding shares, subject to certain conditions and limitations. We may only purchase the shares out of profits available for dividends or out of distributable reserves, in each case as appearing on the latest shareholders-approved financial statements. Further, we may only repurchase fully paid-in shares. Such purchases and the conditions thereto must be authorized by shareholder vote at an ordinary shareholders' meeting and the authorization may be issued for a period not to exceed eighteen (18) months. The aggregate purchase price of such shares may not exceed the earnings reserve specifically approved by shareholders. Shares held in violation of the above conditions and limitations must be sold within one year of the date of purchase; in lack, they must be cancelled and the corporate capital must be reduced accordingly. Similar limitations apply with respect to purchases of the Company's shares by its subsidiaries. A corresponding reserve equal to the purchase price of such shares must be created in the balance sheet, and such reserve is not available for distribution, unless such shares are sold or cancelled. Shares purchased and held by us may be resold only pursuant to a resolution of our shareholders adopted at an ordinary shareholders' meeting. The voting rights attaching to the shares held by us or our subsidiaries cannot be exercised, but the shares can be counted for quorum purposes in shareholders' meetings. Dividends and other rights, including pre-emptive rights, attaching to such shares, will accrue to the benefit of other shareholders. The foregoing limitations do not apply in case we purchase our shares: (i) by giving execution to shareholders' meeting resolution authorizing capital reduction through repurchase or cancellation; (ii) for free, to the extent they are fully paid-in; (iii) as a consequence of universal succession, merger or demerger; (iv) on occasion of foreclosures authorized to satisfy a credit of our company, to the extent they are fully paid-in. As long as such shares remain the property of the company, the right to profits and the right of option are attributed proportionally to the other shares. The right to vote is suspended, but such shares are nevertheless taken into account for the purposes of calculating the majority and the quora required for the constitution and for the resolutions of the shareholders' meetings.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Creation and issuance of new shares	
Shareholder approval is required to authorize capital stock in excess of that provided in the charter. The corporation must file a certificate of amendment to its certificate of incorporation before the creation of additional authorized shares may become effective. The board of directors may, without shareholder consent, authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation, or any combination thereof.	Under Italian law, the issuance of any shares, ordinary or otherwise, requires an amendment to our bylaws to increase our capital, which must be recommended to our shareholders by our board of directors and approved by a vote of our shareholders at an extraordinary meeting of the shareholders. Shares so issued can be placed by the board of directors through delegation of powers resolved upon by the extraordinary shareholders' meeting. Once our shareholders have authorized the issuance of securities and the same have been subscribed, those securities must be paid for before the newly issued shares may be purchased. The board would also need to recommend, and the shareholders would need to approve by vote at the extraordinary meeting, specific terms of the securities. Alternatively, our shareholders can delegate the power to increase our capital to the board of directors, but the board's right to exercise such power, if delegated, will expire after five years. If the board does not approve a capital increase by the end of those five years, our board and shareholders would need to meet again to re-delegate this authority. With respect to shareholders' resolutions approving capital increases, Italian law provides that in the absence of meeting minutes or in the event of the impossibility or illegality of the resolution, any interested person may challenge such resolution for a period of 180 days following the filing of the shareholders' resolution with the Register of Companies. If a shareholders' meeting was not called to approve the capital increase, the relevant resolution should be considered invalid, and any interested person may challenge the capital increase for a period of 90 days following the approval of the financial statements referring to the year during which the shareholders' resolution has been, also partially, executed. Finally, once our shareholders authorize a capital increase, all those authorized shares that have been subscribed must be paid-up entirely before a new capital increase may be executed. By means of shareholders' extraordinary resolution, we can also increase our corporate capital by allocating to capital the reserves and other funds registered in our financial statements. In this case, the newly issued shares must have the same characteristics as those previously issued, and they must be placed to the shareholders proportionally to their shareholdings in the company.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Option Rights	
Under Delaware law, shareholders do not possess option rights with respect to the issuance of additional securities by the corporation, unless the certificate of incorporation provides otherwise.	Under Italian law, shareholders and holders of convertible debentures are entitled to subscribe for issuance of ordinary shares or convertible debentures in proportion to their holdings at the time of authorization of the capital increase for those issuances, except in the case of contributions in kind. Those who exercise such option right, provided they make such request simultaneously, have a pre-emption right on the purchase of shares and bonds convertible into shares that have not been subscribed. The option rights may be excluded or limited by a shareholders' resolution at an extraordinary meeting of the shareholders, if such exclusion or limitation is in the interest of our company, or if the shares are to be paid by means of contributions in kind. Bylaws of Public Companies and of companies with stocks traded in multilateral trading systems may also exclude the option right within the limits of ten per cent of the pre-existing share capital, provided that the issue price corresponds to the market value of the shares and this is confirmed in a specific report issued by an auditor or an auditing company. According to Italian law proposals to increase share capital with exclusion or limitation of option rights must be illustrated by the directors with a specific report which sets out the reasons for the exclusion or limitation of the option right, or, if the exclusion derives from a contribution in kind, the reasons for such contribution in kind, and in any case the criteria adopted for determining the issue price. The report must be communicated by the directors to the board of statutory auditors and to the person appointed to audit the accounts at least thirty days prior to the date set for the shareholders' meeting. Within fifteen days, the board of statutory auditors must express its opinion on the fairness of the issue price of the shares. The opinion of the board of statutory auditors and, only in the case of contribution in kind, the sworn report of the expert appointed by the Court or the documentation provided by Italian law, must remain deposited at the company's registered office during the fifteen days prior to the shareholders' meeting and until the latter has passed a resolution. Such terms may be waived by unanimous consent of the shareholders. The resolution shall determine the issue price of the shares on the basis of the value of shareholders' equity, taking into account, in the case of shares listed on regulated markets, also the trend in prices over the last six months. The foregoing procedure shall apply also in case of capital increase delegated to the board of directors.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Debt-equity ratio	
Under Delaware law, there are no restrictions on the amount of debt securities that a corporation may issue.	Under Italian law, we may issue debt securities in an amount not to exceed twice the sum of our capital, our legal reserve and any other disposable reserves appearing on our latest Italian balance sheet approved by our shareholders. The board of statutory auditors must certify compliance with such limitation. This limitation may be exceeded if the debt securities issued in excess are intended for subscription by professional investors subject to prudential supervision pursuant to special laws. In the event of subsequent circulation of the debt security, whoever transfers them is liable for the solvency of the company vis-à-vis buyers who are not professional investors. The rules indicated above do not apply in case we intend to issue debt securities to be listed on regulated markets or multilateral trading systems or which have attached the right to purchase or subscribe shares. The legal reserve is a reserve to which we allocate 5% of our net income each year until it equals at least 20% of our corporate capital. One of the other reserves that we maintain on our balance sheet is a “share premium reserve,” which reflects the amount paid for our ordinary shares in excess of the amount of such ordinary shares allocated to our capital. We may not voluntarily reduce our capital or distribute our reserves (such as by declaring dividends) until our outstanding debt securities are repaid in full. In the event the aggregate of the capital and reserves, following such reduction of capital and/or distribution of reserves, is less than half of the outstanding amount of the debt securities. If our equity is reduced by losses or otherwise, such that the amount of the outstanding debt securities is more than twice the amount of our equity, we cannot distribute profits to our shareholders until the ratio between the amount of our debt securities and our capital and reserves is restored. Some legal scholars are of the opinion that the ratio must be restored by a recapitalization of our company. If our equity is reduced, we could recapitalize by means of issuing new shares by or having our current shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital. These provisions regarding the ratio of debt securities to capital and reserves do not apply to the issuance of debt securities to professional investors (as defined by Italian law). However, professional investors who transfer such debt securities issued by us to third parties not qualified as professional investors would remain liable to our third-party investors for the payment of such securities.

DELAWARE CORPORATE LAW	ITALIAN CORPORATE LAW
Reduction of equity by losses	
Under Delaware law, shareholder equity in a corporation is reduced by losses and may become negative.	Italian law requires us to reduce our shareholders' equity in certain situations. Our shareholders' equity has three main components: capital, legal reserves and other shareholders' equity (such as any premium paid for the shares over the par value and any retained earnings). We first apply our losses from operations against our shareholders' equity other than legal reserves and capital. If additional losses remain and, after the legal reserves, our corporate capital is reduced by more than one-third as a result of losses, our board of directors must call a shareholders' meeting as soon as possible. The shareholders, having received an updated report on the company financial situation with the board of statutory auditors' opinion, should take appropriate measures, which may include, *inter alia*, reducing the legal reserves and capital by the amount of the remaining losses, or carrying the losses forward up to one year. If the shareholders vote to carry the losses forward up to one year, and the losses are still more than one-third of the amount of the capital at the end of that year, then we must reduce our capital by the amount of the losses suffered. However, as an S.p.A., we must maintain capital of at least €50,000. If the amount of the losses would reduce our corporate capital to less than €50,000, then: ● we would need to increase our capital, which we could do by issuing new shares or having our shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital; ● our shareholders would need to convert our company to an "S.r.l.", a private limited liability company, which has a lower capital requirement of €10,000. Such arrangement would, however, prevent the Company to remain listed on Nasdaq since the S.r.l. form is not consistent with being listed pursuant to Italian law; or ● if neither of these options are pursued, our shareholders or, if the directors do not convene a shareholders' meeting, a court of competent jurisdiction, at the instance of individuals shareholders, could appoint a liquidator, who need not be an Italian citizen, to liquidate our company.

EXCHANGE CONTROLS

No exchange control consent is required in Italy for the transfer of dividends or other distributions with respect to shares of an Italian company or proceeds from the sale thereof to persons outside of Italy.

TAXATION

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, including Italian, or other taxing jurisdiction.

Italy Tax Considerations

General. Under Italian law, financial instruments issued by an Italian company are subject to the same tax regime as are shares, provided that their remuneration is entirely represented by participation in the economic results of the issuer. Pursuant to Article 10(3) of the Income Tax Convention, the tax regime of dividends applies to income from corporate rights of an Italian company, which is subject to the same taxation treatment as income from shares under the laws of Italy.

Income Tax Withholding on Dividends. We do not anticipate making any distributions on our ordinary shares in the foreseeable future. However, if we were to make distributions on our ordinary shares, we would generally be required under Italian law, except as otherwise discussed below, to apply a definitive withholding tax on payments made to holders of our ordinary shares who are not residents of Italy for tax purposes.

Notably, dividends paid to beneficial owners who are not Italian residents and do not have a permanent establishment in Italy are generally subject to a 26 percent substitute tax rate. Therefore, the amount of the dividends that the holders of ADRs or holders of equity shares not residing in Italy will initially receive will be net of such Italian substitute tax.

All non-Italian resident owners of equity shares or ADRs may benefit from reduced withholding tax settled in the relevant anti-double tax treaty undersigned between Italy and the country of residence for tax purposes of the owners of equity shares or ADRs. The reduced withholding tax rate under the relevant anti-double tax treaty will be applicable provided that the non-resident owners of the equity shares or ADRs are able to produce the documentation attesting the requirements to be eligible for the application of the relevant anti-double tax treaty.

Under Italian law, US owners can claim, in accordance with Presidential Decree No. 600 of October 16, 1973, Article 27(3), a refund of up to eleven-twenty-sixths (*i.e.* 11/26) of the Italian withholding tax withheld on dividends upon presenting evidence to the Italian tax authorities that income taxes have been fully paid on the dividends in the country of residence of the US owners in an amount at least equal to the total refund claimed. US holders should consult an independent tax advisor concerning the availability of this refund, which has traditionally become payable only after extensive delays.

Under the double tax treaty in force between Italy and the United States of America (“US/Italy Income Tax Treaty”), if the payee is the beneficial owner of the payment, dividends paid to US owners will be subject to Italian withholding tax at a reduced rate of: 1) 5%, if the beneficiary is a company owning at least 25% of the payer’s voting shares (for at least 12 months preceding the dividend distribution); 2) 15% in any other case. The aforementioned regime (both 1 and 2) is applicable only if the payee does not carry out an entrepreneurial activity in Italy through a permanent establishment or performs independent personal services through a fixed place situated therein.

Companies or entities subject to corporation tax and resident in States that are European Union Member States or participants in the EEA (included in the list provided for by Italian Ministerial Decree, September 4, 1996, amended and supplemented by Ministerial Decree March 23, 2017) may be entitled to a reduced tax rate of 1.2% on dividends distributed. The pensions funds established in an EU Member State or EEA country may be entitled to a reduced tax rate of 11% or, under certain conditions, to exemption from Italian taxation on dividends.

***Income Tax on Capital Gains*.**

As a general rule, gains from shares in Italian companies, under custody in Italy, could give rise to a taxable income for the non-resident transferor.

Capital Gains exempt from taxation in Italy - "Non-qualified shareholdings" are those which are below 2% of the voting rights and 5% of the capital of an exchange-listed company. Gains from the disposal of non-qualified share investments in Italian listed companies by non-Italian residents are not subject to Italian income tax under domestic rule.

Capital Gains subject to tax in Italy - "Qualified shareholdings" in a listed company are those representing more than the 2% of the voting rights or more than the 5% of the capital of an exchange-listed company. Capital gains from the disposal of a qualified shareholding in a listed company are subject to a withholding tax of 26% under the domestic rule.

The "qualified shareholding" thresholds must be verified over a 12-month monitoring period, starting from the day on which the investor has held at least a qualifying stake, either actual or potential (this rule aimed at preventing that a buy/sale kind of trading resulting in an overall disposition of over 2% in 12 months may result in a qualifying gain having to be declared even when the investor has never owned an actual or potential qualifying stake). As a consequence, all trades cumulatively carried out in a 12-month period should be considered. More in details: (i) until the investor holds a qualifying shareholding at any point in time, trades are not relevant for capital gain purposes, even if the overall amount disposed in a 12-month period exceeds the relevant thresholds; and (ii) starting from the day when the taxpayer holds a qualifying shareholding, all the trades carried out in any consecutive 12 months give rise to qualified capital gains if the overall amount disposed of exceeds one of the relevant thresholds.

However please be informed that in accordance with rules stated in the anti-double tax treaty, in force between Italy and the country of residence for tax purposes of the transferor, is possible to claim the benefit of exemption of the 26% taxation on capital gains. In principle, and more in details, the art. 13 of the OECD model convention basically states that the capital gain is only taxed in the transferor's country of tax residence. The Italy – U.S.A. anti-double treaty tax convention states a taxation criterion in line with the above. In the light of the above and upon conditions that all the requirements relevant for the application of the Italy – U.S.A. anti-double treaty tax convention are met, an US investor may benefit from the fully exemption of taxation in Italy.

Furthermore, save for any applicable anti-avoidance provision, pursuant to the Income Tax Convention, a US owner will not be subject to Italian capital gain tax or to Italian individual or corporate income tax unless such US owner has a permanent establishment or fixed base in Italy to which the owner's ordinary shares is effectively connected. To this end, US owners selling ordinary shares and claiming benefits under the Income Tax Convention may be required to produce appropriate documentation establishing that the above-mentioned conditions have been met.

Estate and Gift Tax. Inheritance and gift taxes, which were abolished in 2001, have been re-introduced in the Italian system by Law Decree No. 262 of October 3, 2006 (converted into law, with amendments, by Law Decree No. 286 of November 24, 2006), as amended. Such taxes will apply to the overall net value of the relevant assets, at the following rates, depending on the relationship between the testate (or donor) and the beneficiary (or donee): (a) 4%, if the beneficiary (or donee) is the spouse or a direct ascendant or descendant (such rate only applying on the net asset value exceeding, for each person, €1 million); (b) 6%, if the beneficiary (or donee) is a brother or sister (such rate only applying on the net asset value exceeding, for each person, €100,000); (c) 6% if the beneficiary (or donee) is another relative within the fourth degree or a direct relative-in-law as well as an indirect relative-in-law within the third degree; and (d) 8% if the beneficiary is a person other than those mentioned under (a), (b) and (c), above. If the beneficiary has a serious disability recognized under applicable law, inheritance and gift taxes will apply to its portion of the net asset value exceeding €1.5 million.

Transfer tax. In connection with the Italian stamp duty tax on the transfer of shares, according to article 37 of Law No. 248 of December 31, 2007, converted with amendments into Law No. 31 of February 28, 2008, the stamp duty has been abolished with regard to contracts having as their object the transfer of shares. In certain cases the relevant transfer acts would be subject to the registration tax at a flat amount equal to €200.

Communications Stamp Duty. A stamp duty has been introduced under article 19 of Law Decree No. 201 of December 6, 2011, converted into Law No. 214 of December 22, 2011, to be imposed on communications (issued by banks and financial intermediaries) to clients relating to securities, even where the deposit of such securities is not mandatory (although certain entities are excluded). The amount of the stamp duty is based on the market value of the securities or, in the absence of a market value, on the nominal amount or the amount payable on redemption. As a general comment, the stamp duty rate is 0.2% on a yearly *pro-rata temporis* basis (from January 1 up to December 31). The minimum amount is fixed of € 34,20 up to a maximum amount of €14,000. The communication is deemed to be sent to clients at least once a year, even where there is no obligation to issue any such communication.

Financial Transaction Tax. Law 228 of December 24, 2012, Article 1(491 – 500) introduced the Italian Financial Transaction Tax applicable (i) to the transfer of shares and other participative financial instruments issued by companies resident in Italy ("Italian Equity") and securities representing Italian Equity, regardless of the country where the issuer has its residence (together with Italian Equity are referred to as "Qualifying Equity"); (ii) on the basis of the "value of the transaction"; (iii) regardless of the place where the transaction is concluded and of the State where the parties have their residence; (iv) to transactions on "regulated markets and on multilateral trading facilities" with a reduced rate; (v) to over-the-counter transactions with a full rate.

The taxable event, triggering Italian Financial Transaction Tax, is the transfer of ownership of Qualifying Equity. Securities representing Italian Equity are in scope of the Italian Financial Transaction Tax, regardless of the State where the issuer has its residence. This provision is aimed at including in the scope of the Italian Financial Transaction Tax, American Depository Receipts ("ADRs"), Global Depository Receipts ("GDRs") and any other certificate of deposit, where the underlying securities are Italian Equity.

The value of the transaction is determined on the basis of the net balance of the transactions settled daily, calculated for each taxpayer with reference to the number of securities traded under the transactions settled in the same day and relating to the same financial instrument.

The calculation is made by the financial intermediary responsible for the payment of the tax, i.e., the one receiving the order to execute the transaction directly from the purchaser or final counterparty.

The Italian Financial Transaction Tax is due by the person in whose favor the transfer of ownership of the Qualifying Equities occurs.

The tax rate applicable is 0.20% while the reduced rate for transactions on "regulated markets and on multilateral trading facilities" is 0.10%.

The tax shall be paid by the 16th day of the month following the one in which the relevant triggering event occurs.

The Italian Financial Transaction Tax does not apply to the transfer of ownership of Italian Equity where the issuing companies are listed in regulated markets and have a market capitalization below 500 million Euros. Such exclusion also applies to the transfer of ownership of securities representing Italian Equity.

U.S. Federal Income Tax Consequences

THE FOLLOWING SUMMARY IS INCLUDED HEREIN FOR GENERAL INFORMATION AND IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSIDERED TO BE, LEGAL OR TAX ADVICE. EACH U.S. HOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND SALE OF ADSS, INCLUDING THE EFFECTS OF APPLICABLE STATE, LOCAL, FOREIGN OR OTHER TAX LAWS AND POSSIBLE CHANGES IN THE TAX LAWS.

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a "U.S. Holder" arising from the purchase, ownership and sale of the ADSs. For this purpose, a "U.S. Holder" is a holder of ADSs that is: (1) an individual citizen or resident of the United States, including an alien individual who is a lawful permanent resident of the United States or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) or a partnership (other than a partnership that is not treated as a U.S. person under any applicable U.S. Treasury regulations) created or organized under the laws of the United States or the District of Columbia or any political subdivision thereof; (3) an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of source; (4) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; or (5) a trust that has a valid election in effect to be treated as a U.S. person to the extent provided in U.S. Treasury regulations.

This summary is for general information purposes only and does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a decision to purchase the ADSs. This summary generally considers only U.S. Holders that will own the ADSs as capital assets. This summary does not consider the U.S. federal tax consequences to a person that is not a U.S. Holder, nor does it describe the rules applicable to determine a taxpayer's status as a U.S. Holder. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended, or the Code, final, temporary and proposed U.S. Treasury regulations promulgated thereunder, administrative and judicial interpretations thereof, and the U.S./Italy Income Tax Treaty, all as in effect as of the date hereof and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. We will not seek a ruling from the IRS with regard to the U.S. federal income tax treatment of an investment in the ADSs by U.S. Holders and, therefore, can provide no assurances that the IRS will agree with the conclusions set forth below.

This discussion does not address all of the aspects of U.S. federal income taxation that may be relevant to a particular U.S. holder based on such holder's particular circumstances and in particular does not discuss any estate, gift, generation-skipping, transfer, state, local, excise or foreign tax considerations. In addition, this discussion does not address the U.S. federal income tax treatment of a U.S. Holder who is: (1) a bank, life insurance company, regulated investment company, or other financial institution or "financial services entity;" (2) a broker or dealer in securities or foreign currency; (3) a person who acquired our securities in connection with employment or other performance of services; (4) a U.S. Holder that is subject to the U.S. alternative minimum tax; (5) a U.S. Holder that holds our securities as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) a tax-exempt entity; (7) real estate investment trusts or grantor trusts; (8) an expatriate or a former long-term resident of the United States; or (9) a U.S. Holder having a functional currency other than the U.S. dollar. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly or constructively, at any time, securities representing 10% or more of the voting power or value of our shares. Additionally, the U.S. federal income tax treatment of partnerships (or other pass-through entities) or persons who hold securities through a partnership or other pass-through entity are not addressed.

Each prospective investor is advised to consult his or her own tax adviser for the specific tax consequences to that investor of purchasing, holding or disposing of our securities, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

Taxation of Dividends Paid on Ordinary Shares

We do not intend to pay dividends in the foreseeable future. In the event that we do pay dividends, and subject to the discussion under the heading "Passive Foreign Investment Companies" below and the discussion of "qualified dividend income" below, a U.S. Holder, other than certain U.S. Holders that are U.S. corporations, will be required to include in gross income as ordinary income the amount of any distribution paid on ordinary shares (including the amount of any Italy tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution which exceeds our earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder's tax basis for the ordinary shares to the extent thereof, and then capital gain. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income.

In general, preferential tax rates for "qualified dividend income" and long-term capital gains are applicable for U.S. Holders that are individuals, estates or trusts. For this purpose, "qualified dividend income" means, inter alia, dividends received from a "qualified foreign corporation." A "qualified foreign corporation" is a corporation that is entitled to the benefits of a comprehensive tax treaty with the United States which includes an exchange of information program. The IRS has stated that the Italy/U.S. Tax Treaty satisfies this requirement and we believe we are eligible for the benefits of that treaty.

In addition, our dividends will be qualified dividend income if our ordinary shares are readily tradable on Nasdaq or another established securities market in the United States. Dividends will not qualify for the preferential rates if we are treated, in the year the dividend is paid or in the prior year, as a PFIC, as described below under "Passive Foreign Investment Companies." A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our ordinary shares for at least 61 days of the 121 day period beginning on the date which is 60 days before the ex-dividend date, or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our ordinary shares are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as "investment income" pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

The amount of a distribution with respect to our ordinary shares will be measured by the amount of the fair market value of any property distributed, and for U.S. federal income tax purposes, the amount of any Italian taxes withheld therefrom. Cash distributions paid by us in EUR will be included in the income of U.S. Holders at a U.S. dollar amount based upon the spot rate of exchange in effect on the date the dividend is includible in the income of the U.S. Holder, and U.S. Holders will have a tax basis in such EUR for U.S. federal income tax purposes equal to such U.S. dollar value. If the U.S. Holder subsequently converts the EUR into U.S. dollars or otherwise disposes of it, any subsequent gain or loss in respect of such EUR arising from exchange rate fluctuations will be U.S. source ordinary exchange gain or loss.

Taxation of the Disposition of Ordinary Shares

Except as provided under the PFIC rules described below under "Passive Foreign Investment Companies," upon the sale, exchange or other disposition of our ordinary shares, a U.S. Holder will recognize capital gain or loss in an amount equal to the difference between such U.S. Holder's tax basis for the ordinary shares in U.S. dollars and the amount realized on the disposition in U.S. dollar (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale, exchange or other disposition of ordinary shares will be long-term capital gain or loss if the U.S. Holder has a holding period of more than one year at the time of the disposition. Individuals who recognize long-term capital gains may be taxed on such gains at reduced rates of tax. The deduction of capital losses is subject to various limitations.

Passive Foreign Investment Companies

Special U.S. federal income tax laws apply to U.S. taxpayers who own shares of a corporation that is a PFIC. We will be treated as a PFIC for U.S. federal income tax purposes for any taxable year that either:

- 75% or more of our gross income (including our pro rata share of gross income for any company, in which we are considered to own 25% or more of the shares by value), in a taxable year is passive; or
- At least 50% of our assets, averaged over the year and generally determined based upon fair market value (including our pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value) are held for the production of, or produce, passive income.

For this purpose, passive income generally consists of dividends, interest, rents, royalties, annuities and income from certain commodities transactions and from notional principal contracts. Cash is treated as generating passive income.

We have not made the formal analysis necessary to determine whether or not we are currently a PFIC or whether we have ever been a PFIC, although based upon the general composition of our income and assets, and upon a review of our financial statements, we believe we most likely are and have been a PFIC. The tests for determining PFIC status depend, in part, on the application of complex US federal income tax rules, which are subject to differing interpretations. In addition, whether any corporation will be a PFIC for any taxable year depends on the assets and income of such corporation over the course of each such taxable year and, as a result, it is difficult to make accurate projections of future income and assets which are relevant to this determination for the current taxable year or any future period. Accordingly, there can be no assurance that we currently are not or will not be a PFIC in future taxable years.

If we currently are or become a PFIC, each U.S. Holder who has not elected to mark the shares to market (as discussed below), would, upon receipt of certain distributions by us and upon disposition of our ordinary shares at a gain: (1) have such distribution or gain allocated ratably over the U.S. Holder's holding period for the ordinary shares, as the case may be; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, when shares of a PFIC are acquired by reason of death from a decedent that was a U.S. Holder, the tax basis of such shares would not receive a step-up to fair market value as of the date of the decedent's death, but instead would be equal to the decedent's basis if lower, unless all gain were recognized by the decedent. Indirect investments in a PFIC may also be subject to these special U.S. federal income tax rules.

The PFIC rules described above would not apply to a U.S. Holder who makes a QEF election for all taxable years that such U.S. Holder has held the ordinary shares while we are a PFIC, provided that we comply with specified reporting requirements. Instead, each U.S. Holder who has made such a QEF election is required for each taxable year that we are a PFIC to include in income such U.S. Holder's pro rata share of our ordinary earnings as ordinary income and such U.S. Holder's pro rata share of our net capital gains as long-term capital gain, regardless of whether we make any distributions of such earnings or gain. In general, a QEF election is effective only if we make available certain required information. The QEF election is made on a shareholder-by-shareholder basis and generally may be revoked only with the consent of the IRS. We do not intend to furnish U.S. Holders annually with information needed in order to complete IRS Form 8621 and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

In addition, the PFIC rules described above would not apply if we were a PFIC and a U.S. Holder made a mark-to-market election. A U.S. Holder of our ordinary shares which are regularly traded on a qualifying exchange, including the Nasdaq Capital Market, can elect to mark the ordinary shares to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the ordinary shares and the U.S. Holder's adjusted tax basis in the ordinary shares. Losses are allowed only to the extent of net mark-to-market gain previously included income by the U.S. Holder under the election for prior taxable years.

U.S. Holders who hold our ordinary shares during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules.

Tax on Net Investment Income

U.S. Holders who are individuals, estates or trusts will generally be required to pay a 3.8% Medicare tax on their net investment income (including dividends on and gains from the sale or other disposition of our ordinary shares), or in the case of estates and trusts on their net investment income that is not distributed. In each case, the 3.8% Medicare tax applies only to the extent the U.S. Holder's total adjusted income exceeds applicable thresholds.

Information Reporting and Withholding

A U.S. Holder may be subject to backup withholding at a rate of 24% with respect to cash dividends and proceeds from a disposition of ordinary shares. In general, backup withholding will apply only if a U.S. Holder fails to comply with specified identification procedures. Backup withholding will not apply with respect to payments made to designated exempt recipients, such as corporations and tax-exempt organizations. Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a U.S. Holder, provided that the required information is timely furnished to the IRS.

A U.S. Holder with interests in "specified foreign financial assets" (including, among other assets, our ordinary shares, unless such ordinary shares are held on such U.S. Holder's behalf through a financial institution) may be required to file an information report with the IRS if the aggregate value of all such assets exceeds $50,000 on the last day of the taxable year or $75,000 at any time during the taxable year (or such higher dollar amount as may be prescribed by applicable IRS guidance); and may be required to file a Report of Foreign Bank and Financial Accounts if the aggregate value of the foreign financial accounts exceeds $10,000 at any time during the calendar year. You should consult your own tax advisor as to the possible obligation to file such information report.

UNDERWRITING

Canaccord Genuity LLC is acting as representative of each of the underwriters named below. We have entered into an underwriting agreement dated , 2021 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discount set forth on the cover page of this prospectus supplement, the number of ADSs listed next to its name in the following table:

Underwriter	Number of ADSs
Canaccord Genuity LLC	
Roth Capital Partners, LLC	
Total	

The underwriters are committed to purchase all the ADSs offered by the Company, other than those covered by the over-allotment option to purchase additional ADSs and the reserved share program, each as described below. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, the underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the ADSs offered by us in this prospectus supplement are subject to various representations and warranties and other customary conditions specified in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the ADSs subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus, permits the underwriters to purchase up to an aggregate of additional ADSs (equal to 15% of the total number of ADSs sold in this offering) at the public offering price per share, less underwriting discounts and commissions, solely to cover over-allotments, if any. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional ADSs in proportion to their respective commitments set forth in the prior table.

Discounts, Commissions and Reimbursement

The representative has advised us that the underwriters propose to offer the ADSs to the public at the initial public offering price per share set forth on the cover page of this prospectus. The underwriters may offer ADSs to securities dealers at that price less a concession of not more than $ per ADS of which up to $ per ADS may be reallowed to other dealers. After the initial offering to the public, the public offering price and other selling terms may be changed by the representative.

The following table summarizes the underwriting discounts and commissions and proceeds, before expenses, to us assuming both no exercise and full exercise by the underwriters of their over-allotment option:

		Total	
	Per ADS	Without Option	With Option
Public offering price	$	$	$
Underwriting discounts and commissions (public investors, 7%)			
Underwriting discounts and commissions (reserved share program, 6.5%)	$	$	$
Proceeds, before expenses, to us	$	$	$

In addition, we have also agreed to pay the reasonable and documents expenses of the underwriters relating to the offering (including the costs of document preparation, production and distribution (such as printing and binding, and photocopies), and third party research and database services, and the reasonable fees and disbursements of independent counsel), up to an aggregate of $400,000.

We estimate the expenses of this offering payable by us, not including underwriting discounts and commissions, will be approximately $.

Representative Warrants

Upon the closing of this offering, we have agreed to issue to Canaccord Genuity LLC and Roth Capital Partners LLC warrants, or the Underwriter Warrants, to purchase a number of ADSs equal to 4% of the total number of ADSs sold in this public offering. The Underwriter Warrants will be exercisable at a per share exercise price equal to 125% of the public offering price per ADS sold in this offering. The Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, during the four and one-half year period commencing six months from the deemed effective date of the registration statement related to this offering. The Underwriter Warrants also provide for one demand registration right of the ADSs underlying the Underwriter Warrants, and unlimited "piggyback" registration rights with respect to the registration of the ADSs underlying the Underwriter Warrants and customary antidilution provisions. The demand registration right provided will not be greater than five years from the date of the underwriting agreement related to this offering in compliance with FINRA Rule 5110(g)(8)(D). The piggyback registration right provided will not be greater than seven years from the date of the underwriting agreement related to this offering in compliance with FINRA Rule 5110(g)(8)(D).

The Underwriter Warrants and the ADSs underlying the Underwriter Warrants have been deemed compensation by the Financial Industry Regulatory Authority, or FINRA, and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The representative, or permitted assignees under such rule, may not sell, transfer, assign, pledge, or hypothecate the Underwriter Warrants or the securities underlying the Underwriter Warrants, nor will the representative engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the Underwriter Warrants or the underlying ADSs for a period of 180 days from the deemed effective date of the registration statement. Additionally, the Underwriter Warrants may not be sold transferred, assigned, pledged or hypothecated for a 180-day period following the deemed effective date of the registration statement except to any underwriter and selected dealer participating in the offering and their bona fide officers or partners. The Underwriter Warrants will provide for adjustment in the number and price of the Underwriter Warrants and the ADSs underlying such Underwriter Warrants in the event of recapitalization, merger, stock split or other structural transaction, or a future financing undertaken by us.

Reserved Share Program

At our request, the underwriter has reserved up to ordinary shares, representing % of the ADSs offered by this prospectus, for sale to existing shareholders of the Company ("Reserved Share Investors"). All of the persons purchasing such ordinary shares must commit to purchase no later than the close of business on the day following the date of this prospectus. The number of ADSs available for sale to the general public will be reduced to the extent these persons purchase the reserved ordinary shares. Ordinary shares committed to be purchased by such persons that are not so purchased will be reallocated for sale as ADSs to the general public in the offering. All such sales of reserved ordinary shares will be made at the initial public offering price per ADS set forth on the cover page of this prospectus, less an underwriting discount of 6.5%.

Lock-Up Agreements

We have agreed with the underwriters that we will not, without the prior consent of the representative, for a period of 180 days following the date of this prospectus, offer, sell, contract to sell, pledge, grant any option to purchase, purchase any option or contract to sell, right or warrant to purchase, make any short sale, file a registration statement with respect to any of the ADSs or any securities that are convertible into or exercisable or exchangeable for the ADSs, or otherwise transfer or dispose of (including entering into any swap or other agreement that transfers to any other entity, in whole or in part, any of the economic consequences of ownership interest): (1) the ADSs and depositary shares representing our ordinary shares; (2) shares of our controlled affiliates and depositary shares representing those shares; and (3) securities that are substantially similar to such ADSs or depositary shares. We have also agreed to cause controlled affiliates to abide by the restrictions of the lock-up agreement. In addition, each of our directors and executive officers and each beneficial owner of 10% or more of the ADSs or ordinary shares will abide by similar 180-day lock-up agreement with respect to the ADSs, depositary shares representing the ADSs and securities that are substantially similar to the ADSs or depositary shares representing our ordinary shares, subject to customary exceptions for transfers among affiliates. The restrictions of our lock-up agreement do not apply to: (1) the issuance of securities pursuant to our employee share incentive plan which is described in this prospectus, and (2) a transfer by us to our affiliate, provided that such transfer is not a disposition for value and that such affiliate agrees to be bound in writing by the restrictions set forth in the lock-up agreement to which we are subject. The exceptions also permit our executive officers and directors and other existing security holders, subject to certain restrictions, to transfer ADSs, depositary shares representing the ADSs and securities that are substantially similar to the ADSs or our ordinary shares: (i) as a bona fide gift or gifts, (ii) to the person's immediate family or any trust, partnership or similar entity for the direct or indirect benefit of the person or their immediate family, (iii) by operation of law, such as pursuant to a qualified domestic order or as required by a divorce settlement, (iv) as a distribution to the person's limited partners or stockholders, (v) to the person's affiliates or any investment fund or other entity controlled or managed by the person, or (vi) by will, other testamentary document or intestate succession upon death, including to the transferee's nominee or custodian. Furthermore, during the lock-up period, our executive officers, directors, and other existing security holders may sell shares of common stock purchased in this offering or in the open market following this offering, provided that such sales are not required to be reported in any public report or filing with the SEC or otherwise, and the seller does not voluntarily effect any public filing or report regarding such sales during the lock-up period.

Indemnification

We have agreed to indemnify the several underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters may be required to make in respect of those liabilities.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

No Public Market

Prior to this offering, there has not been a public market for our securities in the U.S. and the public offering price for our ordinary shares and ADSs will be determined through negotiations between us and the underwriters. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the ADSs will trade in the public market subsequent to this offering or that an active trading market for the ADSs will develop and continue after this offering.

Stock Exchange

We plan to apply to list the ADSs on the Nasdaq Capital Market under the symbol "GNTA." There can be no assurance that we will be successful in listing the ADSs on the Nasdaq Capital Market.

Electronic Distribution

A prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters of this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase ADSs so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the ADSs while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of ADSs in excess of the number of ADSs the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of ADSs over-allotted by the underwriters is not greater than the number of ADSs that they may purchase in the over-allotment option. In a naked short position, the number of ADSs involved is greater than the number of ADSs in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing ADSs in the open market.

Syndicate covering transactions involve purchases of ADSs in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of ADSs to close out the short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared with the price at which they may purchase ADSs through exercise of the over-allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the ADSs in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the ADSs originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs. As a result, the price of the ADSs in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the ADSs. These transactions may be effected on Nasdaq in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Other Relationships

Certain of the underwriters and their affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they may in the future receive customary fees.

Offer restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area—Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the EEA (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);

- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or

- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code Monétaire et Financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 ;and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1; and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities Regulator (*Commissione Nazionale per le Società e la Borsa*, "*CONSOB*") pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy, except:

- to Italian qualified investors, as defined in Article 100 of Legislative Decree no.58 of 24 February 1998 ("Decree No. 58") by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 1197l") as amended ("Qualified Investors");
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended; and
- in other circumstances that are exempt from the rules on European prospectus pursuant to Article 1 of EU Regulation No. 2017/1129.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with any applicable laws, regulations or requirements imposed by CONSOB, the Bank of Italy and/or any other Italian authorities.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA") has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

EXPENSES

Set forth below is an itemization of the total expenses, excluding underwriting discounts, expected to be incurred in connection with the offer and sale of the ordinary shares by us. With the exception of the SEC registration fee and the FINRA filing fee, all amounts are estimates:

SEC registration fee	$
Nasdaq listing fee	$
FINRA filing fee	$
Printer fees and expenses	$
Legal fees and expenses	$
Accounting fees and expenses	$
Miscellaneous	$
Total	$

LEGAL MATTERS

Certain legal matters concerning this offering will be passed upon for us by Loeb & Loeb LLP, New York, New York. Certain legal matters with respect to the legality of the issuance of the securities offered by this prospectus will be passed upon for us by Giovannelli e Associati, Studio Legale, Italy. Certain legal matters related to the offering will be passed upon for the underwriters by Goodwin Procter LLP, New York, New York. LCA Studio Legale, Italy is representing the underwriters with respect to certain matters of Italian law.

EXPERTS

The financial statements of Genenta for its fiscal years ended December 31, 2020 and 2019 included herein have been audited by Mayer Hoffman McCann P.C., independent registered public accounting firm, as set forth in their report thereon. Such financial statements are included in this prospectus and registration statement in reliance upon such report given on the authority of such firm as experts in accounting and auditing. The address of Mayer Hoffman McCann P.C. is 13500 Evening Creek Drive North #450, San Diego, California, United States.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of Italy and our registered office and domicile is located in Milan, Italy. Moreover, a majority of our directors and executive officers are not residents of the United States, and all or a substantial portion of our assets are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States.

We have been advised by our Italian counsel that the recognition and enforcement of foreign judgements in Italy is regulated either by (i) treaties or conventions, bilateral or multilateral, between Italy and the foreign country, whose court issued the judgement, or (ii) Italian Law no. 218 of May 31, 1995 (the "International Private Law Act"). In this regard, the provisions of the applicable treaties and conventions, if any, prevail on the provisions of the International Private Law Act. Indeed, Section 2 of the International Private Law Act states that the provisions of the International Private Law Act are "*without prejudice to the application of the international conventions binding on Italy*".

That said, Italian counsels advise us that there exist no treaties or other conventions in existence between the Republic of Italy and the United States, or between the Republic of Italy and the US laws, relating to the recognition and enforcement of civil judgments. There follows that a civil judgment of a court of New York or of a United States federal court applying New York law will be recognized in Italy under the general provisions of the International Private Law Act.

Section 64 of the International Private Law Act provides that a judgment issued in a foreign country is recognized in Italy, without any proceedings (*i.e.*, without a rehearing on the merits) being necessary, if all of the following conditions are met:

a) the judge who issued the judgment had the power to decide the case pursuant to the principles on jurisdiction provided by Italian law;

b) the writ of summons (or equivalent pleading) was duly served upon the defendant in compliance with the applicable provisions of the *lex fori* (i.e., the application of the rules of the legal system to which the judge belongs);

c) the parties entered an appearance, or their default was duly declared in compliance with the applicable provisions of the *lex fori*;

d) the judgment to be recognized is a final judgment subject to no further appeal;

e) the judgment to be recognized does not contrast with a final judgment issued by an Italian Court;

f) there are no pending proceedings between the same parties and in relation to the same matter, which proceedings were commenced prior to the commencement of the foreign proceedings; and

g) the judgment to be recognized does not conflict with Italian public order.

When the foreign civil judgment must be enforced in Italy, the above-mentioned conditions must be verified by the Italian Court of Appeal based in the area where the judgment must be executed, as indicated in Article 67 of the International Private Law Act. The subsequent decision of the competent Court of Appeal constitutes the title to enforce the foreign decision. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the United States securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is an issue for the court making such decision.

Subject to the foregoing, investors may be able to enforce in Italy judgments in civil and commercial matters that have been obtained from U.S. federal or state courts. Nevertheless, we cannot assure you that those judgments will be recognized or enforceable in Italy.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

The SEC maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at www.sec.gov.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements will file reports with the SEC. Those other reports or other information may be inspected without charge at the locations described above. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within 120 days after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on Form 6-K, unaudited quarterly financial information.

We maintain a corporate website at www.genenta.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

INDEX TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2020 AND 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Quotaholders of **Genenta Science S.r.l.**

Opinion on the Financial Statements

We have audited the accompanying balance sheets of **Genenta Science S.r.l.** (the "Company") as of December 31, 2020 and 2019, and the related statements of operations and comprehensive loss, changes in quotaholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2020.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
April 22, 2021

Genenta Science S.r.l.
Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2020	2019
	(in Euros)	
Operating expenses		
Research and development	€ 4,688,461	€ 3,702,982
General and administrative	901,765	921,520
Total operating expenses	5,590,226	4,624,502
Loss from operations	(5,590,226)	(4,624,502)
Other income (expense)		
Other income	5,966	36,331
Finance expense	(7,754)	(9,552)
Total other income (expense), net	(1,788)	26,779
Loss before income taxes	(5,592,014)	(4,597,723)
Income tax benefit (expense)	-	-
Net loss	(5,592,014)	(4,597,723)
Comprehensive loss	-	-
Total comprehensive loss	€ (5,592,014)	€ (4,597,723)
Pro forma information (unaudited):		
Pro forma net loss		
Pro forma net loss per share - basic and diluted		
Weighted average pro forma number of shares outstanding - basic and diluted		

The accompanying notes are an integral part of these financial statements.

Genenta Science S.r.l.
Balance Sheets

	At December 31,	
	2020	2019
	(in Euros)	
Assets		
Current assets		
Cash and cash equivalents	€ 15,465,243	€ 20,141,379
Prepaid expenses and other current assets	947,501	458,118
Prepaid expenses and other current assets - related party	121,432	-
Total current assets	16,534,176	20,599,497
Non-current assets		
Property and equipment, net	18,971	-
Other asset- related party	3,350	-
Other non-current assets	945,618	748,681
Total non-current assets	967,939	748,681
Total assets	€ 17,502,115	€ 21,348,178
Liabilities and quotaholders' equity		
Current liabilities		
Accounts payable	€ 544,988	€ 279,699
Accounts payable - related party	10,027	292,741
Accrued expenses	365,969	213,973
Accrued expenses - related party	1,359,191	1,651,620
Other current liabilities	53,243	48,000
Total current liabilities	2,333,418	2,486,033
Long-term liabilities		
Retirement benefit obligation	17,388	11,332
Total long-term liabilities	17,388	11,332
Commitments and contingencies (Note 13)		
Quotaholders' equity		
Corporate capital	37,056	36,049
Additional paid-in capital	36,604,728	34,713,225
Accumulated deficit	(21,490,475)	(15,898,461)
Total quotaholders' equity	15,151,309	18,850,813
Total liabilities and quotaholders' equity	**€ 17,502,115**	**€ 21,348,178**

The accompanying notes are an integral part of these financial statements.

Genenta Science S.r.l.
Statement of Changes in Quotaholders' Equity

(in Euros, except quotas)	Corporate capital	Additional paid-in capital	Accumulated deficit	Total
Balance at January 1, 2019	€ 29,179	€ 19,202,381	€ (11,300,738)	€ 7,930,822
Capital increase, net of issuance costs	6,870	14,761,332	-	14,768,202
Share-based compensation	-	749,512	-	749,512
Net loss	-	-	(4,597,723)	(4,597,723)
Balance at December 31, 2019	€ 36,049	€ 34,713,225	€ (15,898,461)	€ 18,850,813
Capital increase, net of issuance costs	1,007	1,431,309	-	1,432,316
Share-based compensation	-	460,194	-	460,194
Net loss	-	-	(5,592,014)	(5,592,014)
Balance at December 31, 2020	€ 37,056	€ 36,604,728	€ (21,490,475)	€ 15,151,309

The accompanying notes are an integral part of these financial statements.

Genenta Science S.r.l.
Statements of Cash Flows

	Year-Ended December 31,	
	2020	2019
	(in Euros)	
Cash flows from operating activities		
Net loss	€ (5,592,014)	€ (4,597,723)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,900	-
Retirement benefit obligation	6,056	4,867
Share-based compensation	460,194	749,512
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(454,082)	151,091
Other non-current assets	(200,287)	(588,681)
Accounts payable	265,289	190,088
Accounts payable - related party	(282,714)	(217,670)
Accrued expenses	38,263	133,797
Accrued expenses - related party	(292,429)	1,666,295
Other current liabilities	5,243	18,237
Net cash used in operating activities	(6,044,581)	(2,490,187)
Cash flows from investing activities		
Purchases of property and equipment	(20,871)	-
Net cash used in investing activities	(20,871)	-
Cash flows from financing activities		
Proceeds from the issuance of quotas	1,500,436	15,086,708
Issuance costs	(68,120)	(318,506)
Prepaid offering costs	(43,000)	-
Net cash provided by financing activities	1,389,316	14,768,202
Net (decrease) increase in cash and cash equivalents	(4,676,136)	12,278,015
Cash and cash equivalents at beginning of year	20,141,379	7,863,364
Cash and cash equivalents at end of year	€ 15,465,243	€ 20,141,379
Non-cash financing activities: deferred offering costs accrued at year end	€ 113,733	€ -

The accompanying notes are an integral part of these financial statements.

1. Nature of business

Genenta Science S.r.l. (the "Company") is an early-stage company developing potential ground-breaking cell and gene cancer therapies. The Company is initially developing its clinical leading product, Temferon, to treat glioblastoma multiforme ("GBM"), a solid tumor affecting the brain. The Company intends to start a second clinical trial to study Temferon in liver cancers and is planning to expand its clinical trial on GBM indications in the United States.

Genenta Science S.r.l. is an Italian limited liability company (società a responsabilità limitata, or S.r.l.), which is similar to a limited liability company in the United States. The Company was founded by San Raffaele Hospital ("OSR"), in Milan, Italy, Pierluigi Paracchi, Luigi Naldini and Bernhard Gentner and was incorporated in July 2014. The Company is organized under the laws of Italy, with registered office in Milan. The corporate capital of an S.r.l. is called a "quota." A quota is a varying ownership or portion of subscribed capital in the S.r.l. Each quota has specific rights and value. (See Note 10. Quotaholders' Equity.) The Company's reporting currency is Euros.

The Company is subject to risks and uncertainties common to early-stage clinical companies in the life-science and biotechnology industries, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new competing products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. The clinical product candidates currently under development will require significant additional research and development efforts, including regulatory approval and clinical testing prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Liquidity and Risks

The Company has incurred recurring losses since its inception, including a net loss of €5,592,014 and €4,597,723 for the years ended December 31, 2020 and 2019. In addition, as of December 31, 2020, the Company had an accumulated deficit of €21,490,475. The Company has primarily funded these losses through the proceeds from sales of convertible debt and quotas. Although the Company has incurred recurring losses and expects to continue to incur losses for the foreseeable future, the Company expects that its existing cash and cash equivalents on hand as of December 31, 2020 of €15,465,243 will be more than sufficient to fund current planned operations and capital expenditure requirements for at least the next twelve months from the filing date of these financial statements. However, the future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company has evaluated whether there are conditions and events considered in the aggregate that raise substantial doubt about the Company's ability to continue as a going concern. The Company's business model, typical of biotechnology companies developing new therapeutic products that have not reached a balanced income and financial position, features negative cash flows. This is due to the fact that, at this stage, costs must be borne in relation to services and personnel, directly connected to research and development activities, and return for these activities is not certain and, in any case, it is expected in future years. Based on the accounting policies adopted, requiring full recognition of research and development costs in the statement of operations and comprehensive loss in the year they are incurred, the Company has reported a loss since its inception, and expects to continue to incur significant costs for research and development in the foreseeable future. There is no certainty that the Company will become profitable in the future.

The Company has primarily funded its operations with proceeds from several capital increases and at March 31, 2021, had approximately €13.1 million of cash and cash equivalents. Therefore, management and the Board of Directors believe that the Company has adequate financial resources to support business operations in the foreseeable future and for at least 12 months from the date of this report. Accordingly, the accompanying financial statements have been prepared assuming that the Company will continue as a going concern.

The Company will require additional capital to meet its long-term operating requirements. It expects to raise additional capital through, among other things, the sale of equity or debt securities. If adequate funds are not available in the future, the Company may be forced to delay, reorganize, or cancel research and development programs, or to enter into financing, licensing or collaboration agreements with unfavorable conditions or waive rights to certain products which otherwise it would not have waived, resulting in negative effects on the activity and on the economic, patrimonial and /or financial situation of the Company.

In February 2020, the COVID-19 pandemic commenced in Italy. Regulatory guidance was issued in March and updated in April 2020 relating to the management of clinical trials during the pandemic. As the global healthcare community continues to respond to the COVID-19 pandemic, many hospitals, including the Company's clinical sites, temporarily paused elective medical procedures, including dosing of new patients in clinical trials of our investigational gene therapies. While dosing of new patients and data collection from enrolled patients has resumed at clinical sites, the extent to which clinical activities continue to be delayed or interrupted will depend on future developments that are highly uncertain. The Company has not experienced significant interruptions related to COVID-19, although one patient tested positive for COVID-19 and had to delay treatment with Temferon™. The Company may find it difficult to enroll patients in its clinical trials, which could delay or prevent the Company from proceeding with clinical trials of its product candidates. The Company continues to closely monitor this rapidly evolving situation and the potential impact on the Company.

Basis of presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"), unless otherwise stated.

A summary of the significant accounting policies applied in the preparation of these financial statements is presented below, only for the categories and headings now applicable and that might be applicable in the future based on the Company's business. These policies have been consistently applied, unless otherwise stated.

2. Summary of significant accounting policies

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts reported in the financial statements and the disclosures made in the accompanying notes. Estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual for research and development expenses and related milestone payments, share-based compensation expense, valuation of Research & Development (R&D) tax credits, the valuation of equity and the recoverability of the Company's net deferred tax assets and related valuation allowance. Estimates are periodically reviewed considering changes in circumstances, facts and experience. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are recorded in the period in which they become known. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements are disclosed below.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. In the cash flow statement cash and cash equivalents includes cash on hand, deposits held with banks, and other short-term highly liquid investments. In the balance sheet, bank overdrafts, if any, are shown in current liabilities. Cash and cash equivalents are detailed as follows:

	At December 31,	
	2020	2019
	(in Euros)	
Cash in bank	€ 15,462,805	€ 20,137,033
Cash in hand & prepaid cards	2,438	4,346
Total	€ 15,465,243	€ 20,141,379

Net loss per share

Net loss per share ("EPS") is computed in accordance with U.S. GAAP. Basic EPS is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted EPS reflects potential dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period increased by the number of additional common shares that would have been outstanding if all potential common shares had been issued and were dilutive. Historical EPS or QPS (quota per share) has not been included in these financial statements because the Company has determined it is not a meaningful or material disclosure due to the Company's current capital structure.

Unaudited pro forma net loss per share

Pro forma net loss per share has not been presented at December 31, 2020 and 2019. Pro forma basic and diluted net loss per share will be computed by dividing pro forma net loss by the weighted average number of common shares outstanding when the Company transitions to an S.p.A. in 2021 and the information presented is meaningful to a user of the financial statements. The Company has reported net losses since inception, the potential impact of outstanding options being exercised would be anti-dilutive, and therefore basic and diluted loss per share would be the same when presented.

Foreign currency translation

The reporting and functional currency of the Company is Euros. All amounts are presented in Euros unless otherwise stated. All amounts disclosed in the financial statements and notes have been rounded to the nearest Euro unless otherwise stated. Foreign currency transactions, if any, are translated into Euros using the exchange rates prevailing at the dates of the transactions or valuation where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the statement of operations. During the years ended December 31, 2020 and 2019, foreign exchange gains and losses were insignificant.

Emerging growth company status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company may take advantage of these exemptions until the Company is no longer an "emerging growth company." Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of its initial public offering ("IPO") or such earlier time that it is no longer an "emerging growth company."

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying values of the Company's research and development tax credits, VAT credits, accounts payable, accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

Segment information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company and its chief operating decision-maker view the Company's operations and manages its business in one operating segment, which is the research and development in the pharmaceutical sector with a focus on developing novel therapeutics to treat cancer.

Tax credit on investments in research and development

In line with the legislation in force until December 31, 2020, companies in Italy that invest in eligible research and development activities, regardless of the legal form and economic sector in which they operate, can benefit from a tax credit which can be used in order to reduce most taxes payable, including income tax or regional tax on productive activities, as well as of social security contributions and withholding taxes. The tax credit calculation methodology changed in 2020, and the credit was determined as 12% of eligible expenses up to €3.0 million. Up until December 31, 2019, the tax credit was up to 50% of the increase of annual research and development expenses compared to the median expense for the years 2012-2014.

The eligible activities consist of fundamental research, industrial research, and experimental development as defined respectively of the letters m), q) and j) of point 15, par. 1.3 of the Communication no. 198/2014 of the European Commission.

To determine the cost basis of the benefit, the following expenses are eligible:

- Personnel costs.
- Depreciation charges, costs of the financial or simple lease and other expenses related to movable tangible assets and software used in research and development projects.
- Expenses for extra-euro research contracts concerning the direct execution of eligible research and development activities by the provider.
- Depreciation charges related to industrial privatives.
- Expenses for consultancy services and equivalent services related to research and development eligible activities.
- Expenses for materials, supplies, and other similar products used in the research and development projects.

The Company accounts for this receivable in accordance with International Accounting Standards (IAS) 20, *Accounting for Government Grants and Disclosure of Government Assistance*. The receivable is recognized when there is reasonable assurance that: (1) the recipient will comply with the relevant conditions and (2) the grant will be received. The Company elected to present it net of the related expenditure on the statement of operations and comprehensive loss.

While these tax credits can be carried forward indefinitely, the Company recognized an amount which reflects management's best estimate of the amount that is reasonably assured to be realized or utilized in the foreseeable future based on historical benefits realized, adjusted for expected changes, as applicable. The tax credits are recorded as an offset to research and development expenses in the Company's statement of operations and comprehensive loss.

Share-based compensation

To reward the efforts of employees, directors, and certain consultants to promote the growth of the Company, the Company's Board of Directors has approved, during its existence, various share-based awards. All options have been awarded with an exercise price of €1 per quota and, when exercised, all options have been converted to Quota B. The options granted have the vesting condition that the individual must remain in his/her role at least one year or as otherwise specified for each person.

The Company measures share-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is the vesting period of the respective award. Forfeitures are accounted for as they occur. The measurement date for option awards is the date of the grant. The Company classifies share-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

With the adoption of Accounting Standards Update ("ASU") No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07") on January 1, 2019, the measurement date for non-employee awards is the date of the grant. The compensation expense for non-employees is recognized, without changes in the fair value of the award, over the requisite service period, which is the vesting period of the respective award.

Property and equipment

Property and equipment are stated at cost, including any accessory and direct costs that are necessary to make the assets fit for use, and adjusted by the corresponding accumulated depreciation. The depreciation recorded in the financial statements of operations has been calculated on a straight line basis by taking into consideration the use, purpose and financial-technical duration of the assets, on the basis of their estimated useful economic lives. The Company believes the above criteria to be represented by the following estimated useful lives:

- Equipment & Furniture: 15 years

- Electronic office equipment: 10 years

- Leasehold improvements: based on the length of the lease

Ordinary maintenance costs are entirely attributed to the statements of operations in the year in which they are incurred. Extraordinary maintenance costs, the purpose of which is to extend the useful economic life of the asset, to technologically upgrade it and/or to increase its productivity or safety for the purposes of the economic productivity of the Company, are attributed to the asset to which they refer and depreciated on the basis of its estimated useful economic life. Amortization of leasehold improvements is computed using the straight-line method based upon the terms of the applicable lease or estimated useful life of the improvements, whichever is less.

Impairment of long-lived assets

In accordance with ASC Topic 360-10-20, ‘‘Property, Plant and Equipment,’’ the Company performs an impairment test whenever events or circumstances indicate that the carrying value of long-lived assets with finite lives may be impaired. Impairment is measured by comparing the carrying value of the long-lived assets to the estimated undiscounted pre-tax cash flows expected to result from the use of such assets and their ultimate disposition. In circumstances where impairment is determined to exist, the Company will write down the asset to its fair value based on the present value of estimated cash flows. To date, no impairments have been identified by management for the years ended December 31, 2020 and 2019.

Deferred Offering Costs

Deferred public offering costs, which primarily consist of direct, incremental legal and accounting fees relating to the initial public offering (IPO), are capitalized within prepaid expenses and other current assets. The deferred offering costs will be offset against IPO proceeds upon the consummation of the offering. In the event the offering is terminated, deferred offering costs will be expensed. The Company has incurred €156,000 in IPO offering costs as of December 31, 2020.

Recently issued accounting pronouncements

In December 2019, the FASB issued ASU 2019-12, Income Taxes: Simplifying the Accounting for Income Taxes. The new standard intended to simplify the accounting for income taxes by eliminating certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. For non-public entities, the standard is effective for annual periods beginning after December 15, 2021, with early adoption permitted. Adoption of the standard requires certain changes to primarily be made prospectively, with some changes to be made retrospectively. The Company is currently evaluating the impact that the adoption of ASU 2019-12 will have on its financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (‘‘ASU 2017-11’’). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of non-public entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For non-public entities, ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company does not expect the adoption of ASU 2017-11 to have a significant impact on its financial position, results of operations, or cash flows.

In August 2018, the FASB issued No. ASU 2018-13, Fair Value Measurement (Topic 820)—Disclosure Framework (‘‘ASU 2018-13’’), which improves the disclosure requirements for fair value measurements. For non-public entities, ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the impact that the adoption of ASU 2018-13 will have on its financial statements. The FASB issued authoritative guidance that amends guidance on reporting credit losses for financial assets, including available-for-sale marketable securities and any other financial assets not excluded from the scope that result in a contractual right to receive cash. For available-for-sale marketable securities, credit losses should be measured in a manner similar to current generally accepted accounting standards; however, ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, will require that credit losses be presented as an allowance rather than as a write-down. For non-public entities, the standard is effective for annual periods beginning after December 15, 2022, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-13 will have on its financial statements.

3. Research and development

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, facilities costs, third-party license fees, certain milestone payments, and external costs of outside vendors and consultants engaged to conduct clinical development activities and clinical trials, (e.g., contract research organizations or "CROs"), as well as costs to develop a manufacturing processes, perform analytical testing and manufacture clinical trial materials, (e.g., contract manufacturing organizations or "CMOs"). Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered. In addition, funding from research grants, if any, is recognized as an offset to research and development expense based on costs incurred on the research program.

The Company yearly sustains a significant amount of research costs to meet its business objectives. The Company has various research and development contracts, and the related costs are recorded as research and development expenses as incurred. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations as of period end to those third parties. Any accrual estimates are based on several factors, including the Company's knowledge of the progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs. (For further details please refer to the Related Parties disclosure in Note 12 below.)

4. General and administrative

General and administrative costs consist primarily of salaries, share-based compensation, benefits and other related costs for personnel and consultants in the Company's executive and finance functions, professional fees for legal, finance, accounting, auditing, tax and consulting services, travel expenses and facility-related expenses, which include rent and maintenance of facilities and other operating costs not otherwise included in research and development expense.

5. Income taxes

The Company is subject to taxation in Italy, including the standard corporate income tax ("IRES") and a regional business tax ("IRAP"). Taxes are recorded on an accrual basis. They therefore represent the allowances for taxes paid or to be paid for the year, calculated according to the current enacted rates and applicable laws. Due to the tax loss position reported, no income taxes were due for the years ending December 31, 2020 and 2019. The Company is taxed in various countries where it has permanent establishment, as applicable.

The Company uses the asset and liability method of accounting for deferred income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities, measured at tax rates expected to be enacted at the time of their reversals. These temporary differences primarily relate to net operating losses carried forward available to offset future taxable income.

As of each reporting date, the Company considers existing evidence, both positive and negative, that could impact its view with regards to future realization of deferred tax assets. In consideration of the start-up status of the Company, a full valuation allowance has been established to offset the deferred tax assets, as the related realization is currently uncertain. In the future, should management conclude that it is more likely than not that the deferred tax assets are partially or fully realizable, the valuation allowance will be reduced to the extent of such expected realization, and the corresponding amount will be recognized as income tax benefit in the Company's statement of operations and comprehensive loss.

The Company recognizes tax liabilities from an uncertain tax position if it is more likely than not that the tax position will not be sustained upon examination by the taxing authorities, based on the technical merits of the tax position. There are no uncertain tax positions that have been recognized in the accompanying financial statements. The prior five (5) years' tax returns are potentially subject to audit.

A reconciliation of the Company's effective tax rate is summarized as follows:

	At December 31,	
	2020	2019
	(in Euros)	
Income taxes at Italy statutory rate	€ (1,342,083)	€ (1,103,454)
Permanent differences	3,750	11,370
Change in valuation allowance	1,338,333	1,092,084
Total provision expense for income taxes	€ -	€ -

Significant components of the Company's net deferred tax assets are summarized as follows:

	At December 31,	
	2020	2019
	(in Euros)	
Deferred tax assets		
Net operating loss carryforwards	€ 4,692,844	€ 3,192,643
Other temporary differences	-	144,000
Allowance for corporate equity	210,620	178,972
Total deferred tax assets	4,903,464	3,515,615
Valuation allowance	(4,903,464)	(3,515,615)
Net deferred tax assets	€ -	€ -

Tax loss carryforwards expire as follows:

	At December 31,	
	2020	2019
	(in Euros)	
No expiration date	€ 5,487,085	€ 5,487,085
No expiration date - DL 98/2011	14,066,434	7,815,593
Total	€ 19,553,519	€ 13,302,678

In 2011, the Italian tax authorities issued a set of rules that modified the previous treatment of tax loss carryforwards. According to the DL 98/2011, at the end of 2011, all existing tax loss carryforwards will never expire but they can off-set only 80% of the taxable income of the year. The rules do not affect the tax loss carryforwards that refer to the start-up period, defined as the first three (3) years of operations starting from the inception of the Company.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	At December 31,	
	2020	2019
	(in Euros)	
Value Added Tax (VAT)	€ 480,000	€ 237,569
Research and Development Tax Credit	280,631	192,020
Deferred offering costs	156,261	-
Advances to suppliers – related party	121,432	-
Other	30,609	28,529
Total	€ 1,068,933	€ 458,118

Value Added Tax (VAT) receivables are linked to purchases. Italian VAT (*Imposta sul Valore Aggiunto*) applies to the supply of goods and services carried out in Italy by entrepreneurs, professionals, or artists and on imports carried out by anyone. Intra-Community acquisitions are also subject to VAT under certain situations. The Italian standard VAT rate for 2020 and 2019 is 22%. Reduced rates are provided for specifically listed supplies of goods and services. It is carried forward indefinitely and does not expire. The Company reclassified to other non-current assets a portion of the receivable which is expected to be realized beyond 12 months.

Tax credits on research and development represent a special tax relief offered to Italian companies operating in the research and development sector and can be used to offset most taxes payable. Tax credits on research and development available were €3.9 million at December 31, 2020 and €3.5 million at December 31, 2019, which can be carried forward indefinitely and does not expire. However, given the start-up status of the Company and the fact that it will not be profitable in the foreseeable future which limits the utilization of the credit, the Company recognized a receivable balance at December 31, 2020, that represents the Company's best estimate of the amount of tax credit that can be used in offsetting taxes payable for 2021 and 2022, which represents the current projected available cash to support operations. In 2019, the limitation on the Company's tax credit was based on three years of cash available to support operations. In 2020 and 2019, the Company utilized €280,631 and €192,020 to offset certain taxes payable. The benefit recorded in 2020 and 2019 to offset research and development expenses was €265,834 and €448,079, respectively. The Company reclassified to other non-current assets a portion of the receivable which is expected to be realized beyond 12 months.

The remaining balance is comprised of miscellaneous minor prepaid expenses and deferred offering costs.

7. Property and equipment, net

Property and equipment consist of the following:

	At December 31,	
	2020	2019
	(in Euros)	
Computer	€ 16,196	€ -
Furniture and fixtures	4,675	-
Total property and equipment	20,871	-
Less: accumulated depreciation	(1,900)	-
Property and equipment, net	€ 18,971	€ -

Property and equipment consist of computers and furniture and fixtures of our office space in Milan. No disposals, nor impairments occurred during the periods. Depreciation has been calculated by taking into consideration the use, purpose, and financial-technical duration of the assets, based on their estimated economic lives. Property and equipment were entirely purchased in 2020.

Depreciation expense for the year ended December 31, 2020 was €1,900. There was no depreciation expense for the year ended December 31, 2019.

8. Other non-current assets

Other non-current assets consist of the long-term portion of the VAT receivable and R&D tax credit, as follows:

	At December 31,	
	2020	2019
	(in Euros)	
Value Added Tax (VAT)	€ 664,987	€ 364,641
Research and Development Tax Credit	280,631	384,040
Total	€ 945,618	€ 748,681

9. Retirement benefit obligation

Employees in Italy are entitled to Trattamento di Fine Rapporto (“TFR”), commonly referred to as an employee leaving indemnity, which represents deferred compensation for employees in the private sector. Under Italian law, an entity is obligated to accrue for TFR on an individual employee basis payable to each individual upon termination of employment (including both voluntary and involuntary dismissal). The annual accrual is approximately 7% of total pay, with no ceiling, and is revalued each year by applying a pre-established rate of return of 1.50%, plus 75% of the Consumer Price Index, and is recorded by a book reserve. TFR is an unfunded plan. The costs of the retirement benefit obligation is accounted for under the provisions of ASC 715, *Compensation – Retirement Benefits*. The amount of the obligation at December 31, 2020 and 2019 was €17,388 and €11,332, respectively.

10. Quotaholders’ equity

The Company is an S.r.l., which is an Italian limited liability company similar to a limited liability company in the United States. The Articles of Incorporation, Shareholders’ Agreement and the By-laws of the Company provide for different quotas, which represent the Company’s corporate capital, rather than shares of stock as ownership.

Corporate capital

As an S.r.l., the Company's ownership is called "corporate capital" and "quotas" rather than shares, stock or units.

The Company's capital is divided between the five quotas as summarized below at December 31, 2020 and 2019:

Quota	At December 31, 2019	Ownership %	At December 31, 2020	Ownership %
A	€ 10,458	29%	€ 10,458	28%
B	6,450	18%	6,886	19%
C	8,645	24%	8,645	23%
D	4,034	11%	4,034	11%
E	6,462	18%	7,033	19%
Total	**€ 36,049**	**100%**	**€ 37,056**	**100%**

The Company's corporate capital at January 1, 2019 was €29,179, consisting of quota A from founders, options converted to quota B, and quotas C & D from investment capital. Additional capital was raised in 2019 by the sale of quota E, along with options converted to quota B, so corporate capital at December 31, 2019 was €36,049. Additional capital was raised in 2020 by the sale of quota E, so corporate capital at December 31, 2020 was €37,056.

The Company currently has five (5) quotas:

- Quota A. Quota A was reserved for certain founders. One of the founders has the right to appoint three (3) board members out of five (5), appoint the Chair from these three (3) persons and appoint one (1) member of the Board of Statutory Auditors. One other founder has the right to appoint two (2) board members out of five (5), appoint two (2) statutory auditors and appoint the Chair of the statutory auditors from the two (2) appointees. Quota A has voting rights.

- Quota B. Quota B has no voting rights, the same profit-sharing rights as Quota A and is priced at a nominal amount of €1.00. The Company has historically utilized Quota B for its share-based compensation program offered to board members, employees, and consultants. Quota B is also held by certain co-founders. The Company's stock options are exercisable into Quota B for past and present board members, employees, and consultants.

- Quota C. Quota C has the right to appoint one (1) member of the Board of Statutory Auditors; specifically, the one (1) that a founder had the right to appoint. Investors received Quota C in the Company's first funding round (2014/2015) where approximately €10 million was raised.

- Quota D. Investors received Quota D in the Company's second funding round (2017) where approximately €7 million was raised.

- Quota E. Investors received Quota E in the Company's third funding round (through December 31, 2019) where approximately €14.8 million was raised approximately (€15.1 million gross, net of approximately €0.3 million of financing fees). Investors received Quota E in the Company's second tranche of the third funding round (through December 31, 2020) where approximately €1.4 million was raised (approximately €1.5 million gross, net of approximately €0.1 million of financing fees).

- Quotas A, C, D & E. During a divestiture proceeding (meaning Quotas representing 100% of the corporate capital of the Company) or a dissolution of the Company, Quotas C, D & E all have the same rights with respect to the proceeds of a divestiture, i.e., all three (3) quotas share the divestiture consideration equally (on a *pari passu* basis) up to the amount of their investment. If there is any consideration remaining after payment to quotas C, D & E, then quota A shall be entitled to the amount remaining up to the amount of their investment. If proceeds of a divestiture are less than or equal to €50 million, then any proceeds remaining after payment of quotas A, C, D & E, shall be shared equally among quotas A, C, D & E; however, if proceeds of a divestiture are greater than €50 million, then any proceeds remaining after payment of quotas A, C, D & E, shall be distributed to each quota separately according to a detailed formula specified in the Company's By-Laws, including quota B. Similar to a divestiture, net profits, if any, shall be distributed in the same manner to quotas A, B, C, D & E, after deducting not less than five (5) percent for a legal reserve (up to where this reserve equals one-fifth of the quota capital). A, C, D, E have equal voting rights and the Company By-laws specify protective provisions for each class of quota for A, C, D & E.

11. Share-based compensation

The Company has granted options on its corporate capital to certain directors, officers, employees, and consultants, as an incentive and as additional compensation. All options convert into Quota B when vested and exercised. All options have an exercise price of €1.00 per quota. Options generally vest over a one-to-three-year period and are exercised when vested. All options expire on December 31, 2021, if not exercised. The Board of Directors approves any options granted and has authorized and granted 4,835 options to date. At December 31, 2019, there were no options available for grant, as all remaining authorized options were granted in 2019; therefore, no options were granted in 2020.

The Company's quota option activity for the years ended December 31, 2020 and 2019 is represented by the following:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
		(in €'s)		*(in €'s)*
Outstanding, vested and expected to vest as of December 31, 2019	982	1.00	2.00	1,056,316
Granted	-	-	-	-
Vested and exercised	436	1.00	1.00	472,184
Cancelled or forfeited	-	-	-	-
Outstanding, vested and expected to vest as of December 31, 2020	546	1.00	1.00	584,132
Exercisable as of December 31, 2020	-	-	-	-

The Company's share-based compensation expense for the years ended December 31, 2020 and 2019 is represented by the following table:

	Year ended December 31,	
	2020	**2019**
Research & development expense	€ -	€ 21,804
Research & development expense - related party	326,400	581,949
General & administrative expense	133,794	137,057
Total	460,194	740,810
Unrecognized expense at December 31,	€ 313,273	€ 769,779

The Company awarded eight options to a consultant on September 30, 2019 for assistance in raising additional Quota E capital for the Company in 2019. The Company recorded the €8,702, which was the fair value of the option as a charge to additional paid-in capital. The weighted average grant date fair value of the options granted during 2019 was €1,088. The Company's unrecognized expense was €313,273 and €769,779 at December 31, 2020 and 2019, respectively, and will be expensed as the options vest.

Quota B Valuations

The fair value of the Quota B underlying the Company's stock-based compensation grants has historically been determined by the Company's board of directors, with input from management and third-party valuations. The Company believes that the board of directors has the relevant experience and expertise to determine the fair value of its Quota B, when also securing third-party assistance. Given the absence of a public trading market of the Company's equity, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately- Held Company Equity Securities Issued as Compensation, the board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the Company's equity at each grant date. These factors include:

- valuations of the Quota B equity performed by third-party specialists;
- the price of the Company's equity to third-party, arms-length, sophisticated, and qualified investors, which was used in the OPM Backsolve Model;
- the prices, rights, preferences, and privileges of the Company's Quota C, D, and E preferred equity classes relative to those of the Company's equity;
- lack of marketability of the Quota B;
- lack of voting rights of the Quota B;
- current business conditions and projections;
- hiring of key personnel and the experience of management;
- the Company's stage of development;
- the timing, progress and results of the Company's pre-clinical studies and clinical trials for the Company's programs and product candidates; including statements regarding the timing of initiation and completion of trials or studies and related preparatory work, the period during which the results of the trials will become available and the Company's research and development programs;
- likelihood of achieving a liquidity event, such as an initial public offering, a merger or acquisition of the Company given prevailing market conditions, or other liquidation events;
- the market performance of comparable publicly traded companies; and
- the European, U.S. and global capital market conditions.

In valuing the Company's Quota B class of options, the board of directors determined the equity value of the Company's business using various valuation methods. The board of directors engaged a third-party valuation firm who performed analyses in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The Company's option valuations were prepared using an option pricing method ("OPM"), which used market approaches to estimate the Company's enterprise value.

The OPM treats each equity class as a call options on the total equity value of a company, with exercise prices (i.e., breakpoints) based on the value thresholds at which the allocation among the various holders of a company's securities changes. A discount was considered for Lack of Marketability ("DLOM"), which is an amount or percentage that is deducted from the value in order to reflect the absence of a viable market. The DLOM was then applied to arrive at an indication of value for the option. Also, considered in the valuation was volatility and the fact that the Quota B class of equity did not carry voting rights. The expected volatility used in the OPM is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development.

Application of the Company's approach involved the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding the selection of comparable companies, and the expected timing of an initial public offering ("IPO") or other liquidity event. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact the valuations at each valuation date and may have a material impact on the valuation of the Company's Quota B equity class, and consequently, the Company's share-based compensation expense could be materially different.

12. Related parties

The Company's research and development expenses are a combination of third-party expenses and related party expenses, as detailed below:

	For the Year Ended December 31, 2020		
(In Euros)	Third Parties	Related Parties	Total
Consultants & other third parties	€ 1,454,576	€ 2,009,884	€ 3,464,460
Materials & supplies	709,183	3,124	712,307
Compensation (including share-based)	145,700	326,400	472,100
Travel & entertainment	16,742	17,724	34,466
Other	5,128	-	5,128
Total	€ 2,331,329	€ 2,357,132	€ 4,688,461

	For the Year Ended December 31, 2019		
(In Euros)	Third Parties	Related Parties	Total
Consultants & other third parties	€ 74,518	€ 2,036,870	€ 2,111,388
Compensation (including share-based)	171,289	581,949	753,238
Materials & supplies	649,574	-	649,574
Travel & entertainment	97,063	36,510	133,573
Other	55,209	-	55,209
Total	€ 1,047,653	€ 2,655,329	€ 3,702,982

The Company recorded a research and development tax credit in the amount of €265,834 and €448,079 for the years ended December 31, 2020 and 2019, respectively, to offset Consultants and other third parties related research and development expenses.

The Company's general and administrative expenses are also a combination of third-party and related party expenses, as detailed below:

	For the Year Ended December 31, 2020		
(In Euros)	Third Parties	Related Parties	Total
Compensation (including share-based)	€ 191,998	€ 298,628	€ 490,626
Accounting, legal & other professional	239,861	-	239,861
Communication & IT related	64,430	-	64,430
Facility & insurance related	24,685	14,402	39,087
Consultants & other third parties	59,648	1,495	61,143
Other	6,618	-	6,618
Total	€ 587,240	€ 314,525	€ 901,765

	For the Year Ended December 31, 2019		
(In Euros)	Third Parties	Related Parties	Total
Consultants & other third parties	€ 375,201	€ -	€ 375,201
Compensation (including share-based)	171,698	277,849	449,547
Accounting, legal & other professional	40,745	-	40,745
Communication & IT related	14,759	-	14,759
Facility & insurance related	13,630	-	13,630
Other	22,336	5,302	27,638
Total	€ 638,369	€ 283,151	€ 921,520

The Company's accounts payable to related parties are comprised as follows:

	At December 31,	
	2020	2019
	(in Euros)	
San Raffaele Hospital	€ 4,085	€ 283,115
XDG Biomed	5,942	9,626
Total	€ 10,027	€ 292,741

The Company's accrued expenses to related parties are comprised as follows:

	At December 31,	
	2020	2019
	(in Euros)	
San Raffaele Hospital	€ 1,309,191	€ 1,454,430
Pierluigi Paracchi	25,000	50,000
XDG Biomed	25,000	147,190
Total	€ 1,359,191	€ 1,651,620

The Company has identified the following related parties:

- Pierluigi Paracchi (director and co-founder of the Company);
- Luigi Naldini (co-founder of the Company and executive scientific advisory board chairman);
- Carlo Russo (through XDG Biomed LLC- Chief Medical Officer);
- Bernard Rudolph Gentner (co-founder of the Company and member of scientific advisory board); and,
- San Raffaele Hospital (co-founder and main supplier of services).

The following is a description of the nature of the transactions between the Company and these related parties:

Pierluigi Paracchi

He is the President, Chief Executive Officer and the Company's Chairman of the Board of Directors as well as co-founder. In addition to his annual remuneration of €250,000 for the year 2020 and €201,980 for the year 2019, Mr. Paracchi also obtained a funding fee of €185,510 in 2019 for the funding activity of the first financing as approved by the Board of Directors and by quotaholders at the Quotaholders' Meeting. This was recorded in additional paid-in capital as a direct reduction of proceeds. Mr. Paracchi was awarded a bonus of €50,000 by the Board of Directors in July 2020. The bonus was accrued in the 2019 financial statements and paid in July 2020. At December 31, 2020, the Company also accrued a bonus of €25,000 for the period July to December 2020: as per his Directorship agreement, Mr. Paracchi is entitled to receive a bonus of up to €50,000 to be approved by the Board of Directors each year to cover the period August 1st to July 31st of each year.

Luigi Naldini/Bernard Rudolph Gentner

They are co-founders of Genenta and part of the SAB – Scientific Advisory Board, with Dr. Naldini as Chairman, and Dr. Gentner as a member. Dr. Naldini has an advisory agreement approved by the Board of Directors and performs the pre-clinical studies for Genenta. In particular, the pre-clinical experiments are in solid tumor indications. The last agreement with Dr. Naldini is still in effect and was signed on December 12, 2019. In 2020 and 2019, Dr. Naldini's compensation amounted to €56,250 and €55,500, respectively. Dr. Gentner, like Dr. Naldini, oversees pre-clinical research related to the platform technology. In addition, he analyzes clinical biological data. The last agreement with Dr. Gentner, which is still in force, was signed on October 26, 2017. In 2020 and 2019, Dr. Gentner's compensation was €18,750 and €44,350, respectively.

XDG Biomed LLC

This is the LLC of Dr. Carlo Russo. Dr. Russo has a single contract signed by XDG and the Company that has been approved by the Board of Directors and was subject to multiple amendments. In particular, Dr. Russo, via XDG, serves as the Company's Chief Medical Officer and Head of Development. Dr. Russo is responsible for the clinical development of Temferon™, the Company's gene therapy platform. The applicable recurring fees are €300,000 per year effective from August 1, 2019, (€200,000 prior to that date) plus a variable compensation of €50,000 based on the results obtained and depending on the Company's Board of Directors approval. In 2020, the Company incurred €342,872. The Company accrued €25,000 for a potential bonus relating to the period of July to December 2020. The amounts owed at December 31, 2020 and 2019 are €30,942 and €156,816, respectively. In 2019, the Company granted options on 1,000 class B quotas to Dr. Russo, of which 400 were exercised and converted to class B quotas in 2019 and 300 were exercised and converted to class B quotas in 2020; the remaining 300 are outstanding and will vest by the earlier of July 31, 2021 or the effectiveness of the Company's registration statement. The fair value of the options based on the Company's valuation was €1,084 per quota B. There were no options granted in 2020.

San Raffaele Hospital - OSR

San Raffaele Hospital ("OSR") is a co-founder of the Company and the Company is a corporate and research spin-off of OSR. OSR owns approximately 13% of the Company, as of December 31, 2020. The Hospital is one of the leading biomedical research institutions in Italy and Europe, with a 45-year history of developing innovative therapies and procedures. The Company has several contractual arrangements with OSR. The Company has agreements to license technology, to perform research, pre-clinical and clinical activities, as well as to lease facilities and obtain certain other support functions. The Company's headquarters is currently in an OSR facility.

License Agreement

The Company has a License Agreement with OSR entered in December 2014, for the exclusive use of different patents. In particular, OSR granted the Company an exclusive, world-wide, royalty bearing license under certain technology to conduct research and develop, make, use, import, and sell licensed products. The License Agreement covers patents and patent applications, as well as proprietary technologies. The Company's rights to use these patents and patent applications and to utilize the inventions claimed in these licensed patents are subject to the continuation of, and the Company's compliance with, the terms of the License Agreement.

Based on the preclinical studies carried out by OSR, in particular by its SR-TIGET Institute (San Raffaele Telethon Institute for Gene Therapy), on a specific gene therapy strategy with respect to lympho-hematopoietic indication and/or solid cancer indication, the Company decided to develop a new therapy to treat cancer through a cell and gene therapy strategy. The "Field of Use" as defined in the License Agreement is:

a) Lympho-Hematopoietic Indication; and,
b) Solid Cancer Indication.

The agreement provided for an upfront fee of €250,000 (which was paid by the Company in 2015), plus future option fees are as follows:

- option fee on the first indication = €1.0 million (subsequently reduced to €0.5 million);
- option fee on the second indication = €0.5 million;
- option fee on the third indication = €0.3 million; and,
- option fee on any additional indications = no license fee.

In addition, the Company would be obligated make payments on milestones depending on the Field of Use (as defined in the agreement) and pay royalties of 4% of net sales of each Licensed Product (as defined in the agreement). For information relating to the contingent milestones for these indications, please refer to Note 13 - Commitments and Contingencies.

In February 2019, the Company and OSR entered into Amendment #2 of the License Agreement to conduct a clinical trial according to the protocol TEM-GBM_001 and EudraCT 2018-001404-11 entitled: "A phase I/IIa dose escalation study evaluating the safety and efficacy of autologous CD34+ enriched hematopoietic progenitor cells genetically modified with a lentiviral vector encoding for the human interferon-α2 in patients with glioblastoma multiforme who have an unmethylated O-6-methylguanine-DNA methyltransferase gene promoter." In Amendment #2, the Company and OSR also revised the license fee requirement for the first Solid Cancer indication (GBM). In relation to the GBM trial, the Company and OSR agreed that the Company would be obligated to pay OSR the €1.0 million Option Fee only in the event that the Company was able to dose its tenth patient. Under this Amendment, the Company is also obligated to pay for the costs of the study-related procedures performed on the patients recruited in the trial, according to periodic study reports delivered by OSR. The first GBM patient was recruited in April 2019 and related clinical activity costs were recorded by the Company in the amount of €1,145,202 in 2019. In 2020, the comparable costs incurred and expensed for the glioblastoma program were €989,556.

In December 2020, the Company and OSR entered into Amendment #3 of the License Agreement. The initial €1.0 million license fee for the first indication (i.e., GBM) would have become due when the tenth patient was dosed in the GBM trial; however, the license fee was reduced to €0.5 million, in exchange for the Company's agreement to exercise a second option for an additional Solid Cancer indication (i.e., liver cancer) and an agreement to execute a Sponsored Research Agreement in February 2021. If the Company is not be able to obtain approval from the competent authorities to initiate a human clinical trial in liver cancer on or before the expiration of nine months (from December 2020), the Company has the right, at no additional costs, to convert the second solid cancer indication (i.e., liver cancer) to an "Alternate Indication," as defined in the agreement (i.e., to an indication other than liver cancer.)

In summary, Amendment #3 to the license agreement amended the existing agreement as follows:

- reduction of option fee on the first solid cancer indication = €0.5 million (accrued at December 31, 2019, since it was considered probable and paid in December 2020); plus,
- commitment to enter into a Sponsored Research Agreement, which was executed in February 2021; and,
- exercise of option fee on the second indication = €0.5 million (accrued at December 31, 2020, to be paid by June 30, 2021.

The Company has paid €0.75 million to OSR, since inception under the license agreement. No events have occurred or have been achieved (and none are considered probable) to trigger any contingent payments under the license agreement as of December 31, 2020. For information relating to the contingency payments or future milestones for these indications, please refer to Note 13 - Commitments and Contingencies.

OSR may terminate the Company's rights as to certain fields of use for the Company's failure to develop (a) with respect to a solid cancer indication, upon third anniversary of the date the Company exercised such option, if the Company has not filed an IND with respect to such optioned solid cancer indication specifically, as to GBM, the Company is required to file an IND regarding Temferon for GBM prior to February 2022, or (b) with respect to a lympho-hematopoietic indication, on the earlier of (i) the fifth anniversary of the initiation (first patient dosed) of the first human clinical trial for a licensed product in any lympho hematopoietic indication or solid cancer indication if a patient has not been dosed with a licensed product in a Phase 3 clinical trial and (ii) September 1, 2025.

Research Funding Agreement

In March 2019, the Company and OSR entered into a Research Funding Agreement to conduct a clinical trial according to the multiple myeloma protocol, TEM-MM-101 and EudraCT 2018-001741-14, entitled "A Phase I/II dose escalation study evaluating safety and activity of autologous CD34+ enriched hematopoietic progenitor cells genetically modified with a lentiviral vector encoding for the human interferon-α2 in multiple myeloma patients with early relapse after intensive front-line therapy." This agreement required OSR to perform certain clinical procedures and exploratory analyses on the study population, as per the protocol approved by the relevant competent authorities. The Company was required to fund the costs of the study-related procedures performed on patients recruited in the Trial, according to periodic study reports delivered by OSR. The first TEM-MM-101 trial patient was enrolled in August 2019, after the approval received from national competent authorities.

In 2019, the Company expensed €130,589 for the analysis performed by OSR for multiple myeloma and €364,042 for the clinical procedures performed by OSR's Hematology and Bone Transplant Unit for multiple myeloma. For the multiple myeloma program, the Company recorded expenses in 2020 of €104,626; however, the discussion to discontinue the program began in late 2020. The final decision to discontinue the program was reached in early 2021, mainly due to the small number of eligible patients, the increasing competitive landscape, and the faster progress and promising result on the concurrent solid tumor glioblastoma trial (TEM-GBM_001). No product indication was exercised, and no milestones were achieved related to the multiple myeloma indication, and so no option fee or contingent payments were due to OSR for this indication.

Sponsor Research Agreement (SRA)

As stated above, in exchange for a reduction in the first solid cancer indication (i.e., GBM) option fee from €1.0 million to €0.5 million, the Company agreed to enter into a Sponsored Research Agreement (SRA) in December 2020. Under the SRA, which was executed in February 2021, two sponsored research activities will be conducted for between €0.5 million and €1.0 million. The first SRA payment was made in early 2021 in the amount of €250,000.

Service Agreement

A service agreement to provide certain services (accounting/bookkeeping and rent of spaces, the latter with an addendum effective from January 1, 2016) free of charge was in place between the Company and OSR from 2014 to 2019. Beginning in January 2020, a third-party provider was engaged by the Company to perform these services. The Company determined the value of these services that were provided in 2019 and in prior years were not material to its financial statements.

Beginning January 1, 2020, the Company entered into a six-year lease agreement for the use of office space in the OSR building. The Company paid OSR annual rent of €13,400 in 2020 with a security deposit of €3,350.

13. Commitments and contingencies

The Company exercises considerable judgment in determining the exposure to risks and recognizing provisions or providing disclosure for contingent liabilities related to pending litigations or other outstanding claims and liabilities. Judgment is necessary in assessing the likelihood that a pending claim will succeed, or a liability will arise and to quantify the possible range of the final settlement. Provisions are recorded for liabilities when losses are considered probable and can be reasonably estimated. Because of the inherent uncertainties in making such judgments, actual losses may be different from the originally estimated provision. Estimates are subject to change as new information becomes available, primarily with the support of internal specialists or outside consultants, such as actuaries or legal counsel. Adjustments to provisions may significantly affect future operating results.

The following table summarizes our obligations by contractual maturity for years following December 31, 2020:

	Payments by period				
(in Euros)	Total	Less than a year	1 to 3 years	4 to 5 years	More than 5 years
Sponsored research agreement (SRA) with OSR	€ 1,000,000	€ 500,000	€ 500,000	€ -	€ -
License option fee for liver cancer (or second cancer indication)	500,000	500,000	-	-	-
Operating leases	80,400	13,400	26,800	26,800	13,400
Total	€ 1,580,400	€ 1,013,400	€ 526,800	€ 26,800	€ 13,400

The above amounts include an option fee for the second cancer indication payable to OSR. Refer to the Related parties - Note 12 for further information.

The Company entered into certain license agreements under which it is obligated to pay option license fees and to make contingent milestone payments. The Company has not included future milestone and royalty payments in the table above because the payment obligations under these agreements are contingent upon future events, such as the Company's achievement of specified milestones or generating product sales, and the amount, timing and likelihood of such payments are unknown and are not yet considered probable.

The Company enters into contracts in the normal course of business with CMOs, CROs and other third parties for exploratory studies, manufacturing, clinical trials, testing, and services (shipments, travel logistics, etc.). These contracts do not contain minimum purchase commitments and, except as discussed below, are cancelable by the Company upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of the Company's vendors or third-party service providers, up to the date of cancellation. These payments are not included in the table above as the amount and timing of such payments are not known.

OSR - San Raffaele Hospital

The OSR agreements are non-cancelable, except in the case of breach of contract, and include total potential milestone payments of up to €10 million related to the Lympho-Hematopoietic Indication of each Licensed Product, and up to €53 million related to each Solid Cancer indication; however, starting with the fifth Solid Cancer indication, the first two related milestone payments totaling €7.0 million, are reduced to €3.5 million. The milestones relate to certain events such as, dosing of the first patient with a licensed product in Phase II and III of the trial, MAA (marketing authorization application) and NDA (new-drug application) approval of the licensed product, the first commercial sale of the product in the US and major European countries, and annual sales for the licensed product exceeding a certain amount in different territories.

Multiple myeloma (MM)

As discussed in Note 12, the Company's MM program was discontinued in early 2021 due to the relatively small number of eligible patients, and the highly competitive MM landscape. No milestones were achieved with respect to the MM program, and as such no contingent payments were due under the agreement.

Glioblastoma multiforme (GBM)

As discussed in Note 12, in December 2020, the Company had one indication ongoing, glioblastoma multiforme. The Company's contingent liability for this first solid cancer indication potentially payable to OSR was €53 million.

Liver cancer (LC)

In relation to the option exercised by the Company for the second solid cancer indication, the Company and OSR agreed that the payment due in relation to the "First patient dosed with a Licensed Product in Phase I/II Clinical Trial," as stated in the agreement, was reduced to €0.5 million rather than €1.0 million. The reduction applied to the first license fee payment only. All the additional contingent payments, other than the last contingent payment of €5.0 million, remained a contingent liability of the Company and potentially payable to OSR. Therefore, for the second solid cancer indication (liver cancer), the total potential commitment of possible contingent payments could amount to €47.5 million.

The agreements also include a €7.8 million commitment related to the development and manufacturing of licensed products, of which the Company has incurred €1.5 million of expense in 2020 compared to €2.6 million of cumulative expense for 2019 and prior years.

In February 2021, the Company entered into a Sponsored Research Agreement ("SRA") with OSR to conduct certain research projects related to Temferon. The total consideration to be paid by the Company under the SRA will be €1.0 million with payments scheduled quarterly over 2021 and 2022. The Company made no payments under the SRA in 2020.

AGC Biologics (formerly MolMed)

The AGC Biologics agreement is non-cancelable, except in the case of breach of contract, and includes a potential milestone of €0.3 million if a phase 3 study is approved by the relevant authority, as well as potential royalty fees between 0.5% and 1.0% depending on the volume of annual net sales of the first commercial and named patient sale of the product. In the AGC Agreement, the Company entrusts AGC with certain development activities that will allow the Company to carry out activities related to its clinical research and manufacturing. The AGC agreement also includes a technology transfer fee of €0.5 million related to the transfer of the manufacturing know-how and €1.0 million related to the marketability approval by regulatory authorities. The agreement is a "pay-as-you-go" type arrangement with all services expensed in the period the services were performed. In February 2020, the Company entered into Amendment 4 to the Framework Service Agreement with AGC Biologics related to production and testing of the Company's GBM trials, for a total amount of €360,000. In March 2020, the Company entered into Amendment 5 to the Framework Service Agreement with AGC Biologics related to production and testing of the Company's GBM trials, for a total amount of €259,000. In March 2020, the Company entered into Amendment 6 to the Framework Service Agreement with ACG Biologics related to production and testing of the Company's GBM trials, for a total amount of €41,000. In August 2020, the Company entered into Amendment 7 to the Framework Service Agreement with ACG Biologics related to production and testing of the Company's GBM trials, which provides the Company with an option to accelerate GBM production as stated in Amendment 5 at a 20% cost increase. In October 2020, the Company entered into Amendment 8 to the Framework Service Agreement with ACG Biologics related to production and testing of the Company's GBM trials, for a total amount of €17,000.

Adaptive Biotechnologies

The Adaptive Biotechnologies agreement on exploratory analyses for trial endpoints is non-cancelable, except in the case of breach of contract, and carries a total cost for the entire trial of €0.2 million, of which approximately €3,000 and approximately €50,000 have been incurred as of December 31, 2020 and 2019, respectively.

Biogazelle NV

The Biogazelle NV agreement on exploratory analyses for trial endpoints is non-cancelable, except in the case of breach of contract, and carries a total cost for the entire trial of €106,000, of which €28 thousand and €6 thousand have been incurred as of December 31, 2020 and 2019, respectively.

Operating leases

The Company entered into a non-cancelable lease agreement for office space in January 2020. (See Footnote 12 – Related parties under OSR for further information.)

Legal proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of ASC 450, *Contingencie*s. The Company was notified by Theravectys of the possible infringement by the Company of Theravectys' exclusive license to patents no. EP 1071804, EP 1224314, and EP 1222300 granted from the owner of the patents Institut Pasteur. Each of these patents is now expired, having each reached the end of it its patent term on April 23, 2019 for EP 1071804 and October 10, 2020 for EP 1224314, and EP 1222300. The Company considered the situation and determined that the likelihood of a material adverse effect on its business is remote. To date, the Company has not engaged in any such discussions with Theravectys nor has the Company received any further communication from Theravectys. The Company expenses as incurred the costs related to its legal proceedings, if any.

14. Subsequent events

In February 2021, the Company entered into a Sponsored Research Agreement ("SRA") with OSR to conduct certain research projects related to Temferon. The total consideration to be paid by the Company under the SRA will be €1.0 million with payments scheduled quarterly over 2021 and 2022.

Event (Unaudited) Subsequent to the Date of the Independent Auditor's Report

In April 2021, the Company granted fully vested options on 169 quota B to certain officers, employees, directors and consultants.

American Depositary Shares

Representing Ordinary Shares

Genenta Science S.p.A.

PROSPECTUS

Joint Book-Running Managers

Canaccord Genuity **Roth Capital Partners**

, 2021

Through and including , 2021 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors, Officers and Employees

Under Italian law, a corporation is not required to indemnify its directors or officers against losses and expenses, including attorney's fees, judgments, fines and settlement amounts actually and reasonably incurred in a civil or criminal action, suit or proceeding arising from being the representative of, or serving at the request of, the corporation.

Italian law requires directors and members of any committee designated by the board of directors to perform their duties in good faith and with that degree of diligence that is required by the nature of their office and under their specific level of competence. If directors fail to comply with such obligations, they may be liable towards the company, its creditors, individual shareholders and third parties.

Corporate responsibility action may be brought by:

- the shareholders' meeting of the company;
- shareholders representing at least 20% of the share capital.

The company may waive the liability action and may settle, provided that the waiver and settlement are approved by express resolution of the shareholders' meeting, and provided that there is no vote against by a minority of shareholders representing at least 20% of the share capital.

Liability action against directors for the non-fulfilment of their duties may also be brought by creditors when the company's assets are insufficient to satisfy their claims.

The responsibility of directors is imperative and the articles of association cannot, as general rule, exempt directors from the liability provided for by law nor limit it to malicious conduct alone.

We intend to enter into directors' and officers' liability insurance to cover certain actions undertaken by our board of directors and executive officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers and controlling persons of the Company, the Company has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Item 7. Recent Sales of Unregistered Securities

Set forth below are the sales of all securities by the Company since 2017, which were not registered under the Securities Act. The Company believes that each of such issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Rule 701 and/or Regulation S under the Securities Act.

In 2014, the Company was organized with a total corporate capital equal to €11,650, comprised of €10,458.21 class A Quotas and €1,191.79 class B Quotas.

In 2015 through 2017, the Company issued 8,644.40 class C Quotas from convertible notes and 2,958.50 class B Quotas.

In 2017, the Company issued an aggregate maximum amount of 4,033.85 of class D Quotas.

In 2018 and 2019 the Company issued 2,300 of class B Quotas and an additional 6,462.12 class E Quotas.

In 2020, the Company issued 571.34 class E Quotas, from the 2019 offering which was extended in 2020 to provide an additional €1.5 million plus 436.00 class B Quotas from options.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions were acquiring the securities for investment and not distribution. Such purchasers were advised the securities had not been registered under the Securities Act and that any resale in the United States must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

Item 8. Exhibits and Financial Statement Schedules

Exhibits:

Exhibit Number	Exhibit Description
1.1*	Underwriting Agreement
3.1*	Form of articles of association of Genenta Science S.p.A. (to be effective upon completion of this offering).
3.2*	Form of by-laws of Genenta Science S.p.A. (to be effective upon completion of this offering).
4.1*	Form of Deposit Agreement
4.2*	Form of American Depositary Receipt (included in exhibit 4.1)
5.1**	Opinion of Giovanelli and Associates, Italian counsel to Genenta
10.1*	License Agreement between Ospedale San Raffaele S.r.l. and Genenta Science S.r.l. dated December 15, 2014 (OSR License Agreement)
10.2*	First Amendment to the OSR License Agreement dated March 16, 2017
10.3*	Second Amendment to the OSR License Agreement dated February 1, 2019
10.4*	Third Amendment to the OSR License Agreement dated December 23, 2020
10.5*	Sponsored Research Agreement with OSR dated February 12, 2021
10.6*	Know-How License Agreement with Fondazione Telethon dated February 2, 2016
10.7†*	Master Service Agreement dated March 6, 2019 between Molecular Medicine S.p.A. and Genenta Science S.r.l.
10.8**	Form of 2021-2025 Genenta Science Employee Share Option Plan with Chairman Sub-Plan
10.9*	Form of Employment Agreement of Pierluigi Paracchi
10.10*	Form of Employment Agreement of Carlo Russo
10.11*	Form of Employment Agreement of Richard Slansky
23.1**	Consent of Mayer Hoffman McCann, P.C.
23.2**	Consent of Giovanelli and Associates, Italian counsel to Genenta (included in Exhibit 5.1).
23.3**	Consent of Stephen Squinto to be named as a potential director in the Registration Statement
23.4**	Consent of Anthony Marucci to be named as a potential director in the Registration Statement
24.1*	Power of Attorney (included on the signature page of this Registration Statement).

* Filed herewith.
** To be filed by amendment.
† Portions of this exhibit (indicated by “Redacted”) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv)

Financial Statement Schedules:

All financial statement schedules have been omitted because either they are not required, are not applicable or the information required therein is otherwise set forth in the Company’s financial statements and related notes thereto.

Item 9. Undertakings

(a) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described in Item 6 hereof, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(b) The undersigned registrant hereby undertakes that:

(1) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4), or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement on Form F-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Milan, Italy on , 2021.

Genenta Science S.r.l.

By: _____
Name: Pierluigi Paracchi
Title: Chief Executive Officer

POWER OF ATTORNEY

The undersigned officers and directors of Genenta Science S.r.l. hereby constitute and appoint Pierluigi Paracchi and Richard Slansky with full power of substitution, each of them singly our true and lawful attorneys-in-fact and agents to take any actions to enable the Company to comply with the Securities Act, and any rules, regulations and requirements of the SEC, in connection with this registration statement on Form F-1, including the power and authority to sign for us in our names in the capacities indicated below any and all further amendments to this registration statement and any other registration statement filed pursuant to the provisions of Rule 462 under the Securities Act.

Pursuant to the requirements of the Securities Act of 1933, this registration statement on Form F-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Pierluigi Paracchi	Chief Executive Officer and Chairman (Principal Executive Officer)	
Richard Slansky	Acting Chief Financial Officer (Principal Financial and Accounting Officer)	
Roger Abravanel	Director	
Daniela Bellomo	Director	
Guido Guidi	Director	
Luca Guidotti	Director	

SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the Securities Act of 1933, as amended, the undersigned, Cogency Global Inc., the duly authorized representative in the United States of Genenta Science S.r.l., has signed this registration statement on , 2021.

By: _____
Name:
Title:

Exhibit 1.1

GENENTA SCIENCE S.P.A.

[●] American Depositary Shares
Representing [●] Ordinary Shares ([●] par value)
Underwriting Agreement

[●], 2021

Canaccord Genuity LLC

As Representative of the several Underwriters

c/o Canaccord Genuity LLC
99 High Street, 12th Floor
Boston, Massachusetts 02110

Ladies and Gentlemen:

Genenta Science S.p.A., a Republic of Italy joint stock corporation (the "Company"), proposes to sell to the several underwriters (the "Underwriters") named in Schedule I to this underwriting agreement (this "Agreement"), for whom you (in such capacity, the "Representative") are acting as representative, an aggregate of [●] American Depositary Shares (the "ADSs", and each an "ADS"), each representing one (1) ordinary share, no par value, of the Company ("Ordinary Shares"). The aggregate of [●] ADSs to be issued and sold by the Company are hereinafter referred to as the "Underwritten ADSs." In addition, the Company proposes to issue and sell, at the option of the Underwriters, up to an additional [●] ADSs, representing [●] additional Ordinary Shares (the "Option ADSs"). The Underwritten ADSs and the Option ADSs are herein referred to as the "Offered ADSs." The Ordinary Shares represented by the Underwritten ADSs are hereinafter referred to as the "Underwritten Securities," the Ordinary Shares represented by the Option ADSs are hereinafter referred to as the "Option Securities", and the Underwritten Securities and the Option Securities are hereinafter referred to as the "Underlying Securities." The Offered ADSs and the Underlying Securities are herein called, collectively, the "Securities."

The Representative has also advised the Company that the Underwriters may elect to cause the Company to deposit on its behalf all or any portion of the Underlying Securities to be purchased by them hereunder pursuant to the Deposit Agreement, dated as of [●], 2021 (the "Deposit Agreement"), to be entered into among the Company, The Bank of New York Mellon, as depositary (the "Depositary"), and all holders from time to time of the ADSs. Upon deposit of any Ordinary Shares, the Depositary will issue ADSs representing the Ordinary Shares so deposited. The ADSs will be evidenced by American Depositary Receipts (the "ADRs"). The Offered ADSs will represent Ordinary Shares and each ADR may represent any number of ADSs.

As used in this Agreement, the "Registration Statement" means the registration statement referred to in Section 1(i)(a) hereof, including the exhibits, schedules and financial statements and any prospectus relating to the Securities that is filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (the "Securities Act") and deemed part of such registration statement pursuant to Rule 430A under the Securities Act ("Rule 430A"), as amended at the date and time that this Agreement is executed and delivered by the parties hereto (the "Execution Time"), and, in the event any post-effective amendment thereto or any registration statement and any amendments thereto filed pursuant to Rule 462(b) under the Securities Act (a "Rule 462(b) Registration Statement") becomes effective prior to the Closing Date (as defined in Section 3 hereof), shall also mean such registration statement as so amended or such Rule 462(b) Registration Statement, as the case may be; the "Effective Date" means each date and time that the Registration Statement, any post-effective amendment or amendments thereto or any Rule 462(b) Registration Statement became or becomes effective; the "Preliminary Prospectus" means any preliminary prospectus with respect to the offering of the Securities included in the Registration Statement at the Effective Date that omits information with respect to the Securities and the offering thereof permitted to be omitted from the Registration Statement when it becomes effective pursuant to Rule 430A; and the "Prospectus" means the prospectus relating to the Securities that is first filed pursuant to Rule 424(b) under the Securities Act ("Rule 424(b)") after the Execution Time.

As used in this Agreement, the "Disclosure Package" shall mean (i) the Preliminary Prospectus dated [●], 2021, as generally distributed to investors and used to offer the Securities, (ii) any issuer free writing prospectus, as defined in Rule 433 under the Securities Act ("Rule 433" and, any such issuer free writing prospectus, an "Issuer Free Writing Prospectus"), identified in Schedule II hereto, (iii) any other free writing prospectus, as defined in Rule 405 under the Securities Act ("Rule 405" and, any such free writing prospectus, a "Free Writing Prospectus"), that the parties hereto shall hereafter expressly agree in writing to treat as part of the Disclosure Package.

1. Representations and Warranties.

(i) The Company represents and warrants to, and agrees with, each Underwriter as set forth below in this Section 1.

(a) The Company has prepared and filed with the SEC a registration statement (file number 333-[ ]) on Form F-1, including the Preliminary Prospectus, for the registration of the offering and sale of the Securities under the Securities Act. Such Registration Statement, including any amendments thereto filed prior to the Execution Time, has become effective. The Company may have filed one or more amendments thereto, including the Preliminary Prospectus, each of which has previously been furnished to you. The Company will file with the SEC the Prospectus relating to the Securities in accordance with Rule 424(b) after the Execution Time. As filed, the Prospectus shall contain all information with respect to the Underlying Securities and the offering thereof in the form of ADSs required by the Securities Act and the rules thereunder and, except to the extent the Representative shall agree in writing to a modification, shall be in all substantive respects in the form furnished to you prior to the Execution Time or, to the extent not completed at the Execution Time, shall contain only such specific additional information and other changes (beyond that contained in the latest Preliminary Prospectus) as the Company has advised you, prior to the Execution Time, will be included or made therein.

(b) On the Effective Date, the Registration Statement did, and when the Prospectus is first filed in accordance with Rule 424(b) and on the Closing Date (as defined in this Agreement) and on any date on which Option Securities are purchased, if such date is not the Closing Date (each such date, a "Settlement Date"), the Prospectus (and any supplements thereto) will comply in all material respects with the applicable requirements of the Securities Act and the rules thereunder; on the Effective Date, at the Execution Time and on the Closing Date, the Registration Statement did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the date of any filing pursuant to Rule 424(b) and on the Closing Date and any Settlement Date, the Prospectus (together with any supplement thereto) will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representations or warranties as to the information contained in or omitted from the Registration Statement, the Preliminary Prospectus or the Prospectus (or any supplement thereto) in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representative specifically for inclusion in the Registration Statement, the Preliminary Prospectus or the Prospectus (or any supplement thereto), it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof. The disclosures in the Registration Statement and Prospectus concerning the effects of U.S. laws and European Union, Italian national and local regulations on the Company's business as currently contemplated are correct in all material respects and do not omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) The Company has filed with the SEC a registration statement (file number [●]) on Form F-6 for the registration under the Securities Act of the offering and sale of the Offered ADSs ("ADS Registration Statement"). The Company may have filed one or more amendments thereto, each of which has previously been furnished to you. Such ADS Registration Statement at the time of its effectiveness did comply and on the Closing Date, will comply, in all material respects with the applicable requirements of the Securities Act and the rules thereunder and at the time of its Effective Date and at the Execution Time, did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading.

(d) The Company has been duly established and is validly existing as a joint stock company (*società per azioni*) in good standing under the laws of the Republic of Italy with a registered office at Via Olgettina No. 58, 20132 Milan, Italy, Fiscal Code and number of registration in the Companies Register of Milan No. 08738490963, with a fully paid corporate capital of €[●]. The Company does not own an interest in any corporation, partnership, joint venture, limited liability company, trust or other business entity.

(e) Upon issuance by the Depositary of ADSs evidenced by ADRs against deposit of Underlying Securities in accordance with the provisions of the Deposit Agreement, such ADRs will be duly and validly issued and persons in whose names the ADRs are registered will be entitled to the rights specified in the ADRs and in the Deposit Agreement; and upon the sale and delivery to the Underwriters of the Securities, and payment therefor, pursuant to this Agreement, the Underwriters will acquire good, marketable and valid title to such Securities, free and clear of all pledges, liens, security interests, charges, claims or encumbrances of any kind.

(f) Provided that (i) no Underwriter is resident in Italy for tax purposes and (ii) each Underwriter is a resident of a jurisdiction for the purposes of a double tax treaty between Italy and the jurisdiction, is entitled to the benefits of the treaty and does not, and is not deemed to, carry on business through a permanent establishment in Italy, no stamp, registration, issuance, transfer taxes or other similar taxes, duties, fees or charges ("Transfer Taxes") are payable by or on behalf of the Underwriters in connection with (A) the issuance of the Underlying Securities and the delivery of the Offered ADSs in the manner contemplated by this Agreement, (B) the deposit with the Depositary of the Underlying Securities against issuance of the Offered ADSs or (C) the sale and delivery by the Underwriters of the Underlying Securities or the Offered ADSs, as the case may be, as contemplated herein. For the avoidance of doubt, income taxes, withholding taxes, capital gains taxes and taxes on dividends shall not be considered "Transfer Taxes."

(g) Except as described in each of the Disclosure Package and the Prospectus, all dividends and other distributions declared and payable on the Ordinary Shares may under current Italian law and regulations be paid to the Depositary and to the holders of Ordinary Shares or ADSs, as the case may be, in Euros and may be converted into foreign currency that may be transferred out of Italy in accordance with the Deposit Agreement.

(h) Neither the SEC nor, to the Company's knowledge, any state regulatory authority has issued any order preventing or suspending the use of the Preliminary Prospectus or has instituted or, to the Company's knowledge, threatened to institute, any proceedings with respect to such an order.

(i) (i) The Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, when taken together as a whole, (ii) each electronic road show, when taken together as a whole with the Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, and (iii) any individual Written Testing-the-Waters Communication (as defined below), when taken together as a whole with the Disclosure Package and the price to the public, the number of Underwritten Securities and the number of Option Securities to be included on the cover page of the Prospectus, does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from the Disclosure Package based upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representative specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405.

(j) (i) At the time of filing the Registration Statement and (ii) as of the Execution Time (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405), without taking account of any determination by the SEC pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(k) From the time of initial confidential submission of the Registration Statement to the SEC (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the Execution Time, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company"). "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(l) The Company (i) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representative with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representative or persons known to the Representative to engage in Testing-the-Waters Communications. The Company reconfirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule III hereto.

(m) Each Issuer Free Writing Prospectus does not include any information that conflicts with the information contained in the Registration Statement. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representative specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(n) This Agreement has been duly authorized, executed and delivered by the Company. The execution, delivery and performance by the Company of this Agreement does not violate its Articles of Association (i.e., *atto costitutivo*), its By-laws (i.e., *statuto*) or any law, rule, regulation, judgment, decree or order of any court applicable to it. No consents or approvals and no licenses or orders from, or any registration or filings with, any Republic of Italy court, government department or other regulatory body (with the exception of all filing requirements with the Companies Register of Como which, to our knowledge, have been fully complied with other than filings which are required to and will be made post-closing in connection with the transactions contemplated herein) are required for the due authorization, execution, delivery or performance by the Company of this Agreement or the consummation of the transactions contemplated by this Agreement, the Underwriters' Purchase Option and Prospectus, except such as have been obtained under the Securities Act and such as may be required by FINRA and under state securities, Blue Sky or foreign laws in connection with the purchase and distribution of the Shares by the several Underwriters.

(o) The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction in which it is incorporated with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as described in the Disclosure Package and the Prospectus, and is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except in each case where such failure would not reasonably be expected to have a Material Adverse Effect (as defined below).

(p) There is no franchise, contract or other document of a character required to be described in the Registration Statement, Preliminary Prospectus or Prospectus, or to be filed as an exhibit thereto, which is not described or filed as required (and the Preliminary Prospectus contains in all material respects the same description of the foregoing matters contained in the Prospectus).

(q) The Company has full legal capacity and power to enter into this Agreement and the Deposit Agreement, and each of this Agreement and the Deposit Agreement has been duly authorized, executed and delivered by the Company.

(r) The Company is not and, after giving effect to the offering and sale of the Securities and the application of the proceeds thereof as described in the Registration Statement, Disclosure Package and the Prospectus, will not be an "investment company" as defined in the Investment Company Act of 1940, as amended.

(s) No consent, approval, authorization, filing with or order of any court or governmental agency or body is required in connection with the transactions contemplated herein or in the Deposit Agreement, except such as have been obtained under the Securities Act and such as may be required under the listing rules of the Nasdaq Stock Market, applicable rules of the Financial Industry Regulatory Authority, Inc. and under the applicable state and foreign securities laws of any jurisdiction in connection with the purchase and distribution of the Securities by the Underwriters in the manner contemplated herein and in the Disclosure Package and the Prospectus.

(t) Neither the issue and sale of the Securities nor the consummation of any other of the transactions herein contemplated nor the fulfillment of the terms hereof or of the Deposit Agreement will conflict with, result in a breach or violation of, or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, (i) the constitution of the Company, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which the Company is a party or bound or to which its property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its properties, except in the case of clause (ii) and (iii) above, for any such conflict, breach, violation, default, lien, charge or encumbrance that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect (as defined below).

(u) No holders of securities of the Company have rights to the registration of such securities under the Registration Statement or the issuance of the Securities.

(v) The consolidated historical financial statements and schedules of the Company included in the Preliminary Prospectus, the Prospectus and the Registration Statement present fairly in all material respects the financial condition, results of operations and cash flows of the Company as of the dates and for the periods indicated, comply as to form in all material respects with the applicable accounting requirements of the Securities Act and have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

(w) No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its property is pending or, to the knowledge of the Company, threatened that (i) would reasonably be expected to have a material adverse effect on the performance of this Agreement or the consummation of any of the transactions contemplated hereby or (ii) could reasonably be expected to have a material adverse effect on the condition (financial or otherwise), prospects, earnings, business or properties of the Company, whether or not arising from transactions in the ordinary course of business (a "Material Adverse Effect"), except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(x) The Company leases all such real properties as are reasonably necessary to the conduct of its operations as presently conducted. The Company does not own any real property.

(y) The Company is not in violation or default of (i) any provision of its constitution, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which it is a party or bound or to which its property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its properties, as applicable, except in case of clauses (ii) and (iii), for any such violation or default as would not reasonably expected, individually or in the aggregate, to have a Material Adverse Effect.

(z) Mayer Hoffman McCann P.C., who have issued their audit report with respect to the consolidated financial statements of the Company and its affiliates included in the Disclosure Package and the Prospectus, are independent public accountants with respect to the Company and its affiliates within the meaning of the Securities Act and the applicable published rules and regulations thereunder.

(aa) The Company has filed all tax returns that are required to be filed or has requested extensions thereof, except in any case in which the failure so to file would not have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto) and has paid all taxes required to be paid by it and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(bb) With respect to the Company, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto): (i) no labor problem, dispute, slowdown, work stoppage or disturbance involving any employees of it exists or, to the Company's knowledge is threatened or imminent, and it is not aware of any existing or imminent labor problem, dispute, slowdown, work stoppage or disturbance by the employees of any of its or its principal suppliers, contractors or customers, that could have a Material Adverse Effect; and (ii) compliance subsists for all its obligations under employment contracts, industrial agreements and awards and with all codes of conduct and practice relevant to conditions of service and to the relations between it and the employees employed by it, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The term "taxes" mean all net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments, or charges of any kind whatever imposed by the U.S., the European Union, Italy or any Italian subdivision or local authority, together with any interest and any penalties, additions to tax, or additional amounts with respect thereto.

(cc) The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as the Company reasonably believes are prudent and customary in the business in which it is engaged; all policies of insurance insuring the Company or its business, assets, employees, officers and directors are in full force and effect; the Company is in compliance with the terms of such policies and instruments in all material respects; and there are no material claims by the Company under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; the Company has not been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(dd) The Company possesses all licenses, sub-licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, all applicable federal, state, local or foreign governmental or other authorities that are necessary to conduct its business ("Permits"), except where the failure to possess such Permit would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company is not in violation of, or in default under, any of the Permits nor has received any revocation, suspension or modification of any such Permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto). The Company has not received any notice that any such Permit will not be renewed in the ordinary course, and, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, all Permits are valid and in full force.

(ee) The Company maintains a system of internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with U.S. GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Disclosure Package and the Prospectus, the Company's internal controls over financial reporting are effective and the Company is not aware of any material weakness in its internal controls over financial reporting.

(ff) The Company maintains "disclosure controls and procedures" (as such term is defined in Rule 13a-15(e) under the Securities and Exchange Act 1934, as amended, and the rules and regulations promulgated thereunder (the "Exchange Act")); such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms.

(gg) The Company is (i) in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "Environmental Laws"), (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business and (iii) has not received notice of any actual or potential liability under any environmental law, except in each case where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not, individually or in the aggregate, have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto). Except as set forth in the Disclosure Package and the Prospectus, the Company has not been named as a "potentially responsible party" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(hh) There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection thereunder, that are then in effect and with which the Company is required to comply as of the effectiveness of the Registration Statement.

(ii) Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company (i) has used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) has made any direct or indirect unlawful payment to any foreign or domestic government official or employee (including of any government owned or controlled entity, or any person acting in an official capacity for or on behalf of any of the foregoing) from corporate funds; or (iii) has made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment, or (iv) is aware of or has taken any action, directly or indirectly, that could result in a violation or a sanction for violation by such persons of the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010, OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or any other applicable anti-bribery or anti-corruption law, each as may be amended, or the rules or regulations thereunder (collectively, the "Anti-Corruption Laws"); and the Company has instituted and maintains policies and procedures to ensure compliance with the Anti-Corruption Laws. No part of the proceeds of the offering will be used, directly or indirectly, in violation of the Anti-Corruption Laws.

(jj) The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes of all jurisdictions where the Company conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(kk) Neither the Company nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company (i) is, or is controlled or 50% or more owned in the aggregate by or is acting on behalf of, one or more individuals or entities that are currently the subject of any sanctions administered or enforced by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury, the U.S. Department of State or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, a member state of the European Union (including sanctions administered or enforced by Her Majesty's Treasury of the United Kingdom and the Italian Department of the Treasury) or other relevant sanctions authority (collectively, "Sanctions" and such persons, "Sanctioned Persons" and each such person, a "Sanctioned Person"), (ii) is located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that country or territory (currently, the Crimea region, Cuba, Iran, North Korea, and Syria) (collectively, "Sanctioned Countries" and each, a "Sanctioned Country") or (iii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other individual or entity in any manner that would result in a violation of any Sanctions by, or could result in the imposition of Sanctions against, any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(ll) The Company has not engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding three years, nor does the Company have any plans to engage in dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country.

(mm) Except as would not reasonably be expected to result in a Material Adverse Effect, the Company owns, possesses, licenses or has other rights to use, on reasonable terms, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the "Intellectual Property") necessary for the conduct of the Company's business as now conducted or as proposed in the Disclosure Package and Prospectus to be conducted. Except as set forth in the Disclosure Package and the Prospectus under the captions "Risk Factors—Risks Relating to Intellectual Property" and "Business—Intellectual Property," or as would not reasonably be expected to result in a Material Adverse Effect (a) there are no rights of third parties to any such Intellectual Property; (b) to the Company's knowledge, there is no material infringement by third parties of any such Intellectual Property; (c) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (d) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (e) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any other fact which would form a reasonable basis for any such claim; (f) to the Company's knowledge, there is no prior art of which the Company is aware that may render any U.S. patent held by the Company invalid or any U.S. patent application held by the Company un-patentable which has not been disclosed to the U.S. Patent and Trademark Office.

(nn) Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of Canaccord Genuity LLC and (ii) does not intend to use any of the proceeds from the sale of the Securities hereunder to repay any outstanding debt owed to any affiliate of Canaccord Genuity LLC.

(oo) Neither the Company nor any of its properties or assets has any immunity from the jurisdiction of any court or from any legal process (whether through service or notice, attachment prior to judgment, attachment in aid of execution or otherwise) under the laws of Italy.

(pp) The Company is, and at all times has been, in material compliance with all applicable Health Care Laws. For purposes of this Agreement, "Health Care Laws" means: (i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), the Public Health Service Act (42 U.S.C. Section 201 et seq.), and the regulations promulgated thereunder; (ii) all applicable federal, state, local and foreign health care fraud and abuse laws, including, without limitation, the Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal false statements law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286 and 287, the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. Section 1320d et seq.), the Stark Law (42 U.S.C. Section 1395nn), the civil monetary penalties law (42 U.S.C. Section 1320a-7a), the exclusion law (42 U.S.C. Section 1320a-7), the Physician Payments Sunshine Act (42 U.S.C. Section 1320-7h), and applicable laws governing government funded or sponsored healthcare programs; (iii) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.); (iv) the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010; (v) licensure, quality, safety and accreditation requirements under applicable federal, state, local or foreign laws or regulatory bodies; (vi) all other local, state, federal, national, supranational and foreign laws, relating to the clinical drug development activities conducted by the Company, and (vii) the directives and regulations promulgated pursuant to such statutes and any state or non-U.S. counterpart thereof. The Company has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws nor, to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened. The Company has filed, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed or were corrected or supplemented by a subsequent submission, except as would not cause a Material Adverse Effect. The Company is not a party to any corporate integrity agreement, monitoring agreement, consent decree, settlement order, or similar agreement with or imposed by any governmental or regulatory authority. Additionally, neither the Company, nor any of its employees, officers, directors or, to the Company's knowledge, agents, has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to Company's knowledge, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

(qq) The Company's information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "IT Systems and Data") are adequate for, and operate and perform as required in connection with the operation of the business of the Company as currently conducted, free and clear of all bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants, except as would not reasonably be expected to result in a Material Adverse Effect. The Company has implemented and maintains commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data, including "Personal Data," used in connection with its business. "Personal Data" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by the European Union General Data Protection Regulation (EU 2016/679); (iv) any information which would qualify as "protected health information" under HIPAA; and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. There have been no breaches, violations, outages or unauthorized uses of or accesses to Personal Data, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company has been and is presently in material compliance with all applicable laws, directives, or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data, including Personal Data and to the protection of such IT Systems and Data and Personal Data from unauthorized use, access, misappropriation or modification, except as would not reasonably be expected to result in a Material Adverse Effect. There has been no security breach or other material compromise of or relating to any of the Company's IT Systems and Data and the Company has not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other material compromise to its IT Systems and Data, except for any breaches or compromises that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(rr) The Company is, and has at all times been, in material compliance with all applicable data privacy and security laws and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations regarding the privacy and security of IT Systems and Data and Personal Data (collectively, the "Privacy Laws"), except as would not, individually or in the aggregate, result in a Material Adverse Effect. To ensure compliance with the Privacy Laws, the Company has in place, complies with, and takes appropriate steps reasonably designed to ensure compliance in all material respects with its policies and contractual obligations governing the collection, storage, use, disclosure, handling and analysis of Personal Data. The Company has at all times made all material disclosures to users or customers required by the Privacy Laws, except as would not, individually or in the aggregate, result in a Material Adverse Effect. The Company further certifies that the Company: (i) has not received notice of, any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in, any such notice; (ii) is not currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Laws; or (iii) is not a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law, except with respect to subsection (i), (ii) and (iii) as would not, individually or in the aggregate, result in a Material Adverse Effect.

(ss) The preclinical studies and clinical trials that are described in the Registration Statement, the Disclosure Package or the Prospectus (collectively, "Studies") were conducted by or, to the knowledge of the Company, on behalf of the Company were and, if still ongoing, are being conducted in all material respects in accordance with the protocols, procedures and controls designed for such Studies and pursuant to, where applicable, accepted professional scientific standards; the descriptions of the results of such studies contained in the Registration Statement, the Disclosure Package or the Prospectus are accurate and complete and fairly present the data derived from such Studies, in each case in all material respects, and the Company has no knowledge of any other Studies the results of which are materially inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Disclosure Package or the Prospectus; the Company has made all such filings and obtained all such approvals as may be required by the United States Food and Drug Administration ("FDA") or any committee thereof, the European Medicines Agency ("EMA") or any committee thereof, or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "Regulatory Agencies"), except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect; the Company has not received any notice from, or correspondence from, any Regulatory Agency requiring the termination, suspension or material modification of any Studies conducted by or on behalf of the Company; and the Company is in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies.

(tt) The Company has generally enjoyed a satisfactory employer-employee relationship with its employees and is in compliance in all material respects with all collective and individual contracts with or involving its employees and with all European Union laws applicable to Italian companies and Italian national, and local laws and regulations respecting the employment of its employees and employment practices, terms and conditions of employment and wages and hours relating thereto and, to the knowledge of the Company, there is no dispute with any employee existing or threatened, which dispute would have a Material Adverse Effect. There are no pending investigations involving the Company, its employees or any collective bargaining organization by any other governmental agency responsible for the enforcement of European Union, Italian national, and local laws and regulations or collective bargaining agreements. There is no unfair labor practice charge or complaint against the Company or any officer of the Company, pending before any regulatory authority, or any strike, picketing, boycott, dispute, slowdown or stoppage pending or threatened against or involving the Company or any officer of the Company, or any predecessor entity, and none has ever occurred. No question concerning representation exists respecting the employees of the Company and no collective bargaining agreement or modification thereof is currently being negotiated by the Company. No grievance or arbitration proceeding is pending under any expired or existing collective bargaining agreements of the Company, if any.

(ww) All translations of each agreement, document or other writing provided by the Company for use by the Representative or for use as exhibits to the Registration Statement which the Company reasonably believes (i) have been provided by parties whom the Company believes are reliable in their capacity to fairly and accurately translate such documents, and (ii) fairly and accurately represent the provisions of the original versions of the documents which they represent. To the extent such translations were provided by others, nothing has come to attention of officers of the Company familiar with such documents that causes them to believe the translations provided are inaccurate in any material respect.

(xx) The choice of laws of the State of New York as the governing law of this Agreement is a valid choice of law under the laws of Italy and will be honored by the courts of Italy, subject to the restrictions described under the caption “Enforcement of Civil Liabilities” in the Registration Statement and the Prospectus. Any final judgment for a fixed or determined sum of money rendered by any U.S. federal or New York state court located in the State of New York having jurisdiction under its own laws in respect of any suit, action or proceeding against the Company based upon this Agreement would be recognized by the courts of Italy, without reconsideration or reexamination of the merits, subject to the restrictions described under the caption “Enforcement of Civil Liabilities” in the Registration Statement and the Prospectus, and the applicable bankruptcy, insolvency, reorganization or similar laws affecting the rights of creditors and secured parties in general.

(yy) Except as provided by laws or statutes generally applicable to transactions of the type described in this Agreement, neither the Company nor any of its respective properties, assets or revenues has any right of immunity under Italian, New York or United States law, from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any Italian, New York or United States federal court, from service of process, attachment upon or prior judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of a judgment, in any such court, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with this Agreement. To the extent that the Company or any of its respective properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings may at any time be commenced, the Company waives or will waive such right to the extent permitted by law.

(zz) The Company is a "foreign private issuer" as defined in Rule 405 of the Securities Act.

Any certificate signed by any officer of the Company and delivered to the Representative or counsel for the Underwriters in connection with the offering of the Securities shall be deemed a representation and warranty by the Company, as to matters covered thereby, to each Underwriter.

2. Purchase and Sale.

(a) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company agrees to sell to each Underwriter, and each Underwriter agrees, severally and not jointly, to purchase from the Company, at a purchase price of $[●] per ADS, the amount of the Underwritten ADSs set forth opposite such Underwriter's name in Schedule I hereto.

(b) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to [●] Option ADSs at the same purchase price per share as the Underwriters shall pay for the Underwritten ADSs, less an amount per ADS equal to any dividends or distributions declared by the Company and payable on the Ordinary Shares underlying the Underwritten ADSs but not payable on the Ordinary Shares underlying the Option ADSs. Said option may be exercised only to cover over-allotments in the sale of the Underwritten Securities by the Underwriters. Said option may be exercised in whole or in part at any time on or before the 30th day after the date of the Prospectus upon written or telegraphic notice by the Representative to the Company setting forth the number of shares of the Option ADSs as to which the several Underwriters are exercising the option and the settlement date. The maximum number of Option ADSs to be sold by the Company is [●]. In the event that the Underwriters exercise less than their full option to purchase Option ADSs, the number of Option ADSs to be sold by the Company shall be, as nearly as practicable, in the same proportion to each other as are the maximum number of Option ADSs to be sold by the Company and the number of Option ADSs listed opposite their names on Schedule I. The number of Option ADSs to be purchased by each Underwriter shall be the same percentage of the total number of shares of the Option ADSs to be purchased by the several Underwriters as such Underwriter is purchasing of the Underwritten ADSs, subject to such adjustments as you in your absolute discretion shall make to eliminate any fractional ADSs.

3. Delivery and Payment. Delivery of and payment for the Underwritten ADSs and the Option ADSs (if the option provided for in Section 2(b) hereof shall have been exercised on or before the second Business Day immediately preceding the Closing Date) shall be made at 10:00 AM, New York City time, on [●], or at such time on such later date not more than two Business Days after the foregoing date as the Representative shall designate, which date and time may be postponed by agreement among the Representative and the Company or as provided in Section 10 hereof (such date and time of delivery and payment for the Securities being called in this Agreement the "Closing Date"). As used herein, "Business Day" shall mean any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions or trust companies are authorized or obligated by law to close in New York City. Delivery of the Securities shall be made to the Representative for the respective accounts of the several Underwriters against payment by the several Underwriters through the Representative of the respective aggregate purchase prices of the Offered ADSs being sold by the Company to or upon the order of the Company by wire transfer payable in same-day funds to the accounts specified by the Company. Delivery of the Offered ADSs shall be made through the facilities of The Depository Trust Company unless the Representative shall otherwise instruct. For the purposes only of the delivery of the Underwritten ADSs, the parties agree that where an Underwriter has an obligation to on-transfer an Underwritten ADS to another party, that Underwriter receives delivery of and holds such Underwritten ADSs as bare trustee for the person they are obliged to transfer those Underwritten ADSs to.

If the option provided for in Section 2(b) hereof is exercised after the second Business Day immediately preceding the Closing Date, the Company will deliver (at the expense of the Company) to the Representative, at 99 High Street, 12th Floor, Boston, Massachusetts 02110, on the date specified by the Representative (which shall be within two Business Days after exercise of said option), certificates for the Option ADSs in such names and denominations as the Representative shall have requested for the respective accounts of the several Underwriters, against payment by the several Underwriters through the Representative of the purchase price thereof to or upon the order of the Company by wire transfer payable in same-day funds. If settlement for the Option ADSs occurs after the Closing Date, the Company will deliver to the Representative on the settlement date for the Option ADSs, and the obligation of the Underwriters to purchase the Option ADSs shall be conditioned upon receipt of, supplemental opinions, certificates and letters confirming as of such date the opinions, certificates and letters delivered on the Closing Date pursuant to Section 6 hereof.

The ADRs evidencing the Offered ADSs shall be registered in such names and in such denominations as the Representative may request not less than one full business day prior to the applicable Closing Date.

4. Offering by Underwriters. It is understood that the several Underwriters propose to offer the Securities for sale to the public as set forth in the Prospectus.

5. Agreements.

(i) The Company agrees with the several Underwriters that:

(a) Prior to the termination of the offering of the Securities, the Company will not file any amendment of the Registration Statement or the ADS Registration Statement or supplement to the Prospectus or any Rule 462(b) Registration Statement unless the Company has furnished you a copy for your review prior to filing and will not file any such proposed amendment or supplement to which you reasonably object. The Company will cause the Prospectus, properly completed, and any supplement thereto to be filed in a form approved by the Representative with the SEC pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed and will provide evidence satisfactory to the Representative of such timely filing. The Company will promptly advise the Representative (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the SEC pursuant to Rule 424(b) or when any Rule 462(b) Registration Statement or the ADS Registration Statement shall have been filed with the SEC, (ii) when, prior to termination of the offering of the Securities, any amendment to the Registration Statement or the ADS Registration Statement shall have been filed or become effective, (iii) of any request by the SEC or its staff for any amendment of the Registration Statement, the ADS Registration Statement or any Rule 462(b) Registration Statement, or for any supplement to the Prospectus or for any additional information, (iv) of the issuance by the SEC of any stop order suspending the effectiveness of the Registration Statement or the ADS Registration Statement or of any notice objecting to their use or the institution or threatening of any proceeding for that purpose and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Securities for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its best efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or the ADS Registration Statement or a new registration statement and using its best efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) If, at any time prior to the filing of the Prospectus pursuant to Rule 424(b), any event occurs as a result of which the Disclosure Package would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Representative so that any use of the Disclosure Package may cease until it is amended or supplemented; (ii) amend or supplement the Disclosure Package to correct such statement or omission; and (iii) supply any amendment or supplement to you in such quantities as you may reasonably request.

(c) If, at any time when a prospectus relating to the Securities is required to be delivered under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act ("Rule 172")), any event occurs as a result of which either of the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, or if it shall be necessary to amend the Registration Statement or supplement either of the Prospectus to comply with the Securities Act or the rules thereunder, the Company promptly will (i) notify the Representative of any such event; (ii) prepare and file with the SEC, subject to the second sentence of paragraph (i)(a) of this Section 5, an amendment or supplement which will correct such statement or omission or effect such compliance; and (iii) supply any supplemented Prospectus to you in such quantities as you may reasonably request.

(d) As soon as practicable, the Company will make generally available to its security holders and to the Representative an earnings statement or statements of the Company which will satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act; provided that the Company will be deemed to have furnished such statements to its security holders and the Representative to the extent such statements are filed on the Commission's Electronic Data Gathering, Analysis and Retrieval system.

(e) Upon request, the Company will furnish to the Representative and counsel for the Underwriters, without charge, signed copies of the Registration Statement and the ADS Registration Statement (including exhibits thereto) and to each other Underwriter a copy of the Registration Statement and the ADS Registration Statement (without exhibits thereto) and, so long as delivery of a prospectus by an Underwriter or dealer may be required (including in circumstances where such requirement may be satisfied pursuant to Rule 172) by the Securities Act, as many copies of each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Representative may reasonably request. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) The Company will arrange, if necessary, for the qualification of the Securities for sale under the laws of such jurisdictions as the Representative may designate and will maintain such qualifications in effect so long as required for the distribution of the Securities; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Securities, in any jurisdiction where it is not now so subject.

(g) The Company will not, without the prior written consent of the Representative, offer, sell, contract to sell, pledge, or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the Company or any affiliate of the Company or any person in privity with the Company or any affiliate of the Company) directly or indirectly, including the filing (or participation in the filing) of a registration statement with the SEC in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act, any Ordinary Shares or ADSs or any securities convertible into, or exercisable, or exchangeable for, Ordinary Shares or ADSs; or publicly announce an intention to effect any such transaction, for a period of 90 days after the date of this Agreement, provided, however, that the Company may (i) issue and sell Ordinary Shares or ADSs or any securities convertible into, or exercisable, or exchangeable for, Ordinary shares or ADSs pursuant to any employee stock option plan, stock ownership plan or dividend reinvestment plan of the Company in effect at the Execution Time, (ii) may issue Ordinary Shares issuable upon the conversion of securities or the exercise of warrants outstanding at the Execution Time, (iii) file one or more registration statements on Form S-8 relating to stock options or employee benefit plans of the Company described in the Disclosure Package and the Prospectus, (iv) offer, issue and sell Ordinary Shares or ADSs, or any securities convertible into, or exercisable, or exchangeable for, Ordinary shares or ADSs, in connection with any merger, acquisition or strategic investment (including any joint venture, strategic alliance, partnership, the acquisition or license of the business, property, technology or other assets of another individual or entity, or the assumption of an employee benefit plan in connection with such a merger or acquisition), or (v) offer, issue and sell Ordinary Shares or ADSs, or any securities convertible into, or exercisable, or exchangeable for, Ordinary shares or ADSs, on an arm's length basis to any unaffiliated collaborators, manufacturers, distributors, or any other similar parties pursuant to a collaboration, licensing agreement, strategic alliance, manufacturing or distribution agreement or similar transaction; provided, however, that the aggregate number of securities (on an as-converted basis) that the Company may issue or agree to issue pursuant to clauses (iv) and (v) shall not exceed 5% of the number of Ordinary Shares outstanding immediately after the issuance and sale of such securities, and provided, further, that each recipient of such securities pursuant to clauses (iv) and (v) agrees to restrictions on the resale of securities that are consistent with the provisions set forth in the lock-up letter described in Section 6(n) hereof.

(h) If the Representative in its sole discretion, agrees to release or waive the restrictions set forth in a lock-up letter described in Section 6(g) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three (3) Business Days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two (2) Business Days before the effective date of the release or waiver.

(i) The Company will not take, directly or indirectly, any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act, Italian law or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities.

(j) The Company agrees to pay the costs and expenses relating to the following matters: (i) the preparation, printing or reproduction and filing with the SEC of the Registration Statement (including financial statements and exhibits thereto), the Preliminary Prospectus, the Prospectus, each Issuer Free Writing Prospectus, the ADS Registration Statement, and each amendment or supplement to any of them; (ii) the preparation of the Deposit Agreement, the deposit of the Underlying Securities under the Deposit Agreement, the issuance thereunder of ADSs representing such deposited Underlying Securities, the issuance of ADRs evidencing such ADSs and the fees of the Depositary; (iii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, the Preliminary Prospectus, the Prospectus, the ADS Registration Statement, and each Issuer Free Writing Prospectus and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Securities; (iv) the preparation, printing, authentication, issuance and delivery of certificates for the Securities, including any Transfer Taxes in connection with the original issuance and sale of the Securities; (v) the printing (or reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Securities; (vi) the registration of the Securities under the Exchange Act and the listing of the ADSs on the Nasdaq Capital Market; (vii) any registration or qualification of the Securities for offer and sale under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such registration and qualification); (viii) any filings required to be made with the Financial Industry Regulatory Authority, Inc. (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such filings); (ix) the reasonable fees and expenses of counsel for the Underwriters, provided that such fees and expenses of counsel contained in this clause (ix), together with clauses (vii) and (viii), shall not exceed $400,000 in the aggregate; (x) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Securities; (xi) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; and (xii) all other costs and expenses incident to the performance by the Company of its obligations under this Agreement.

(k) The Company agrees that, unless it has or shall have obtained the prior written consent of the Representative, and each Underwriter, severally and not jointly, agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, in each case such consent not to be unreasonably withheld, it has not made and will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a Free Writing Prospectus required to be filed by the Company with the SEC or retained by the Company under Rule 433. Any such free writing prospectus consented to by the Representative or the Company is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company agrees that (x) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (y) it has complied and will comply, as the case may be, with the requirements of Rule 164 under the Securities Act ("Rule 164") and Rule 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the SEC, legending and record keeping.

(l) The Company will promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Securities within the meaning of the Securities Act and (b) completion of the 90-day restricted period referred to in Section 5(g) hereof.

(m) If at any time following the distribution of any Written Testing-the-Waters Communication, any event occurs as a result of which such Written Testing-the-Waters Communication would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Representative so that use of the Written Testing-the-Waters Communication may cease until it is amended or supplemented; (ii) amend or supplement the Written Testing-the-Waters Communication to correct such statement or omission; and (iii) supply any amendment or supplement to the Representative in such quantities as may be reasonably requested.

(n) Each Underwriter agrees that (i) it is not purchasing any of the Securities for the account of anyone other than a United States or Canadian Person, (ii) it has not offered or sold, and will not offer or sell, directly or indirectly, any of the Securities or distribute any Prospectus to any person outside the United States or Canada, or to anyone other than a United States or Canadian Person, and (iii) any dealer to whom it may sell any of the Securities will represent that it is not purchasing for the account of anyone other than a United States or Canadian Person and agree that it will not offer or resell, directly or indirectly, any of the Securities outside the United States or Canada, or to anyone other than a United States or Canadian Person or to any other dealer who does not so represent and agree; provided, however, that the foregoing shall not restrict sales to or through (or distributions of the Disclosure Package or the Prospectus to) United States or Canadian Persons who are investment advisors, or who otherwise exercise investment discretion, and who are purchasing for the account of anyone other than a United States or Canadian Person.

(o) The agreements of the Underwriters set forth in paragraph (n) of this Section 5 shall terminate upon the expiration of a period of thirty (30) days after the Closing Date.

6. Conditions to the Obligations of the Underwriters. The obligations of the Underwriters to purchase the Underwritten ADSs and the Option ADSs, as the case may be, shall be subject to the accuracy of the representations and warranties on the part of the Company contained in this Agreement as of the Execution Time, the Closing Date and any settlement date pursuant to Section 3 hereof, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations under this Agreement and to the following additional conditions:

(a) The Prospectus, and any supplement thereto, have been filed in the manner and within the time period required by Rule 424(b); any other material required to be filed by the Company pursuant to Rule 433(d) shall have been filed with the SEC within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or the ADS Registration Statement or any notice objecting to their use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) The Company shall have requested and caused Loeb & Loeb LLP, counsel for the Company, to have furnished to the Representative an opinion and a negative assurance letter, each dated as of the Closing Date and addressed to the Representative, in form and substance reasonably satisfactory to the Underwriters.

(c) The Company shall have requested and caused Giovannelli e Associati, Studio Legale, Italian counsel for the Company, to have furnished to the Representative an opinion, dated as of the Closing Date and addressed to the Representative, in form and substance reasonably satisfactory to the Underwriters.

(d) The Depositary shall have requested and caused [●], counsel for the Depositary, to have furnished to the Representative their opinion dated as of the Closing Date and addressed to the Representative, in form and substance reasonably satisfactory to the Underwriters.

(e) The Representative shall have received from Goodwin Procter LLP, counsel for the Underwriters, such opinion or opinions, dated the Closing Date and addressed to the Representative, with respect to the issuance and sale of the Securities, the Registration Statement, the ADS Registration Statement, the Disclosure Package, the Prospectus (together with any supplement thereto) and other related matters as the Representative may reasonably require, and the Company shall have furnished to such counsel such documents as they request for the purpose of enabling them to pass upon such matters.

(f) The Company shall have furnished to the Representative a certificate of the Company, signed by the Chairman of the Board or the Chief Executive Officer and the Acting Chief Financial Officer of the Company, dated as of the Closing Date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the ADS Registration Statement, the Disclosure Package, the Prospectus and any amendment or supplement thereto, as well as each electronic road show used in connection with the offering of the Securities, and the Underwriting Agreement and that:

(i) the representations and warranties of the Company in the Underwriting Agreement are true and correct on and as of the Closing Date with the same effect as if made on the Closing Date and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the Closing Date;

(ii) no stop order suspending the effectiveness of the Registration Statement or the ADS Registration Statement or of any notice objecting to their use has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and

(iii) since the date of the most recent financial statements included in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto), there has been no material adverse change in the condition (financial or otherwise), prospects, earnings, business or properties of the Company, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(g) The Company shall have requested and caused Mayer Hoffman McCann P.C. to have furnished to the Representative, at the Execution Time and at the Closing Date, letters, dated respectively as of the Execution Time and as of the Closing Date, in form and substance satisfactory to the Representative, (i) confirming that they are independent accountants within the meaning of the Securities Act and the Exchange Act and the applicable rules and regulations adopted by the SEC thereunder and (ii) containing statements and information of the type customarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Disclosure Package and the Prospectus; provided, that the letter delivered on the Closing Date, shall use a "cut-off" date no more than three Business Days prior to such Closing Date.

(h) Subsequent to the Execution Time or, if earlier, the dates as of which information is given in the Registration Statement (exclusive of any amendment thereof) and the Prospectus (exclusive of supplement thereto), there shall not have been any Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto) the effect of which is, in the sole judgment of the Representative, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated by the Registration Statement (exclusive of any amendment thereof), the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(i) The Company and the Depositary shall have executed and delivered the Deposit Agreement in form and substance satisfactory to the Representative, and the Deposit Agreement shall be in full force and effect.

(j) The Depositary shall have furnished or caused to be furnished to the Representative certificates satisfactory to the Representative evidencing the deposit with it or its nominee of the Underlying Securities in respect of which Offered ADSs to be purchased by the Underwriters on such Closing Date are to be issued, and the execution, issuance, countersignature (if applicable) and delivery of the ADRs evidencing such Offered ADSs pursuant to the Deposit Agreement and such other matters related thereto as the Representative reasonably requests.

(k) Prior to the Closing Date, the Company shall have furnished to the Representative such further information, certificates and documents as the Representative may reasonably request.

(l) Subsequent to the Execution Time, there shall not have been any decrease in the rating of any of the Company's debt securities by any "nationally recognized statistical rating organization" (as defined for purposes of Rule 3(a)(62) under the Exchange Act) or any notice given of any intended or potential decrease in any such rating or of a possible change in any such rating that does not indicate the direction of the possible change.

(m) The Securities shall have been listed and admitted and authorized for trading on the Nasdaq Capital Market, and satisfactory evidence of such actions shall have been provided to the Representative.

(n) At the Execution Time, the Company shall have furnished to the Representative a letter, substantially in the form of Exhibit A hereto from each executive officer and director of the Company addressed to the Representative.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Representative and counsel for the Underwriters, this Agreement and all obligations of the Underwriters hereunder may be canceled at, or at any time prior to, the Closing Date by the Representative. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered at the office of Goodwin Procter LLP, counsel for the Underwriters, at 620 Eighth Avenue, New York, NY 10018, on the Closing Date.

7. Reimbursement of Underwriters' Expenses. If the sale of the Securities provided for in this Agreement is not consummated because any condition to the obligations of the Underwriters set forth in Section 6 hereof is not satisfied, because of any termination pursuant to Section 10(i) hereof or because of any refusal, inability or failure on the part of the Company to perform any agreement herein or comply with any provision hereof other than by reason of a default by any of the Underwriters, the Company will reimburse the Underwriters severally through Canaccord Genuity LLC on demand for all expenses (including reasonable fees and disbursements of counsel) that shall have been incurred by them in connection with the proposed purchase and sale of the Securities.

8. Indemnification and Contribution.

(a) The Company agrees to indemnify and hold harmless each Underwriter, the directors, officers, employees, affiliates within the meaning of Rule 405 under the Securities Act, and agents of each Underwriter and each person who controls any Underwriter within the meaning of either the Securities Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement for the registration of the Securities as originally filed or in any amendment thereof, or in the ADS Registration Statement as originally filed or in any amendment thereof, or in the Preliminary Prospectus, the Prospectus, Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and agrees to reimburse each such indemnified party, as incurred, for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representative specifically for inclusion therein. This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signs the Registration Statement or the ADS Registration Statement, and each person who controls the Company within the meaning of either the Securities Act or the Exchange Act, to the same extent as the foregoing indemnity to each Underwriter, but only with reference to written information relating to such Underwriter furnished to the Company by or on behalf of such Underwriter through the Representative specifically for inclusion in the documents referred to in the foregoing indemnity. This indemnity agreement will be in addition to any liability which any Underwriter may otherwise have. The Company acknowledges that the statements set forth (i) in the last paragraph of the cover page regarding delivery of the Securities, syndicate covering transactions and penalty bids and, under the heading "Underwriting", (ii) the sentences related to concessions and reallowances and (iii) the paragraph related to stabilization, syndicate covering transactions and penalty bids in any Preliminary Prospectus and the Prospectus constitute the only information furnished in writing by or on behalf of the several Underwriters for inclusion in any Preliminary Prospectus, Prospectus or any Issuer Free Writing Prospectus.

(c) Promptly after receipt by an indemnified party under this Section 8 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be reasonably satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ separate counsel (including local counsel), and the indemnifying party shall bear the reasonable fees, costs and expenses of such separate counsel (which, if the Issuer is the indemnifying party, shall be limited to one such separate counsel for any Underwriter together with all persons who control such Underwriter within the meaning of the Exchange Act or the Securities Act, and no more than three such separate counsel for all of the Underwriters collectively) if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest, (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, (iii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of the institution of such action or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent (which shall not be unreasonably withheld) of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

(d) In the event that the indemnity provided in paragraph (a) or (b) of this Section 8 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company, and the Underwriters agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending same) (collectively, "Losses") to which the Company, and one or more of the Underwriters may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company and by the Underwriters from the offering of the Securities. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Underwriters shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company and of the Underwriters in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by each of them, and benefits received by the Underwriters shall be deemed to be equal to the total underwriting discounts and commissions, in each case as set forth on the cover page of the Prospectus. Relative fault shall be determined by reference to, among other things, whether any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company, on the one hand or the Underwriters on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company, and the Underwriters agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (d), in no event shall any Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 8, each person who controls an Underwriter within the meaning of either the Securities Act or the Exchange Act and each director, officer, employee, affiliate and agent of an Underwriter shall have the same rights to contribution as such Underwriter, and each person who controls the Company within the meaning of either the Securities Act or the Exchange Act, each officer of the Company who shall have signed the Registration Statement or the ADS Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (d).

9. Default by an Underwriter. If any one or more Underwriters shall fail to purchase and pay for any of the Securities agreed to be purchased by such Underwriter or Underwriters under this Agreement and such failure to purchase shall constitute a default in the performance of its or their obligations under this Agreement, the remaining Underwriters shall be obligated severally to take up and pay for (in the respective proportions which the amount of Securities set forth opposite their names in Schedule I hereto bears to the aggregate amount of Securities set forth opposite the names of all the remaining Underwriters) the Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase; provided, however, that in the event that the aggregate amount of Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase shall exceed 10% of the aggregate amount of Securities set forth in Schedule I hereto, the remaining Underwriters shall have the right to purchase all, but shall not be under any obligation to purchase any, of the Securities, and if such nondefaulting Underwriters do not purchase all the Securities, this Agreement will terminate without liability to any nondefaulting Underwriter or the Company. In the event of a default by any Underwriter as set forth in this Section 9, the Closing Date shall be postponed for such period, not exceeding five Business Days, as the Representative shall determine in order that the required changes in the Registration Statement, the ADS Registration Statement and the Prospectus or in any other documents or arrangements may be effected. Nothing contained in this Agreement shall relieve any defaulting Underwriter of its liability, if any, to the Company and any nondefaulting Underwriter for damages occasioned by its default under this Agreement.

10. Termination. This Agreement shall be subject to termination in the absolute discretion of the Representative, by notice given to the Company prior to delivery of and payment for the Securities, if at any time prior to such delivery and payment (i) trading in the Company's Ordinary Shares shall have been suspended by the SEC, (ii) trading in securities generally on the New York Stock Exchange or the Nasdaq Stock Market shall have been suspended or limited or minimum prices shall have been established on either of such exchanges, (iii) a banking moratorium shall have been declared by U.S. Federal, New York State or Italian authorities, (iv) there shall have occurred a material disruption in commercial banking or securities settlement or clearance services or (v) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States or Italy of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the sole judgment of the Representative, impractical or inadvisable to proceed with the offering or delivery of the Securities as contemplated by the Preliminary Prospectus and the Prospectus (exclusive of any amendment or supplement thereto).

11. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers or directors and of the Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of the officers, directors, employees, agents, affiliates or controlling persons referred to in Section 8 hereof, and will survive delivery of and payment for the Securities. The provisions of Sections 7 and 8 hereof shall survive the termination or cancellation of this Agreement.

12. Notices. All communications hereunder will be in writing and effective only on receipt, and, if sent to the Representative, will be mailed or delivered to Canaccord Genuity LLC at 99 High Street, 12th floor, Boston, MA 02110, Attention: Syndicate Department; or, if sent to Genenta Science S.p.A., will be mailed or delivered to Via Olgettina No. 58, 20132 Milan, Italy, Attention: Pierluigi Paracchi, with a copy (which shall not constitute notice) to Loeb & Loeb LLP, 345 Park Avenue, New York, NY 10154, Attention: Norwood Beveridge.

13. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 8 hereof, and no other person will have any right or obligation hereunder.

14. Jurisdiction. The Company agrees that any suit, action or proceeding against the Company brought by any Underwriter, the directors, officers, employees, affiliates and agents of any Underwriter, or by any person who controls any Underwriter, arising out of or based upon this Underwriting Agreement or the transactions contemplated hereby may be instituted in any state or U.S. federal court in The City of New York and County of New York, and waives any objection which it may now or hereafter have to the laying of venue of any such proceeding, and irrevocably submits to the non-exclusive jurisdiction of such courts in any suit, action or proceeding. The Company has appointed Cogency Global Inc., 122 East 42nd Street, 18th Floor, New York, New York 10168, as its authorized agent (the "Authorized Agent") upon whom process may be served in any suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated herein that may be instituted in any State or U.S. federal court in The City of New York and County of New York, by any Underwriter, the directors, officers, employees, affiliates and agents of any Underwriter, or by any person who controls any Underwriter, and expressly accepts the non-exclusive jurisdiction of any such court in respect of any such suit, action or proceeding. The Company hereby represents and warrants that the Authorized Agent has accepted such appointment and has agreed to act as said agent for service of process, and the Company agrees to take any and all action, including the filing of any and all documents that may be necessary to continue such appointment in full force and effect as aforesaid. Service of process upon the Authorized Agent shall be deemed, in every respect, effective service of process upon the Company. Notwithstanding the foregoing, any action arising out of or based upon this Agreement may be instituted by any Underwriter, the directors, officers, employees and agents of any Underwriter, or by any person who controls any Underwriter, in any court of competent jurisdiction in Italy.

15. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 15, "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b), (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b) or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b); "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

16. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Securities pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriters and any affiliate through which it may be acting, on the other, (b) the Underwriters are acting as principal and not as an agent or fiduciary of the Company and (c) the Company's engagement of the Underwriters in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether any of the Underwriters has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Underwriters have rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

17. Integration. This Agreement, together with the letter agreement dated November 24, 2020 (the "Engagement Letter"), by and among the Company, Canaccord Genuity LLC and Roth Capital Partners, LLC, supersedes all prior agreements and understandings (whether written or oral) between the Company, and the Underwriters, with respect to the subject matter hereof, provided however that the provisions of Section 5(j) shall supersede the provisions of the Engagement Letter regarding such reimbursement arrangements regarding the expenses of the Underwriters.

18. Applicable Law. This Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York.

19. Currency. Each reference in this Agreement to U.S. Dollars (the "relevant currency") is of the essence. To the fullest extent permitted by law, the obligations of each of the Company in respect of any amount due under this Agreement will, notwithstanding any payment in any other currency (whether pursuant to a judgment or otherwise), be discharged only to the extent of the amount in the relevant currency that the party entitled to receive such payment may, in accordance with its normal procedures, purchase with the sum paid in such other currency (after any premium and costs of exchange) on the Business Day immediately following the day on which such party receives such payment. If the amount in the relevant currency that may be so purchased for any reason falls short of the amount originally due, the Company making such payment will pay such additional amounts, in the relevant currency, as may be necessary to compensate for the shortfall. Any obligation of any of the Company not discharged by such payment will, to the fullest extent permitted by applicable law, be due as a separate and independent obligation and, until discharged as provided herein, will continue in full force and effect.

20. Waiver of Immunity. To the extent that the Company has or hereafter may acquire any immunity (sovereign or otherwise) from any legal action, suit or proceeding, from jurisdiction of any court or from set-off or any legal process (whether service or notice, attachment in aid or otherwise) with respect to itself or any of its property, the Company hereby irrevocably waives and agrees not to plead or claim such immunity in respect of its obligations under this Agreement.

21. Waiver of Jury Trial. The Company hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

22. Counterparts. This Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement.

23. Headings. The section headings used herein are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the several Underwriters.

Very truly yours,

GENENTA SCIENCE S.P.A.

By: _____
Name: Pierluigi Paracchi
Title: Chief Executive Officer

[*Signature Page to Underwriting Agreement*]

The foregoing Agreement is hereby confirmed and accepted as of the date first above written.

Canaccord Genuity LLC

By: Canaccord Genuity LLC

By: _____
Name:
Title:

For itself and the other several Underwriters named in Schedule I to the foregoing Agreement.

SCHEDULE I

Underwriters	Number of ADSs to be Purchased
Canaccord Genuity LLC	[●]
Roth Capital Partners, LLC	[●]
Total	[●]

SCHEDULE II

Schedule of Free Writing Prospectuses included in the Disclosure Package

None.

SCHEDULE III

Schedule of Written Testing-the-Waters Communications

Testing-the-Waters presentations:

- Corporate Presentation dated January 2021
- [●]
- [●]
- [●]

EXHIBIT A

Form of Lock-Up Agreement

[Circulated under separate cover]

EXHIBIT B

Form of Press Release

Genenta Science S.p.A.
[*insert date***]**

Genenta Science S.p.A. (the "Company") announced today that Canaccord Genuity LLC and Roth Capital Partners, LLC, the joint book-running managers in the Company's recent public sale of [●] American Depositary Shares ("ADSs") representing the Company's Ordinary Shares, is [waiving] [releasing] a lock-up restriction with respect to [●] shares of the Company's [ADSs] [Ordinary Shares] held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on **[***insert date***],** 20__, and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

[Form of Waiver of Lock-up] ADDENDUM

[*Letterhead of Canaccord Genuity LLC***]**

GENENTA SCIENCE S.P.A.
Public Offering of Ordinary Shares represented by American Depositary Shares

[*insert date***]**, 20__

[*name and address of officer or director requesting waiver***]**

Dear Mr./Ms. **[***insert name***]**:

This letter is being delivered to you in connection with the offering by Genenta Science S.p.A. (the "Company") of an aggregate of [●] American Depositary Shares ("ADSs"), representing Ordinary Shares, no par value, of the Company, represented by and the lock-up letter dated **[***insert date***]**, 2021 (the "Lock-up Letter"), executed by you in connection with such offering, and your request for a [waiver] [release] dated **[***insert date***]**, 20__, with respect to [●] shares of [ADSs] [Ordinary Shares] (the "Shares").

Canaccord Genuity LLC hereby agrees to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective **[***insert date***]**, 20__; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Yours very truly,

Canaccord Genuity LLC

By: _____
Name:
Title:

cc: Genenta Science S.p.A.

Exhibit 3.2

[*note: in case of discrepancies, Italian version shall prevail*]

CORPORATE CHARTER

TITLE I
CORPORATE NAME – CORPORATE PURPOSE – REGISTERED OFFICE – SHAREHOLDERS' DOMICILE – TERM

Article 1 - Corporate name

A joint stock company has been incorporated under the name: "Genenta Science S.p.A.".

Article 2 - Registered office

The Company has its registered office in the Municipality of Milan, at the address resulting from the registration with the Register of Enterprises of Milan, pursuant to section 111 -ter of the preliminary dispositions prefacing the Italian Civil Code and transitory provisions.

The Board of Directors is entitled to establish or close down, both in Italy and abroad, local units (such as, for instance, branch offices, subsidiaries, administrative offices, representative offices, warehouses and stores), or to resolve upon the establishment of secondary offices or upon the transfer of the registered office to a Municipality other than the one above indicated, provided that it is within the national territory of Italy.

Article 3 - Shareholders' domicile

A shareholder's address for all relationships with the Company is deemed to be the address resulting from the Shareholders' ledger. Each Shareholder must communicate any change in address to the Company.

Article 4 - Corporate purpose

The Company achieves the following purpose:

a) research, development, production, mass production and sale of new therapeutic compounds of bio-technological, biologic and chemical origin relating to the pharmaceutical, biotechnological, molecular and cellular medicine, genetic and diagnostic segments of industry (hereinafter also the **"Business**");

b) production, processing of materials and provision of services in relation to the Business;

c) development and improvement of new technologies and procedures in relation to the Business;

d) mass production, production and distribution on own behalf and on behalf of third parties of pharmaceutical and para-pharmaceutical products, bio-technological, biologic and chemical products and their derivatives;

e) promotion and organisation or updates to its offering of scientific courses.

In order to achieve the Company purpose, the Company may execute any transaction it considers necessary or useful, albeit only secondarily and only as a means to achieving its stated purpose, which may involve transactions in securities, real property, commercial, industrial or financial in nature, including taking on mortgages and unsecured debt, in any form, with private individuals, companies, and banks, and issue collateral and other guarantees, including personal guarantees, letters of indemnity and guarantee. The Company may also take on and sell, directly or indirectly, interests in or investments in other companies or enterprise whether established or in the process of establishment, whose purpose is similar, related or in any way connected to its own.

Expressly excluded from the company purpose is any activity vis-à-vis the public that the law defines as "financial activity" and, except in certain cases and the full compliance with the related provisions set forth by law, any reserved professional activities and activities allowed by law only to certain individuals and legal entities.

Article 5 – Duration

The term of the Company is scheduled to expire on 31 December 2050.

TITLE II
CAPITAL AND SHARES

Article 6 - Capital and shares

The corporate capital of the Company is equal to Euro [●] and is divided into number [●] shares. Pursuant to section 2441 of the Italian Civil Code, the corporate capital may be increased and subscribed proportionately by the shareholders, all at once or at different times, through contributions in kind and/or contributions of receivables and/or capitalization of available reserves, by means of resolutions of the Shareholders' meeting and in compliance with applicable law.

The corporate capital may also be increased by issuing shares entailing rights other than those granted by the previous shares.

The capital increase may take place through contribution in cash or in kind or of receivables, whether proportional or not, in compliance with applicable law.

The shareholders may also grant the Company loans, which shall be governed by the laws and regulations then in effect. Shareholder loans calling for repayment of principal need not be made in proportion to shares held in the Company's corporate capital, in compliance with procedures and restrictions set out in applicable laws and regulations in effect from time to time.

Pursuant to section 2346, par. 1, of the Italian Civil Code, unless otherwise provided by applicable law, evidencing shares representing the Company's capital shall not be represented by share certificates. The shares shall be uncertificated (*dematerializzate*) pursuant to section 83-bis *et seq*. of Legislative Decree no. 58 of 24 February 1998. [***NOTE: to be evaluated. Technical assessment underway***]

Pursuant to section 2443 of the Italian Civil Code, Shareholders acting at a properly convened Shareholders' meeting may delegate to the Board of Directors the power to increase the corporate capital, on one or more occasions, up to a specified amount for a period not to exceed the maximum term of five years from the date of the relevant resolution.

[NOTE: to be drafted details concerning capital increases as indicated in the Notarial deed issuing shares for IPO]

Article 7 - Transfer of Shares

The shares may be freely transferred.

TITLE III
DEBT SECURITIES

Article 8 – Issuance of Debt Securities

The Board of Directors may approve the issuance of debt securities (*obbligazioni*) in registered or bearer form, with the terms and conditions thereof to be set forth in the applicable resolutions of the Board of Directors, subject to compliance with section 2412 of the Italian Civil Code. Shareholders acting at a properly convened Shareholders' meeting may resolve to issue convertible debt securities, with the conversion rate and other terms and conditions, including conversion procedures being set forth in the applicable resolutions, as well as to issue participating securities, with the terms and conditions thereof being set forth in the applicable resolutions.

TITLE IV
Article 9 - Shareholders' meetings

9.1 Shareholders' meetings shall be held at the registered office of the Company or elsewhere, provided that the location is in Italy or in another country within the European Union or in the United States of America.

Shareholders' meetings can be called at any time as the Board of Directors deems it necessary or upon request by Shareholders representing at least 10% of the share capital.

Ordinary Shareholders' meetings shall be held at least once a year, within 120 days following the end of the financial year or, if special circumstances so warrant or the Company is required to prepare consolidated financial statements, within 180 days following the end of the financial year. In such cases the Board of Directors shall specify the reasons for such extension in its report to Shareholders.

9.2 [Shareholders with voting rights are entitled to attend Shareholders' meetings. The right to attend the meeting and exercise voting rights shall be attested by a a report of eligible Shareholders delivered to the Company by the transfer agent based on its books and records as of the close of business on the seventh business day prior to the date established for the Shareholders' meeting (assuming that the meeting is convened on the earliest date noticed to Shareholders).] [***NOTE: to be evaluated. Technical assessment underway***]

Subject to applicable law, Shareholders entitled to vote at a Shareholders' Meeting may vote in advance of the Shareholders' Meeting by mail or, if specified in the notice of the meeting, electronically in such manner as specified therein.

9.3 Shareholders' meetings, both ordinary and special, shall be called by notice published in the Italian daily newspaper "Il Sole 24 Ore" at least fifteen days prior to the date of the meeting or otherwise given by the Company, provided that so long as the Company is allowed by applicable Italian law, by sending, either in the alternative to or in addition to the foregoing published notice, a notice to the Shareholders, to the members of the Board of Directors and to the members of the Board of Auditors, by:

(a) registered mail with return receipt requested;

(b) e-mail with electronic acknowledgment of receipt;

as long as the notice is received by the addressee at least 8 calendar days before the date set for the meeting with evidence thereof as provided above.

The notice shall also be posted on the Company's web site.

The notice shall set forth the agenda for the meeting as well as the date and place where the meeting is to be held and the date for an adjourned meeting in the event a quorum is missing on the original date set for the meeting.

9.4 The Shareholders' meeting shall be chaired by a person selected by those in attendance.

9.5 Both ordinary and special Shareholders' meetings may also be held via teleconference or videoconference, provided that all participants can be identified, that they can follow the discussion and that they can hear and be heard live with respect to the matters on the agenda and are able to express their vote simultaneously on such items.

The meeting notice may specify alternative locations, whether in the registered office or elsewhere, where Shareholders may convene to participate via teleconference or videoconference connection.

Should these conditions be met, it is not necessary for the person chairing the meeting and the person acting as secretary for the meeting to be present at the same location. The meeting shall be deemed to be held at the location where the person acting as secretary to record the minutes of the meeting is present. In the event that the above conditions are not met, the meeting shall be deemed to have been validly convened and held so long as the entire share capital is present or duly represented and a majority of the members of the Board of Directors and the Board of Auditors are in attendance; provided that in such event, any Shareholder or other participant present may object to the discussion of items with respect to which he/she does not deem to have been adequately informed.

9.6 A Shareholders' meeting shall be deemed to have been validly called and convened and can duly act according to such majorities as provided by applicable law.

9.7 At an ordinary Shareholders' meeting Shareholders may adopt resolutions with respect to any and all matters as to which Shareholders have the power to vote pursuant to applicable law or this corporate charter.

9.8 At a special Shareholders' meeting Shareholders may adopt resolutions with respect to any amendments to this corporate charter, the issuance of debt securities convertible into shares, any issuance of additional shares (*aumento di capitale*), the appointment, replacement and powers of receivers and liquidators, and any and all other matters as to which Shareholders have the power to vote pursuant to applicable law or this corporate charter.

9.9 Each share entitles the holder to one vote, subject to the provisions of this corporate charter with respect to particular classes of shares.

9.10 Any shareholder may name a proxy to represent such Shareholder at the Shareholders' meeting subject to section 2372 of the Italian Civil Code.

TITLE V
Article 10 – Board of Directors

10.1 The Company shall be managed by a Board of Directors composed of a minimum of three directors and a maximum of seven directors, as determined by the resolution of the shareholders at the time of the election.

The non-compete obligation upon directors, pursuant to Article 2390 of the Italian Civil Code, does not apply.

Candidates for election to the Board of Directors shall be elected on the basis of slates submitted by shareholders, on which candidates must be listed in the order in which they will be elected on the basis of the requisite vote. Slates shall be deposited at the Company's registered office no later than twenty-five calendar days prior to the date set for the Shareholders' Meeting for which the election of directors is on the agenda. Any Shareholder, acting individually or through a nominee, may submit or join in the submission of a single slate and may cast its vote for a single slate. Each candidate for election to the Board of Directors may be listed on a single slate, and shall automatically be ineligible for election if named on multiple slates. Only Shareholders who, alone or together with other Shareholders joining in the submission of the slate, represent at least 6% of the share capital eligible to vote at the Shareholders' meeting at which directors are to be elected, such eligibility to be established by filing an appropriate certification to that effect. Certification of the ownership of the number of shares necessary for submission of a slate must be produced at the time of deposit of the slate or at a later date, provided that such certification is provided by the deadline for the deposit of a slate.] [***NOTE: to be evaluated. Technical assessment underway***]

Together with and at the same time as the deposit of a slate, the following shall be filed, with failure to comply with such filing requirements leading to the candidates named on the slate being automatically ineligible for election: (i) biographical information for each candidate; (ii) information on the identity of the Shareholders who have submitted the slate, with an indication of the total percentage of the Company's share capital held: (iii) consent by each candidate to be named in the slate and certification, under his/her own responsibility, that no grounds for ineligibility or incompatibility to serve as a member of the Board of Directors, as well as the satisfaction of the requirements prescribed by applicable law to be a director of the Company, including, where applicable, whether the candidate would be an independent director, if elected, and (iv) such other statements or information as required by law or applicable securities exchange rules and regulations.

Any slates submitted without compliance with the above requirements shall be deemed not to have been submitted.

Directors shall be elected as follows: a) candidates for election as directors equal to the number of seats on the Board of Directors minus 1 shall be selected from the slate that receives the greatest number of votes cast (the "Majority Slate") shall be elected in the order in which they are listed on the slate; b) the first candidate listed on the slate that receives the second greatest number of votes cast (the "Minority Slate") shall be elected as director so long as the Minority Slate is not connected in any way, directly or indirectly, with the Shareholders who submitted or voted for the Majority Slate. In the event that the Majority Slate does not contain a sufficient number of candidates to fill the number of vacancies on the Board of Directors to be filled as provided in clause a) above, all candidates listed in the Majority Slate shall be elected directors and the remaining directors shall be elected from the Minority Slate according to the order in which they are listed in such slate. The voting procedure according to slates provided above shall be applicable only in case of election of the entire Board of Directors.

In the event of a tie between slates, a new vote shall be taken and the candidates obtaining the largest number of votes shall be elected without regard to the slate on which they are listed or application of the slate voting mechanism.

Should a single slate be submitted, the Shareholders eligible to vote at the meeting shall cast their vote on such slate and, so long as more votes are cast for such slate than votes cast against such slate, all the members of the Board of Directors shall be elected from that slate in accordance with applicable law at the time.

If no slates are submitted, or a single slate is submitted and such slate does not obtain the requisite number of votes, or the number of directors to be elected on the basis of the slates submitted is less than the full number of directors to be elected, or the entire Board of Directors is not to be entirely elected, or it is otherwise not possible for any reason to elect the Board of Directors in accordance with the provisions of this title, the members of the Board of Directors shall be elected at the Shareholders' meeting in accordance with generally applicable procedures and required majorities under applicable law, without application of the slate voting mechanism.

10.2 Directors shall be elected for a three-year term and may be re-elected, except as otherwise resolved by Shareholders at the time of their election.

10.3 The Board of Directors shall appoint a Chairman among its members, unless the Chairman is not appointed by a vote of Shareholders', as well as a Deputy Chairman.

10.4 Meetings of the Board of Directors may be called by the Chairman or the Deputy Chairman and shall be called upon request by at least one director or by the Board of Auditors.

10.5 Resolutions of the Board of Directors' shall be deemed validly adopted if a majority of directors in office are present at the meeting.

10.6 Resolutions of the Board of Directors shall be deemed approved with the favourable vote of a majority of the directors present at the meeting.

10.7 The Board of Directors may act with respect to any and all matters related to the ordinary and extraordinary affairs of the Company as necessary and/or appropriate for the conduct of the Company's business in accordance with its purpose.

The Board of Directors shall also have authority with respect to the following matters:

(i) resolutions concerning mergers in the cases referred to in Articles 2505, 2505-bis and 2506-ter of the Civil Code;

(ii) reduction of the share capital in case of withdrawal of a shareholder;

(iii) amendments to the Articles of Association to comply with applicable law provisions.

10.8 The Board of Directors may establish one or more committees with advisory, deliberative or oversight functions in accordance with applicable laws and regulations in whatsoever applicable jurisdiction, as well as with codes of conduct and corporate governance best practices. If one or more committees are established, their composition, powers and operation shall be as determined by the Board of Directors.

The Board of Directors may delegate its powers to one or more of its members or to an executive committee comprised of members of the Board of Directors and shall determine the scope of their delegated authority and related restrictions, policies and procedures, in compliance with this corporate charter.

10.9 The Board of Directors may appoint one or more deputy chairs and designate a Secretary, which need not be a director.

10.10 If the Board of Directors delegate some of its powers to one or more managing directors and/or an executive committee, they shall report to the full Board of Directors at least every six months (or more frequently if resolved by the Board of Directors in delegating such powers) on their activities generally and their expected activities as well as on the most important matters, in a quantitative or qualitative sense, carried out by the Company or by any of its controlled subsidiaries.

10.11 Shareholders acting at a regular meeting may establish aggregate compensation for the entire Board of Directors, which the Board of Directors shall have authority to allocate among individual directors on the basis of their respective duties and responsibilities, including service on specific committees of the Board.

Members of the Board of Directors shall be entitled to reimbursement of the expenses incurred in fulfilling to their responsibilities.

10.12 The Board of Directors may appoint such officers, agents and other representatives of the Company, which need not be employees of the Company, and delegate to them such powers with respect to specific matters or categories of matters in the name and on behalf of the Company. The Board of Directors may also appoint one or more General Managers, establishing their powers and duties.

10.13 The power to bind the Company and to act as its legal representative with third parties and in front of courts shall belong to the Chairman of the Board of Directors, the Deputy Chairman and such managing director(s), if any, in accordance with the powers delegated to them upon their appointment.

10.14 Notice of any meeting of the Board of Directors shall be sent by the Chairman, the Deputy Chairman or any managing director by registered letter or e-mail to be sent at least four calendar days prior to the meeting to each director and to the members of the Board of Auditors, or, in case of urgency, by telegram or fax or by e-mail sent at least twenty-four hours before the meeting.

The notice of a meeting must indicate the place of the meeting, which may be the registered office or the Company or elsewhere, provided that it is in Italy, in another country within the European Union or in the United States of America.

10.15 Meetings of the Board of Directors may also be held via teleconference or videoconference, provided that all directors in attendance can be identified, can participate in the discussion and may hear and be heard live on the matters to be dealt with and acted upon.

10.16 Subject to satisfaction of the above requirements, it is not necessary for the Chairman and the person acting as the secretary for the meeting to be present in the same location. The meeting is deemed to be held in the location where the person acting as the secretary for the meeting is present.

Meetings of the Board of Directors shall be chaired by the Chairman or, in the event of his or her absence, incapacity or refusal, by the Deputy Chairman or by a managing director, if one has been appointed, or by a director designated by the directors present at the meeting.

10.17 Any director who has a conflict of interest with respect to a matter to be acted upon must disclose it to the other directors according section 2391 of the Italian Civil Code.

10.18 Meetings of the Board of Directors shall be deemed to have been validly held even in the absence of any formal call, provided that all directors and all members of the Board of Auditors are in attendance, including via teleconference or videoconference.

10.19 Board of Directors' resolutions shall be set forth in minutes signed by the Chairman and the secretary of the meeting.

TITLE VI
Article 11 - Board of Auditors and Internal Auditing

11.1 The Board of Auditors shall consist of three statutory and two alternate members and shall act in accordance with applicable law.

The Board of Auditors shall be elected on the basis of slates submitted by Shareholders, on which candidates must be listed in the order in which they will be elected on the basis of the requisite vote. Slates shall be deposited at the Company's registered office no later than twenty-five calendar days prior to the date set for the Shareholders' Meeting for which the election of members of the Board of Auditors is on the agenda. Any Shareholder, acting individually or through a nominee, may submit or join in the submission of a single slate and may cast its vote for a single slate. Each candidate for election to the Board of Auditors may be listed on a single slate, and shall automatically be ineligible for election if named on multiple slates. Only Shareholders who, alone or together with other Shareholders joining in the submission of the slate, represent at least 6% of the share capital eligible to vote at the Shareholders' meeting at which members of the Board of Auditors are to be elected, such eligibility to be established by filing an appropriate certification to that effect. Certification of the ownership of the number of shares necessary for submission of a slate must be produced at the time of deposit of the slate or at a later date, provided that such certification is provided by the deadline for the deposit of a slate. [***NOTE: to be evaluated. Technical assessment underway***]

Together with and at the same time as the deposit of a slate, the following shall be filed, with failure to comply with such filing requirements leading to the candidates named on the slate being automatically ineligible for election: (i) biographical information for each candidate; (ii) information on the identity of the Shareholders who have submitted the slate, with an indication of the total percentage of the Company's share capital held: (iii) consent by each candidate to be named in the slate and certification, under his/her own responsibility, that no grounds for ineligibility or incompatibility to serve as a member of the Board of Auditors, as well as the satisfaction of the requirements prescribed by applicable law to be an internal auditor, including those relating to independency, and (iv) such other statements or information as required by law or applicable securities exchange rules and regulations.

Any slates submitted without compliance with the above requirements shall be deemed not to have been submitted.

Members of the Board of Auditors shall be elected as follows: a) candidates for election as auditors equal to two statutory members and one alternate for the Board of Auditors shall be selected from the slate that receives the greatest number of votes cast (the "Majority Slate") shall be elected in the order in which they are listed on the slate; b) the remaining statutory member (who will act as President of the Board of Auditors) and alternate for the Board of Auditors will be drawn from the slate that receives the second greatest number of votes cast (the "Minority Slate") so long as the Minority Slate is not connected in any way, directly or indirectly, with the Shareholders who submitted or voted for the Majority Slate. In the event that the Majority Slate does not contain a sufficient number of candidates to fill the number of vacancies on the Board of Auditors to be filled as provided in clause a) above, all candidates listed in the Majority Slate shall be elected internal auditors and the remaining internal auditors shall be drawn from the Minority Slate according to the order in which they are listed in such slate. The voting procedure according to slates provided above shall be applicable only in case of election of the entire Board of Auditors.

In the event of a tie between slates, a new vote shall be taken and the candidates obtaining the largest number of votes shall be elected without regard to the slate on which they are listed or application of the slate voting mechanism.

Should a single slate be submitted, the Shareholders eligible to vote at the meeting shall cast their vote on such slate and, so long as more votes are cast for such slate than votes cast against such slate, all the members of the Board of Auditors shall be elected from that slate in accordance with applicable law at the time.

If no slates are submitted, or a single slate is submitted and such slate does not obtain the requisite number of votes, or the number of internal auditors to be elected on the basis of the slates submitted is less than the full number of internal auditors to be elected, or the Board of Auditors is not to be entirely elected, or it is otherwise not possible for any reason to elect the Board of Auditors in accordance with the provisions of this title, the members of the Board of Auditors shall be elected at the Shareholders' meeting in accordance with generally applicable procedures and required majorities under applicable law, without application of the slate voting mechanism.

In the event of the resignation or removal termination of a member of the Board of Auditors who was drawn from the Majority Slate or from the Minority Slate, as the case may be, alternate internal auditors drawn from the same slate shall fill the vacancy in declining order of age, subject to compliance with the requirements of this corporate charter regarding the composition of the Board of Auditors. The election of internal auditors to fill other vacancies on the Board of Auditors pursuant to Article 2401 of the Italian Civil Code shall be approved at a Shareholders' Meeting with the affirmative vote of an absolute majority of those present and voting and in compliance with the principle of the appropriate representation of minority shareholders. In the event of the removal or resignation of an internal auditor chosen from the Minority Slate, the principle of appropriate representation of minority shareholders shall be deemed to have been complied with is an alternate auditor drawn from the Minority Slate is appointed.

11.2 Should the Board of Auditors also be engaged to audit the financial statements and accounts of the Company pursuant to section 2409-bis, par. 2, of the Italian Civil Code, the Board of Auditors shall be comprised entirely of auditors listed in the applicable register.

11.3 Meetings of the Board of Auditors may be held via teleconference or videoconference, provided that all internal auditors in attendance can be identified, can participate in the discussion and may hear and be heard live on the matters to be dealt with and acted upon. The meeting shall be deemed to have been held at the location where the President and the Secretary are present.

11.4 For anything not provided herein, the Italian Civil Code and applicable laws concerning internal audit committees and the auditing function shall apply.

TITLE VII
Article 12 - Withdrawal

12.1 Shareholders may exercise their right of withdrawal in the cases and according to the procedures provided by applicable law.

12.2 However, withdrawal right shall be excluded for those shareholders who have not taken part in or have voted against the resolutions concerning:

(a) the introduction or removal of any restraint on circulation of the shares;

(b) the extension of the Company's term.

TITLE VIII
Article 13 - Financial statements and Profits

13.1 The Company's fiscal year shall end on 31 December of each year. At the end of each fiscal year, the Board of Directors shall have financial statements prepared in accordance with applicable law.

13.2 5% of the net profits resulting from the year-end financial statements shall be set aside as legal reserves, until the aggregate amount allocated to such reserve equals one fifth of the share capital.

13.3 The remaining net profits shall be available for the payment of dividends as approved at a meeting of Shareholders or for such other purposes as the Shareholders will deem most appropriate or necessary.

13.4 Dividends not collected within five years following the day on which they became payable shall be deemed forfeited back to the Company.

TITLE IX
Article 14 - Winding-up and Liquidation

14.1 Should the Company be wound up at any time, the Shareholders acting at a duly called and convened meeting shall approve procedures to be followed for liquidation and shall appoint one or more receivers or liquidators, as their powers.

TITLE X
Article 15 - Final provisions

15.1 Any matter not specifically provided in this corporate charter shall be governed by the provisions of the Italian Civil Code and other applicable laws then in force with respect to joint stock companies.

Exhibit 4.1

GENETA SCIENCE S.P.A.

AND

THE BANK OF NEW YORK MELLON

As Depositary

AND

OWNERS AND HOLDERS OF AMERICAN DEPOSITARY SHARES

Deposit Agreement

_____, 2021

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DEPOSIT AGREEMENT

DEPOSIT AGREEMENT dated as of _____, 2021 among GENETA SCIENCE S.P.A., a company incorporated under the laws of Italy (herein called the Company), THE BANK OF NEW YORK MELLON, a New York banking corporation (herein called the Depositary), and all Owners and Holders (each as hereinafter defined) from time to time of American Depositary Shares issued hereunder.

W I T N E S S E T H:

WHEREAS, the Company desires to provide, as set forth in this Deposit Agreement, for the deposit of Shares (as hereinafter defined) of the Company from time to time with the Depositary or with the Custodian (as hereinafter defined) under this Deposit Agreement, for the creation of American Depositary Shares representing the Shares so deposited and for the execution and delivery of American Depositary Receipts evidencing the American Depositary Shares; and

WHEREAS, the American Depositary Receipts are to be substantially in the form of Exhibit A annexed to this Deposit Agreement, with appropriate insertions, modifications and omissions, as set forth in this Deposit Agreement;

NOW, THEREFORE, in consideration of the premises, it is agreed by and between the parties hereto as follows:

ARTICLE 1. DEFINITIONS

The following definitions shall for all purposes, unless otherwise clearly indicated, apply to the respective terms used in this Deposit Agreement:

SECTION 1.1. American Depositary Shares.

The term "American Depositary Shares" shall mean the securities created under this Deposit Agreement representing rights with respect to the Deposited Securities. American Depositary Shares may be certificated securities evidenced by Receipts or uncertificated securities. The form of Receipt annexed as Exhibit A to this Deposit Agreement shall be the prospectus required under the Securities Act of 1933 for sales of both certificated and uncertificated American Depositary Shares. Except for those provisions of this Deposit Agreement that refer specifically to Receipts, all the provisions of this Deposit Agreement shall apply to both certificated and uncertificated American Depositary Shares.

Each American Depositary Share shall represent the number of Shares specified in Exhibit A to this Deposit Agreement, except that, if there is a distribution upon Deposited Securities covered by Section 4.3, a change in Deposited Securities covered by Section 4.8 with respect to which additional American Depositary Shares are not delivered or a sale of Deposited Securities under Section 3.2 or 4.8, each American Depositary Share shall thereafter represent the amount of Shares or other Deposited Securities that are then on deposit per American Depositary Share after giving effect to that distribution, change or sale.

SECTION 1.2. Commission.

The term "Commission" shall mean the Securities and Exchange Commission of the United States or any successor governmental agency in the United States.

SECTION 1.3. Company.

The term "Company" shall mean Geneta Science S.p.A., a company incorporated under the laws of Italy, and its successors.

SECTION 1.4. Custodian.

The term "Custodian" shall mean The Bank of New York Mellon, acting through an office located in the United Kingdom, as custodian for the Depositary for the purposes of this Deposit Agreement, and any other firm or corporation the Depositary appoints under Section 5.5 as a substitute or additional custodian under this Deposit Agreement, and shall also mean all of them collectively.

SECTION 1.5. Deliver; Surrender.

(a) The term "deliver", or its noun form, when used with respect to Shares or other Deposited Securities, shall mean (i) book-entry transfer of those Shares or other Deposited Securities to an account maintained by an institution authorized under applicable law to effect transfers of such securities designated by the person entitled to that delivery or (ii) physical transfer of certificates evidencing those Shares or other Deposited Securities registered in the name of, or duly endorsed or accompanied by proper instruments of transfer to, the person entitled to that delivery.

(b) The term "deliver", or its noun form, when used with respect to American Depositary Shares, shall mean (i) registration of those American Depositary Shares in the name of DTC or its nominee and book-entry transfer of those American Depositary Shares to an account at DTC designated by the person entitled to that delivery, (ii) registration of those American Depositary Shares not evidenced by a Receipt on the books of the Depositary in the name requested by the person entitled to that delivery and mailing to that person of a statement confirming that registration or (iii) if requested by the person entitled to that delivery, execution and delivery at the Depositary's Office to the person entitled to that delivery of one or more Receipts evidencing those American Depositary Shares registered in the name requested by that person.

(c) The term "surrender", when used with respect to American Depositary Shares, shall mean (i) one or more book-entry transfers of American Depositary Shares to the DTC account of the Depositary, (ii) delivery to the Depositary at its Office of an instruction to surrender American Depositary Shares not evidenced by a Receipt or (iii) surrender to the Depositary at its Office of one or more Receipts evidencing American Depositary Shares.

SECTION 1.6. Deposit Agreement.

The term "Deposit Agreement" shall mean this Deposit Agreement, as it may be amended from time to time in accordance with the provisions of this Deposit Agreement.

SECTION 1.7. Depositary; Depositary's Office.

The term "Depositary" shall mean The Bank of New York Mellon, a New York banking corporation, and any successor as depositary under this Deposit Agreement. The term "Office", when used with respect to the Depositary, shall mean the office at which its depositary receipts business is administered, which, at the date of this Deposit Agreement, is located at 240 Greenwich Street, New York, New York 10286.

SECTION 1.8. Deposited Securities.

The term "Deposited Securities" as of any time shall mean Shares at such time deposited or deemed to be deposited under this Deposit Agreement, including without limitation, Shares that have not been successfully delivered upon surrender of American Depositary Shares, and any and all other securities, property and cash received by the Depositary or the Custodian in respect of Deposited Securities and at that time held under this Deposit Agreement.

SECTION 1.9. Disseminate.

The term "Disseminate," when referring to a notice or other information to be sent by the Depositary to Owners, shall mean (i) sending that information to Owners in paper form by mail or another means or (ii) with the consent of Owners, another procedure that has the effect of making the information available to Owners, which may include (A) sending the information by electronic mail or electronic messaging or (B) sending in paper form or by electronic mail or messaging a statement that the information is available and may be accessed by the Owner on an Internet website and that it will be sent in paper form upon request by the Owner, when that information is so available and is sent in paper form as promptly as practicable upon request.

SECTION 1.10. Dollars.

The term "Dollars" shall mean United States dollars.

SECTION 1.11. DTC.

The term "DTC" shall mean The Depository Trust Company or its successor.

SECTION 1.12. Foreign Registrar.

The term "Foreign Registrar" shall mean the entity that carries out the duties of registrar for the Shares and any other agent of the Company for the transfer and registration of Shares, including, without limitation, any securities depository for the Shares.

SECTION 1.13. Holder.

The term "Holder" shall mean any person holding a Receipt or a security entitlement or other interest in American Depositary Shares, whether for its own account or for the account of another person, but that is not the Owner of that Receipt or those American Depositary Shares.

SECTION 1.14. Owner.

The term "Owner" shall mean the person in whose name American Depositary Shares are registered on the books of the Depositary maintained for that purpose.

SECTION 1.15. Receipts.

The term "Receipts" shall mean the American Depositary Receipts issued under this Deposit Agreement evidencing certificated American Depositary Shares, as the same may be amended from time to time in accordance with the provisions of this Deposit Agreement.

SECTION 1.16. Registrar.

The term "Registrar" shall mean any corporation or other entity that is appointed by the Depositary to register American Depositary Shares and transfers of American Depositary Shares as provided in this Deposit Agreement.

SECTION 1.17. Replacement.

The term "Replacement" shall have the meaning assigned to it in Section 4.8.

SECTION 1.18. Restricted Securities.

The term "Restricted Securities" shall mean Shares that (i) are "restricted securities," as defined in Rule 144 under the Securities Act of 1933, except for Shares that could be resold in reliance on Rule 144 without any conditions, (ii) are beneficially owned by an officer, director (or person performing similar functions) or other affiliate of the Company, (iii) otherwise would require registration under the Securities Act of 1933 in connection with the public offer and sale thereof in the United States or (iv) are subject to other restrictions on sale or deposit under the laws of Italy, a shareholder agreement or the articles of association or similar document of the Company.

SECTION 1.19. Securities Act of 1933.

The term "Securities Act of 1933" shall mean the United States Securities Act of 1933, as from time to time amended.

SECTION 1.20. Shares.

The term "Shares" shall mean [ordinary] shares of the Company that are validly issued and outstanding, fully paid and nonassessable and that were not issued in violation of any pre-emptive or similar rights of the holders of outstanding securities of the Company; provided, however, that, if there shall occur any change in nominal or par value, a split-up or consolidation or any other reclassification or, upon the occurrence of an event described in Section 4.8, an exchange or conversion in respect of the Shares of the Company, the term "Shares" shall thereafter also mean the successor securities resulting from such change in nominal value, split-up or consolidation or such other reclassification or such exchange or conversion.

SECTION 1.21. SWIFT.

The term "SWIFT" shall mean the financial messaging network operated by the Society for Worldwide Interbank Financial Telecommunication, or its successor.

SECTION 1.22. Termination Option Event.

The term "Termination Option Event" shall mean any of the following events or conditions:

(i) the Company institutes proceedings to be adjudicated as bankrupt or insolvent, consents to the institution of bankruptcy or insolvency proceedings against it, files a petition or answer or consent seeking reorganization or relief under any applicable law in respect of bankruptcy or insolvency, consents to the filing of any petition of that kind or to the appointment of a receiver, liquidator, assignee, trustee, custodian or sequestrator (or other similar official) of it or any substantial part of its property or makes an assignment for the benefit of creditors, or if information becomes publicly available indicating that unsecured claims against the Company are not expected to be paid;

(ii) the Shares are delisted, or the Company announces its intention to delist the Shares, from a stock exchange outside the United States, and the Company has not applied to list the Shares on any other stock exchange outside the United States;

(iii) the American Depositary Shares are delisted from a stock exchange in the United States on which the American Depositary Shares were listed and, 30 days after that delisting, the American Depositary Shares have not been listed on another stock exchange in the United States, nor is there a symbol available for over-the-counter trading of the American Depositary Shares in the United States;

(iv) the Depositary has received notice of facts that indicate, or otherwise has reason to believe, that the American Depositary Shares have become, or with the passage of time will become, ineligible for registration on Form F-6 under the Securities Act of 1933; or

(v) an event or condition that is defined as a Termination Option Event in Section 4.1, 4.2 or 4.8.

ARTICLE 2. FORM OF RECEIPTS, DEPOSIT OF SHARES, DELIVERY, TRANSFER AND SURRENDER OF AMERICAN DEPOSITARY SHARES

SECTION 2.1. Form of Receipts; Registration and Transferability of American Depositary Shares.

Definitive Receipts shall be substantially in the form set forth in Exhibit A to this Deposit Agreement, with appropriate insertions, modifications and omissions, as permitted under this Deposit Agreement. No Receipt shall be entitled to any benefits under this Deposit Agreement or be valid or obligatory for any purpose, unless that Receipt has been (i) executed by the Depositary by the manual signature of a duly authorized officer of the Depositary or (ii) executed by the facsimile signature of a duly authorized officer of the Depositary and countersigned by the manual signature of a duly authorized signatory of the Depositary or the Registrar or a co-registrar. The Depositary shall maintain books on which (x) each Receipt so executed and delivered as provided in this Deposit Agreement and each transfer of that Receipt and (y) all American Depositary Shares delivered as provided in this Deposit Agreement and all registrations of transfer of American Depositary Shares, shall be registered. A Receipt bearing the facsimile signature of a person that was at any time a proper officer of the Depositary shall, subject to the other provisions of this paragraph, bind the Depositary, even if that person was not a proper officer of the Depositary on the date of issuance of that Receipt.

The Receipts and statements confirming registration of American Depositary Shares may have incorporated in or attached to them such legends or recitals or modifications not inconsistent with the provisions of this Deposit Agreement as may be required by the Depositary or required to comply with any applicable law or regulations thereunder or with the rules and regulations of any securities exchange upon which American Depositary Shares may be listed or to conform with any usage with respect thereto, or to indicate any special limitations or restrictions to which any particular Receipts and American Depositary Shares are subject by reason of the date of issuance of the underlying Deposited Securities or otherwise.

American Depositary Shares evidenced by a Receipt, when the Receipt is properly endorsed or accompanied by proper instruments of transfer, shall be transferable as certificated registered securities under the laws of the State of New York. American Depositary Shares not evidenced by Receipts shall be transferable as uncertificated registered securities under the laws of the State of New York. The Depositary, notwithstanding any notice to the contrary, may treat the Owner of American Depositary Shares as the absolute owner thereof for the purpose of determining the person entitled to distribution of dividends or other distributions or to any notice provided for in this Deposit Agreement and for all other purposes, and neither the Depositary nor the Company shall have any obligation or be subject to any liability under this Deposit Agreement to any Holder of American Depositary Shares (but only to the Owner of those American Depositary Shares).

SECTION 2.2. Deposit of Shares.

Subject to the terms and conditions of this Deposit Agreement, Shares or evidence of rights to receive Shares may be deposited under this Deposit Agreement by delivery thereof to any Custodian, accompanied by any appropriate instruments or instructions for transfer, or endorsement, in form satisfactory to the Custodian.

As conditions of accepting Shares for deposit, the Depositary may require (i) any certification required by the Depositary or the Custodian in accordance with the provisions of this Deposit Agreement, (ii) a written order directing the Depositary to deliver to, or upon the written order of, the person or persons stated in that order American Depositary Shares representing those deposited Shares, (iii) evidence satisfactory to the Depositary that those Shares have been re-registered in the books of the Company or the Foreign Registrar in the name of the Depositary, a Custodian or a nominee of the Depositary or a Custodian, (iv) evidence satisfactory to the Depositary that any necessary approval for the transfer or deposit has been granted by any governmental body in each applicable jurisdiction and (v) an agreement or assignment, or other instrument satisfactory to the Depositary, that provides for the prompt transfer to the Custodian of any dividend, or right to subscribe for additional Shares or to receive other property, that any person in whose name those Shares are or have been recorded may thereafter receive upon or in respect of those Shares, or, in lieu thereof, such agreement of indemnity or other agreement as shall be satisfactory to the Depositary.

At the request and risk and expense of a person proposing to deposit Shares, and for the account of that person, the Depositary may receive certificates for Shares to be deposited, together with the other instruments specified in this Section, for the purpose of forwarding those Share certificates to the Custodian for deposit under this Deposit Agreement.

The Depositary shall instruct each Custodian that, upon each delivery to a Custodian of a certificate or certificates for Shares to be deposited under this Deposit Agreement, together with the other documents specified in this Section, that Custodian shall, as soon as transfer and recordation can be accomplished, present that certificate or those certificates to the Company or the Foreign Registrar, if applicable, for transfer and recordation of the Shares being deposited in the name of the Depositary or its nominee or that Custodian or its nominee.

Deposited Securities shall be held by the Depositary or by a Custodian for the account and to the order of the Depositary or at such other place or places as the Depositary shall determine.

SECTION 2.3. Delivery of American Depositary Shares.

The Depositary shall instruct each Custodian that, upon receipt by that Custodian of any deposit pursuant to Section 2.2, together with the other documents or evidence required under that Section, that Custodian shall notify the Depositary of that deposit and the person or persons to whom or upon whose written order American Depositary Shares are deliverable in respect thereof. Upon receiving a notice of a deposit from a Custodian, or upon the receipt of Shares or evidence of the right to receive Shares by the Depositary, the Depositary, subject to the terms and conditions of this Deposit Agreement, shall deliver, to or upon the order of the person or persons entitled thereto, the number of American Depositary Shares issuable in respect of that deposit, but only upon payment to the Depositary of the fees and expenses of the Depositary for the delivery of those American Depositary Shares as provided in Section 5.9, and of all taxes and governmental charges and fees payable in connection with that deposit and the transfer of the deposited Shares. However, the Depositary shall deliver only whole numbers of American Depositary Shares.

SECTION 2.4. Registration of Transfer of American Depositary Shares; Combination and Split-up of Receipts; Interchange of Certificated and Uncertificated American Depositary Shares.

The Depositary, subject to the terms and conditions of this Deposit Agreement, shall register a transfer of American Depositary Shares on its transfer books upon (i) in the case of certificated American Depositary Shares, surrender of the Receipt evidencing those American Depositary Shares, by the Owner or by a duly authorized attorney, properly endorsed or accompanied by proper instruments of transfer or (ii) in the case of uncertificated American Depositary Shares, receipt from the Owner of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9), and, in either case, duly stamped as may be required by the laws of the State of New York and of the United States of America. Upon registration of a transfer, the Depositary shall deliver the transferred American Depositary Shares to or upon the order of the person entitled thereto.

The Depositary, subject to the terms and conditions of this Deposit Agreement, shall upon surrender of a Receipt or Receipts for the purpose of effecting a split-up or combination of such Receipt or Receipts, execute and deliver a new Receipt or Receipts for any authorized number of American Depositary Shares requested, evidencing the same aggregate number of American Depositary Shares as the Receipt or Receipts surrendered.

The Depositary, upon surrender of certificated American Depositary Shares for the purpose of exchanging for uncertificated American Depositary Shares, shall cancel the Receipt evidencing those certificated American Depositary Shares and send the Owner a statement confirming that the Owner is the owner of the same number of uncertificated American Depositary Shares. The Depositary, upon receipt of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9) from the Owner of uncertificated American Depositary Shares for the purpose of exchanging for certificated American Depositary Shares, shall cancel those uncertificated American Depositary Shares and register and deliver to the Owner a Receipt evidencing the same number of certificated American Depositary Shares.

The Depositary may appoint one or more co-transfer agents for the purpose of effecting registration of transfers of American Depositary Shares and combinations and split-ups of Receipts at designated transfer offices on behalf of the Depositary, and the Depositary shall notify the Company if it makes an appointment of that kind. In carrying out its functions, a co-transfer agent may require evidence of authority and compliance with applicable laws and other requirements by Owners or persons entitled to American Depositary Shares and will be entitled to protection and indemnity to the same extent as the Depositary.

SECTION 2.5. Surrender of American Depositary Shares and Withdrawal of Deposited Securities.

Upon surrender of American Depositary Shares for the purpose of withdrawal of the Deposited Securities represented thereby and payment of the fee of the Depositary for the surrender of American Depositary Shares as provided in Section 5.9 and payment of all taxes and governmental charges payable in connection with that surrender and withdrawal of the Deposited Securities, and subject to the terms and conditions of this Deposit Agreement, the Owner of those American Depositary Shares shall be entitled to delivery (to the extent delivery can then be lawfully and practicably made), to or as instructed by that Owner, of the amount of Deposited Securities at the time represented by those American Depositary Shares, but not any money or other property as to which a record date for distribution to Owners has passed (since money or other property of that kind will be delivered or paid on the scheduled payment date to the Owner as of that record date), and except that the Depositary shall not be required to accept surrender of American Depositary Shares for the purpose of withdrawal to the extent it would require delivery of a fraction of a Deposited Security. That delivery shall be made, as provided in this Section, without unreasonable delay.

As a condition of accepting a surrender of American Depositary Shares for the purpose of withdrawal of Deposited Securities, the Depositary may require (i) that each surrendered Receipt be properly endorsed in blank or accompanied by proper instruments of transfer in blank and (ii) that the surrendering Owner execute and deliver to the Depositary a written order directing the Depositary to cause the Deposited Securities being withdrawn to be delivered to or upon the written order of a person or persons designated in that order.

Thereupon, the Depositary shall direct the Custodian to deliver, subject to Sections 2.6, 3.1 and 3.2, the other terms and conditions of this Deposit Agreement and local market rules and practices, to the surrendering Owner or to or upon the written order of the person or persons designated in the order delivered to the Depositary as above provided, the amount of Deposited Securities represented by the surrendered American Depositary Shares, and the Depositary may charge the surrendering Owner a fee and its expenses for giving that direction by cable (including SWIFT) or facsimile transmission.

If Deposited Securities are delivered physically upon surrender of American Depositary Shares for the purpose of withdrawal, that delivery will be made at the Custodian's office, except that, at the request, risk and expense of an Owner surrendering American Depositary Shares for withdrawal of Deposited Securities, and for the account of that Owner, the Depositary shall direct the Custodian to forward any cash or other property comprising, and forward a certificate or certificates, if applicable, and other proper documents of title, if any, for, the Deposited Securities represented by the surrendered American Depositary Shares to the Depositary for delivery at the Depositary's Office or to another address specified in the order received from the surrendering Owner.

SECTION 2.6. Limitations on Delivery, Registration of Transfer and Surrender of American Depositary Shares.

As a condition precedent to the delivery, registration of transfer or surrender of any American Depositary Shares or split-up or combination of any Receipt or withdrawal of any Deposited Securities, the Depositary, Custodian or Registrar may require payment from the depositor of Shares or the presenter of the Receipt or instruction for registration of transfer or surrender of American Depositary Shares not evidenced by a Receipt of a sum sufficient to reimburse it for any tax or other governmental charge and any stock transfer or registration fee with respect thereto (including any such tax or charge and fee with respect to Shares being deposited or withdrawn) and payment of any applicable fees as provided in this Deposit Agreement, may require the production of proof satisfactory to it as to the identity and genuineness of any signature and may also require compliance with any regulations the Depositary may establish consistent with the provisions of this Deposit Agreement, including, without limitation, this Section 2.6.

The Depositary may refuse to accept deposits of Shares for delivery of American Depositary Shares or to register transfers of American Depositary Shares in particular instances, or may suspend deposits of Shares or registration of transfer generally, whenever it or the Company considers it necessary or advisable to do so. The Depositary may refuse surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities in particular instances, or may suspend surrenders for the purpose of withdrawal generally, but, notwithstanding anything to the contrary in this Deposit Agreement, only for (i) temporary delays caused by closing of the Depositary's register or the register of holders of Shares maintained by the Company or the Foreign Registrar, or the deposit of Shares, in connection with voting at a shareholders' meeting or the payment of dividends, (ii) the payment of fees, taxes and similar charges, (iii) compliance with any U.S. or foreign laws or governmental regulations relating to the American Depositary Shares or to the withdrawal of the Deposited Securities or (iv) any other reason that, at the time, is permitted under paragraph I(A)(1) of the General Instructions to Form F-6 under the Securities Act of 1993 or any successor to that provision; in each case, the Depositary shall notify the Company as promptly as practicable of any suspension of that kind that is outside the ordinary course of business.

The Depositary shall not knowingly accept for deposit under this Deposit Agreement any Shares that, at the time of deposit, are Restricted Securities.

SECTION 2.7. Lost Receipts, etc.

If a Receipt is mutilated, destroyed, lost or stolen, the Depositary shall deliver to the Owner the American Depositary Shares evidenced by that Receipt in uncertificated form or, if requested by the Owner, execute and deliver a new Receipt of like tenor in exchange and substitution for such mutilated Receipt, upon surrender and cancellation of that mutilated Receipt, or in lieu of and in substitution for that destroyed, lost or stolen Receipt. However, before the Depositary will deliver American Depositary Shares in uncertificated form or execute and deliver a new Receipt, in substitution for a destroyed, lost or stolen Receipt, the Owner must (a) file with the Depositary (i) a request for that replacement before the Depositary has notice that the Receipt has been acquired by a bona fide purchaser and (ii) a sufficient indemnity bond and (b) satisfy any other reasonable requirements imposed by the Depositary.

SECTION 2.8. Cancellation and Destruction of Surrendered Receipts.

The Depositary shall cancel all Receipts surrendered to it and is authorized to destroy Receipts so cancelled.

SECTION 2.9. DTC Direct Registration System and Profile Modification System.

(a) Notwithstanding the provisions of Section 2.4, the parties acknowledge that DTC's Direct Registration System ("DRS") and Profile Modification System ("Profile") apply to the American Depositary Shares upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC that facilitates interchange between registered holding of uncertificated securities and holding of security entitlements in those securities through DTC and a DTC participant. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of an Owner of American Depositary Shares, to direct the Depositary to register a transfer of those American Depositary Shares to DTC or its nominee and to deliver those American Depositary Shares to the DTC account of that DTC participant without receipt by the Depositary of prior authorization from the Owner to register that transfer.

(b) In connection with DRS/Profile, the parties acknowledge that the Depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an Owner in requesting a registration of transfer and delivery as described in paragraph (a) above has the actual authority to act on behalf of that Owner (notwithstanding any requirements under the Uniform Commercial Code). For the avoidance of doubt, the provisions of Sections 5.3 and 5.8 apply to the matters arising from the use of the DRS/Profile. The parties agree that the Depositary's reliance on and compliance with instructions received by the Depositary through the DRS/Profile system and otherwise in accordance with this Deposit Agreement shall not constitute negligence or bad faith on the part of the Depositary.

ARTICLE 3. CERTAIN OBLIGATIONS OF OWNERS AND HOLDERS OF AMERICAN DEPOSITARY SHARES

SECTION 3.1. Filing Proofs, Certificates and Other Information.

Any person presenting Shares for deposit or any Owner or Holder may be required from time to time to file with the Depositary or the Custodian such proof of citizenship or residence, exchange control approval, or such information relating to the registration on the books of the Company or the Foreign Registrar, if applicable, to execute such certificates and to make such representations and warranties, as the Depositary may deem necessary or proper. The Depositary may withhold the delivery or registration of transfer of American Depositary Shares, the distribution of any dividend or other distribution or of the proceeds thereof or the delivery of any Deposited Securities until that proof or other information is filed or those certificates are executed or those representations and warranties are made.

SECTION 3.2. Liability of Owner for Taxes.

If any tax or other governmental charge shall become payable by the Custodian or the Depositary with respect to or in connection with any American Depositary Shares or any Deposited Securities represented by any American Depositary Shares or in connection with a transaction to which Section 4.8 applies, that tax or other governmental charge shall be payable by the Owner of those American Depositary Shares to the Depositary. The Depositary may refuse to register any transfer of those American Depositary Shares or any withdrawal of Deposited Securities represented by those American Depositary Shares until that payment is made, and may withhold any dividends or other distributions or the proceeds thereof, or may sell for the account of the Owner any part or all of the Deposited Securities represented by those American Depositary Shares and apply those dividends or other distributions or the net proceeds of any sale of that kind in payment of that tax or other governmental charge but, even after a sale of that kind, the Owner of those American Depositary Shares shall remain liable for any deficiency. The Depositary shall distribute any net proceeds of a sale made under this Section that are not used to pay taxes or governmental charges to the Owners entitled to them in accordance with Section 4.1. If the number of Shares represented by each American Depositary Share decreases as a result of a sale of Deposited Securities under this Section, the Depositary may call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares and may sell American Depositary Shares to the extent necessary to avoid distributing fractions of American Depositary Shares in that exchange and distribute the net proceeds of that sale to the Owners entitled to them.

SECTION 3.3. Warranties on Deposit of Shares.

Every person depositing Shares under this Deposit Agreement shall be deemed thereby to represent and warrant that those Shares and each certificate therefor, if applicable, are validly issued, fully paid and nonassessable and were not issued in violation of any preemptive or similar rights of the holders of outstanding securities of the Company and that the person making that deposit is duly authorized so to do. Every depositing person shall also be deemed to represent that the Shares, at the time of deposit, are not Restricted Securities. All representations and warranties deemed made under this Section shall survive the deposit of Shares and delivery of American Depositary Shares.

SECTION 3.4. Disclosure of Interests.

When required in order to comply with applicable laws and regulations or the articles of association or similar document of the Company, the Company may from time to time request each Owner and Holder to provide to the Depositary information relating to: (a) the capacity in which it holds American Depositary Shares, (b) the identity of any Holders or other persons or entities then or previously interested in those American Depositary Shares and the nature of those interests and (c) any other matter where disclosure of such matter is required for that compliance. Each Owner and Holder agrees to provide all information known to it in response to a request made pursuant to this Section. Each Holder consents to the disclosure by the Depositary and the Owner or any other Holder through which it holds American Depositary Shares, directly or indirectly, of all information responsive to a request made pursuant to this Section relating to that Holder that is known to that Owner or other Holder. The Depositary agrees to use reasonable efforts to comply with written instructions requesting that the Depositary forward any request authorized under this Section to the Owners and to forward to the Company any responses it receives in response to that request. The Depositary may charge the Company a fee and its expenses for complying with requests under this Section 3.4.

ARTICLE 4. THE DEPOSITED SECURITIES

SECTION 4.1. Cash Distributions.

Whenever the Depositary receives any cash dividend or other cash distribution on Deposited Securities, the Depositary shall, subject to the provisions of Section 4.5, convert that dividend or other distribution into Dollars and distribute the amount thus received (net of the fees and expenses of the Depositary as provided in Section 5.9) to the Owners entitled thereto, in proportion to the number of American Depositary Shares representing those Deposited Securities held by them respectively; provided, however, that if the Custodian or the Depositary shall be required to withhold and does withhold from that cash dividend or other cash distribution an amount on account of taxes or other governmental charges, the amount distributed to the Owners of the American Depositary Shares representing those Deposited Securities shall be reduced accordingly. However, the Depositary will not pay any Owner a fraction of one cent, but will round each Owner's entitlement to the nearest whole cent.

The Company or its agent will remit to the appropriate governmental agency in each applicable jurisdiction all amounts withheld and owing to such agency.

If a cash distribution would represent a return of all or substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may:

(i) require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that cash distribution; or

(ii) sell all Deposited Securities other than the subject cash distribution and add any net cash proceeds of that sale to the cash distribution, call for surrender of all those American Depositary Shares and require that surrender as a condition of making that cash distribution.

If the Depositary acts under this paragraph, that action shall also be a Termination Option Event.

SECTION 4.2. Distributions Other Than Cash, Shares or Rights.

Subject to the provisions of Sections 4.11 and 5.9, whenever the Depositary receives any distribution other than a distribution described in Section 4.1, 4.3 or 4.4 on Deposited Securities (but not in exchange for or in conversion or in lieu of Deposited Securities), the Depositary shall cause the securities or property received by it to be distributed to the Owners entitled thereto, after deduction or upon payment of any fees and expenses of the Depositary and any taxes or other governmental charges, in proportion to the number of American Depositary Shares representing such Deposited Securities held by them respectively, in any manner that the Depositary deems equitable and practicable for accomplishing that distribution (which may be a distribution of depositary shares representing the securities received); provided, however, that if in the opinion of the Depositary such distribution cannot be made proportionately among the Owners entitled thereto, or if for any other reason (including, but not limited to, any requirement that the Company or the Depositary withhold an amount on account of taxes or other governmental charges or that securities received must be registered under the Securities Act of 1933 in order to be distributed to Owners or Holders) the Depositary, after consultation with the Company to the extent practicable, deems such distribution not to be lawful and feasible, the Depositary may adopt such other method as it may deem equitable and practicable for the purpose of effecting such distribution, including, but not limited to, the public or private sale of the securities or property thus received, or any part thereof, and distribution of the net proceeds of any such sale (net of the fees and expenses of the Depositary as provided in Section 5.9) to the Owners entitled thereto, all in the manner and subject to the conditions set forth in Section 4.1. The Depositary may withhold any distribution of securities under this Section 4.2 if it has not received satisfactory assurances from the Company that the distribution does not require registration under the Securities Act of 1933. The Depositary may sell, by public or private sale, an amount of securities or other property it would otherwise distribute under this Section 4.2 that is sufficient to pay its fees and expenses in respect of that distribution.

If a distribution to be made under this Section 4.2 would represent a return of all or substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may:

(i) require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that distribution; or

(ii) sell all Deposited Securities other than the subject distribution and add any net cash proceeds of that sale to the distribution, call for surrender of all those American Depositary Shares and require that surrender as a condition of making that distribution.

If the Depositary acts under this paragraph, that action shall also be a Termination Option Event.

SECTION 4.3. Distributions in Shares.

Whenever the Depositary receives any distribution on Deposited Securities consisting of a dividend in, or free distribution of, Shares, the Depositary may deliver to the Owners entitled thereto, in proportion to the number of American Depositary Shares representing those Deposited Securities held by them respectively, an aggregate number of American Depositary Shares representing the amount of Shares received as that dividend or free distribution, subject to the terms and conditions of this Deposit Agreement with respect to the deposit of Shares and issuance of American Depositary Shares, including withholding of any tax or governmental charge as provided in Section 4.11 and payment of the fees and expenses of the Depositary as provided in Section 5.9 (and the Depositary may sell, by public or private sale, an amount of the Shares received (or American Depositary Shares representing those Shares) sufficient to pay its fees and expenses in respect of that distribution). In lieu of delivering fractional American Depositary Shares, the Depositary may sell the amount of Shares represented by the aggregate of those fractions (or American Depositary Shares representing those Shares) and distribute the net proceeds, all in the manner and subject to the conditions described in Section 4.1. If and to the extent that additional American Depositary Shares are not delivered and Shares or American Depositary Shares are not sold, each American Depositary Share shall thenceforth also represent the additional Shares distributed on the Deposited Securities represented thereby.

If the Company declares a distribution in which holders of Deposited Securities have a right to elect whether to receive cash, Shares or other securities or a combination of those things, or a right to elect to have a distribution sold on their behalf, the Depositary may, after consultation with the Company, make that right of election available for exercise by Owners in any manner the Depositary considers to be lawful and practical. As a condition of making a distribution election right available to Owners, the Depositary may require satisfactory assurances from the Company that doing so does not require registration of any securities under the Securities Act of 1933 that has not been effected.

SECTION 4.4. Rights.

(a) If rights are granted to the Depositary in respect of deposited Shares to purchase additional Shares or other securities, the Company and the Depositary shall endeavor to consult as to the actions, if any, the Depositary should take in connection with that grant of rights. The Depositary may, to the extent deemed by it to be lawful and practical (i) if requested in writing by the Company, grant to all or certain Owners rights to instruct the Depositary to purchase the securities to which the rights relate and deliver those securities or American Depositary Shares representing those securities to Owners, (ii) if requested in writing by the Company, deliver the rights to or to the order of certain Owners, or (iii) sell the rights to the extent practicable and distribute the net proceeds of that sale to Owners entitled to those proceeds. To the extent rights are not exercised, delivered or disposed of under (i), (ii) or (iii) above, the Depositary shall permit the rights to lapse unexercised.

(b) If the Depositary will act under (a)(i) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon instruction from an applicable Owner in the form the Depositary specified and upon payment by that Owner to the Depositary of an amount equal to the purchase price of the securities to be received upon the exercise of the rights, the Depositary shall, on behalf of that Owner, exercise the rights and purchase the securities. The purchased securities shall be delivered to, or as instructed by, the Depositary. The Depositary shall (i) deposit the purchased Shares under this Deposit Agreement and deliver American Depositary Shares representing those Shares to that Owner or (ii) deliver or cause the purchased Shares or other securities to be delivered to or to the order of that Owner. The Depositary will not act under (a)(i) above unless the offer and sale of the securities to which the rights relate are registered under the Securities Act of 1933 or the Depositary has received an opinion of United States counsel that is satisfactory to it to the effect that those securities may be sold and delivered to the applicable Owners without registration under the Securities Act of 1933.

(c) If the Depositary will act under (a)(ii) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon (i) the request of an applicable Owner to deliver the rights allocable to the American Depositary Shares of that Owner to an account specified by that Owner to which the rights can be delivered and (ii) receipt of such documents as the Company and the Depositary agreed to require to comply with applicable law, the Depositary will deliver those rights as requested by that Owner.

(d) If the Depositary will act under (a)(iii) above, the Depositary will use reasonable efforts to sell the rights in proportion to the number of American Depositary Shares held by the applicable Owners and pay the net proceeds to the Owners otherwise entitled to the rights that were sold, upon an averaged or other practical basis without regard to any distinctions among such Owners because of exchange restrictions or the date of delivery of any American Depositary Shares or otherwise. The Depositary may enter into any arrangements with the Company or persons acting on behalf of the Company to effect the orderly disposal of such rights.

(e) Payment or deduction of the fees of the Depositary as provided in Section 5.9 and payment or deduction of the expenses of the Depositary and any applicable taxes or other governmental charges shall be conditions of any delivery of securities or payment of cash proceeds under this Section 4.4.

(f) The Depositary shall not be responsible for any failure to determine that it may be lawful or feasible to make rights available to or exercise rights on behalf of Owners in general or any Owner in particular, or to sell rights.

SECTION 4.5. Conversion of Foreign Currency.

Whenever the Depositary or the Custodian receives foreign currency, by way of dividends or other distributions or the net proceeds from the sale of securities, property or rights, and if at the time of the receipt thereof the foreign currency so received can in the judgment of the Depositary be converted on a reasonable basis into Dollars and the resulting Dollars transferred to the United States, the Depositary or one of its agents or affiliates or the Custodian shall convert or cause to be converted by sale or in any other manner that it may determine that foreign currency into Dollars, and those Dollars shall be distributed to the Owners entitled thereto. A cash distribution may be made upon an averaged or other practicable basis without regard to any distinctions among Owners based on exchange restrictions, the date of delivery of any American Depositary Shares or otherwise and shall be net of any expenses of conversion into Dollars incurred by the Depositary as provided in Section 5.9.

If a conversion of foreign currency or the repatriation or distribution of Dollars can be effected only with the approval or license of any government or agency thereof, the Depositary may, but will not be required to, file an application for that approval or license.

If the Depositary, after consultation with the Company to the extent practicable, determines that in its judgment any foreign currency received by the Depositary or the Custodian is not convertible on a reasonable basis into Dollars transferable to the United States, or if any approval or license of any government or agency thereof that is required for such conversion is not filed or sought by the Depositary or is not obtained within a reasonable period as determined by the Depositary, the Depositary may distribute the foreign currency received by the Depositary to, or in its discretion may hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the Owners entitled to receive the same.

If any conversion of foreign currency, in whole or in part, cannot be effected for distribution to some of the Owners entitled thereto, the Depositary may in its discretion make that conversion and distribution in Dollars to the extent practicable and permissible to the Owners entitled thereto and may distribute the balance of the foreign currency received by the Depositary to, or hold that balance uninvested and without liability for interest thereon for the account of, the Owners entitled thereto.

The Depositary may convert currency itself or through any of its affiliates, or the Custodian or the Company may convert currency and pay Dollars to the Depositary. Where the Depositary converts currency itself or through any of its affiliates, the Depositary acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under this Deposit Agreement and the rate that the Depositary or its affiliate receives when buying or selling foreign currency for its own account. The Depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under this Deposit Agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to Owners, subject to the Depositary's obligations under Section 5.3. The methodology used to determine exchange rates used in currency conversions made by the Depositary is available upon request. Where the Custodian converts currency, the Custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to Owners, and the Depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the Depositary may receive dividends or other distributions from the Company in Dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by or on behalf of the Company and, in such cases, the Depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor the Company makes any representation that the rate obtained or determined by the Company is the most favorable rate and neither it nor the Company will be liable for any direct or indirect losses associated with the rate.

SECTION 4.6. Fixing of Record Date.

Whenever a cash dividend, cash distribution or any other distribution is made on Deposited Securities or rights to purchase Shares or other securities are issued with respect to Deposited Securities (which rights will be delivered to or exercised or sold on behalf of Owners in accordance with Section 4.4) or the Depositary receives notice that a distribution or issuance of that kind will be made, or whenever the Depositary receives notice that a meeting of holders of Shares will be held in respect of which the Company has requested the Depositary to send a notice under Section 4.7, or whenever the Depositary will assess a fee or charge against the Owners, or whenever the Depositary causes a change in the number of Shares that are represented by each American Depositary Share, or whenever the Depositary otherwise finds it necessary or convenient, the Depositary shall fix a record date, which shall be the same as, or as near as practicable to, any corresponding record date set by the Company with respect to Shares, (a) for the determination of the Owners (i) who shall be entitled to receive the benefit of that dividend or other distribution or those rights, (ii) who shall be entitled to give instructions for the exercise of voting rights at that meeting, (iii) who shall be responsible for that fee or charge or (iv) for any other purpose for which the record date was set, or (b) on or after which each American Depositary Share will represent the changed number of Shares. Subject to the provisions of Sections 4.1 through 4.5 and to the other terms and conditions of this Deposit Agreement, the Owners on a record date fixed by the Depositary shall be entitled to receive the amount distributable by the Depositary with respect to that dividend or other distribution or those rights or the net proceeds of sale thereof in proportion to the number of American Depositary Shares held by them respectively, to give voting instructions or to act in respect of the other matter for which that record date was fixed, or be responsible for that fee or charge, as the case may be.

SECTION 4.7. Voting of Deposited Shares.

(a) Upon receipt of notice of any meeting of holders of Shares at which holders of Shares will be entitled to vote, if requested in writing by the Company, the Depositary shall, as soon as practicable thereafter, Disseminate to the Owners a notice, the form of which shall be in the sole discretion of the Depositary, that shall contain (i) the information contained in the notice of meeting received by the Depositary, (ii) a statement that the Owners as of the close of business on a specified record date will be entitled, subject to any applicable provision of Italian law and of the articles of association or similar documents of the Company, to instruct the Depositary as to the exercise of the voting rights pertaining to the amount of Shares represented by their respective American Depositary Shares, (iii) a statement as to the manner in which those instructions may be given and (iv) the last date on which the Depositary will accept instructions (the "Instruction Cutoff Date").

(b) Upon the written request of an Owner of American Depositary Shares, as of the date of the request or, if a record date was specified by the Depositary, as of that record date, received on or before any Instruction Cutoff Date established by the Depositary, the Depositary may, and if the Depositary sent a notice under the preceding paragraph shall, endeavor, in so far as practicable, to vote or cause to be voted the amount of deposited Shares represented by those American Depositary Shares in accordance with the instructions set forth in that request. The Depositary shall not vote or attempt to exercise the right to vote that attaches to the deposited Shares other than in accordance with instructions given by Owners and received by the Depositary.

(c) There can be no assurance that Owners generally or any Owner in particular will receive the notice described in paragraph (a) above in time to enable Owners to give instructions to the Depositary prior to the Instruction Cutoff Date.

(d) In order to give Owners a reasonable opportunity to instruct the Depositary as to the exercise of voting rights relating to Shares, if the Company will request the Depositary to Disseminate a notice under paragraph (a) above, the Company shall give the Depositary notice of the meeting, details concerning the matters to be voted upon and copies of materials to be made available to holders of Shares in connection with the meeting not less than 45 days prior to the meeting date.

Notwithstanding anything in this Section 4.7 to the contrary, the Depositary and the Company may modify, amend or adopt additional procedures with respect to voting Deposited Securities from time to time as they determine may be necessary or appropriate to comply with applicable laws and regulations.

SECTION 4.8. Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities.

(a) The Depositary shall not tender any Deposited Securities in response to any voluntary cash tender offer, exchange offer or similar offer made to holders of Deposited Securities (a "Voluntary Offer"), except when instructed in writing to do so by an Owner surrendering American Depositary Shares and subject to any conditions or procedures the Depositary may require.

(b) If the Depositary receives a written notice that Deposited Securities have been redeemed for cash or otherwise purchased for cash in a transaction that is mandatory and binding on the Depositary as a holder of those Deposited Securities (a "Redemption"), the Depositary, at the expense of the Company, shall (i) if required, surrender Deposited Securities that have been redeemed to the issuer of those securities or its agent on the redemption date, (ii) Disseminate a notice to Owners (A) notifying them of that Redemption, (B) calling for surrender of a corresponding number of American Depositary Shares and (C) notifying them that the called American Depositary Shares have been converted into a right only to receive the money received by the Depositary upon that Redemption and those net proceeds shall be the Deposited Securities to which Owners of those converted American Depositary Shares shall be entitled upon surrenders of those American Depositary Shares in accordance with Section 2.5 or 6.2 and (iii) distribute the money received upon that Redemption to the Owners entitled to it upon surrender by them of called American Depositary Shares in accordance with Section 2.5 (and, for the avoidance of doubt, Owners shall not be entitled to receive that money under Section 4.1). If the Redemption affects less than all the Deposited Securities, the Depositary shall call for surrender a corresponding portion of the outstanding American Depositary Shares and only those American Depositary Shares will automatically be converted into a right to receive the net proceeds of the Redemption. The Depositary shall allocate the American Depositary Shares converted under the preceding sentence among the Owners pro-rata to their respective holdings of American Depositary Shares immediately prior to the Redemption, except that the allocations may be adjusted so that no fraction of a converted American Depositary Share is allocated to any Owner. A Redemption of all or substantially all of the Deposited Securities shall be a Termination Option Event.

(c) If the Depositary is notified of or there occurs any change in nominal value or any subdivision, combination or any other reclassification of the Deposited Securities or any recapitalization, reorganization, sale of assets substantially as an entirety, merger or consolidation affecting the issuer of the Deposited Securities or to which it is a party that is mandatory and binding on the Depositary as a holder of Deposited Securities and, as a result, securities or other property have been or will be delivered in exchange, conversion, replacement or in lieu of, Deposited Securities (a "Replacement"), the Depositary shall, if required, surrender the old Deposited Securities affected by that Replacement of Shares and hold, as new Deposited Securities under this Deposit Agreement, the new securities or other property delivered to it in that Replacement. However, the Depositary may elect to sell those new Deposited Securities if in the opinion of the Depositary, after consultation with the Company to the extent practicable, it is not lawful or not practical for it to hold those new Deposited Securities under this Deposit Agreement because those new Deposited Securities may not be distributed to Owners without registration under the Securities Act of 1933 or for any other reason, at public or private sale, at such places and on such terms as it deems proper and proceed as if those new Deposited Securities had been Redeemed under paragraph (b) above. A Replacement shall be a Termination Option Event.

(d) In the case of a Replacement where the new Deposited Securities will continue to be held under this Deposit Agreement, the Depositary may call for the surrender of outstanding Receipts to be exchanged for new Receipts specifically describing the new Deposited Securities and the number of those new Deposited Securities represented by each American Depositary Share. If the number of Shares represented by each American Depositary Share decreases as a result of a Replacement, the Depositary may, after consultation with the Company to the extent practicable, call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares and may sell American Depositary Shares to the extent necessary to avoid distributing fractions of American Depositary Shares in that exchange and distribute the net proceeds of that sale to the Owners entitled to them.

(e) If there are no Deposited Securities with respect to American Depositary Shares, including if the Deposited Securities are cancelled, or the Deposited Securities with respect to American Depositary Shares have become apparently worthless, the Depositary may call for surrender of those American Depositary Shares or may cancel those American Depositary Shares, upon notice to Owners, and that condition shall be a Termination Option Event.

SECTION 4.9. Reports.

The Depositary shall make available for inspection by Owners at its Office any reports and communications, including any proxy solicitation material, received from the Company which are both (a) received by the Depositary as the holder of the Deposited Securities and (b) made generally available to the holders of those Deposited Securities by the Company. The Company shall furnish reports and communications, including any proxy soliciting material to which this Section applies, to the Depositary in English, to the extent those materials are required to be translated into English pursuant to any regulations of the Commission.

SECTION 4.10. Lists of Owners.

Upon written request by the Company, the Depositary shall, at the expense of the Company, furnish to it a list, as of a recent date, of the names, addresses and American Depositary Share holdings of all Owners.

SECTION 4.11. Withholding.

If the Depositary determines that any distribution received or to be made by the Depositary (including Shares and rights to subscribe therefor) is subject to any tax or other governmental charge that the Depositary is obligated to withhold, the Depositary may sell, by public or private sale, all or a portion of the distributed property (including Shares and rights to subscribe therefor) in the amounts and manner the Depositary deems necessary and practicable to pay those taxes or charges, and the Depositary shall distribute the net proceeds of that sale, after deduction of those taxes or charges, to the Owners entitled thereto in proportion to the number of American Depositary Shares held by them respectively.

Services for Owners and Holders that may permit them to obtain reduced rates of tax withholding at source or reclaim excess tax withheld, and the fees and costs associated with using services of that kind, are not provided under, and are outside the scope of, this Deposit Agreement.

Each Owner and Holder agrees to indemnify the Company, the Depositary, the Custodian and their respective directors, employees, agents and affiliates for, and hold each of them harmless against, any claim by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced withholding at source or other tax benefit received by it. The obligations of Owners and Holders under the preceding sentence shall survive any transfer of American Depositary Shares or surrender of American Depositary Shares and withdrawal of Deposited Securities and the termination of this Deposit Agreement.

ARTICLE 5. THE DEPOSITARY, THE CUSTODIANS AND THE COMPANY

SECTION 5.1. Maintenance of Office and Register by the Depositary.

Until termination of this Deposit Agreement in accordance with its terms, the Depositary shall maintain facilities for the delivery, registration of transfers and surrender of American Depositary Shares in accordance with the provisions of this Deposit Agreement.

The Depositary shall keep a register of all Owners and all outstanding American Depositary Shares, which shall be open for inspection by the Owners at the Depositary's Office during regular business hours, but only for the purpose of communicating with Owners regarding the business of the Company or a matter related to this Deposit Agreement or the American Depositary Shares.

The Depositary may close the register for delivery, registration of transfer or surrender for the purpose of withdrawal from time to time as provided in Section 2.6.

If any American Depositary Shares are listed on one or more stock exchanges, the Depositary shall act as Registrar or appoint a Registrar or one or more co-registrars for registration of those American Depositary Shares in accordance with any requirements of that exchange or those exchanges.

SECTION 5.2. Prevention or Delay of Performance by the Company or the Depositary.

Neither the Depositary nor the Company nor any of their respective directors, employees, agents or affiliates shall incur any liability to any Owner or Holder:

(i) if by reason of (A) any provision of any present or future law or regulation or other act of the government of the United States, any State of the United States or any other state or jurisdiction, or of any governmental or regulatory authority or stock exchange; (B) (in the case of the Depositary only) any provision, present or future, of the articles of association or similar document of the Company, or any provision of any securities issued or distributed by the Company, or any offering or distribution thereof; or (C) any event or circumstance, whether natural or caused by a person or persons, that is beyond the ability of the Depositary or the Company, as the case may be, to prevent or counteract by reasonable care or effort (including, but not limited to, earthquakes, floods, severe storms, fires, explosions, war, terrorism, civil unrest, labor disputes, criminal acts or outbreaks of infectious disease; interruptions or malfunctions of utility services, Internet or other communications lines or systems; unauthorized access to or attacks on computer systems or websites; or other failures or malfunctions of computer hardware or software or other systems or equipment), the Depositary or the Company is, directly or indirectly, prevented from, forbidden to or delayed in, or could be subject to any civil or criminal penalty on account of doing or performing and therefore does not do or perform, any act or thing that, by the terms of this Deposit Agreement or the Deposited Securities, it is provided shall be done or performed;

(ii) for any exercise of, or failure to exercise, any discretion provided for in this Deposit Agreement (including any determination by the Depositary to take, or not take, any action that this Deposit Agreement provides the Depositary may take);

(iii) for the inability of any Owner or Holder to benefit from any distribution, offering, right or other benefit that is made available to holders of Deposited Securities but is not, under the terms of this Deposit Agreement, made available to Owners or Holders; or

(iv) for any special, consequential or punitive damages for any breach of the terms of this Deposit Agreement.

Where, by the terms of a distribution to which Section 4.1, 4.2 or 4.3 applies, or an offering to which Section 4.4 applies, or for any other reason, that distribution or offering may not be made available to Owners, and the Depositary may not dispose of that distribution or offering on behalf of Owners and make the net proceeds available to Owners, then the Depositary shall not make that distribution or offering available to Owners, and shall allow any rights, if applicable, to lapse.

SECTION 5.3. Obligations of the Depositary and the Company.

The Company assumes no obligation nor shall it be subject to any liability under this Deposit Agreement to any Owner or Holder, except that the Company agrees to perform its obligations specifically set forth in this Deposit Agreement without negligence or bad faith.

The Depositary assumes no obligation nor shall it be subject to any liability under this Deposit Agreement to any Owner or Holder (including, without limitation, liability with respect to the validity or worth of the Deposited Securities), except that the Depositary agrees to perform its obligations specifically set forth in this Deposit Agreement without negligence or bad faith, and the Depositary shall not be a fiduciary or have any fiduciary duty to Owners or Holders.

Neither the Depositary nor the Company shall be under any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any Deposited Securities or in respect of the American Depositary Shares on behalf of any Owner or Holder or any other person.

Each of the Depositary and the Company may rely, and shall be protected in relying upon, any written notice, request, direction or other document believed by it to be genuine and to have been signed or presented by the proper party or parties.

Neither the Depositary nor the Company shall be liable for any action or non-action by it in reliance upon the advice of or information from legal counsel, accountants, any person presenting Shares for deposit, any Owner or any other person believed by it in good faith to be competent to give such advice or information.

The Depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the Depositary or in connection with any matter arising wholly after the removal or resignation of the Depositary, provided that in connection with the issue out of which such potential liability arises the Depositary performed its obligations without negligence or bad faith while it acted as Depositary.

The Depositary shall not be liable for the acts or omissions of any securities depository, clearing agency or settlement system in connection with or arising out of book-entry settlement of American Depositary Shares or Deposited Securities or otherwise.

In the absence of bad faith on its part, the Depositary shall not be responsible for any failure to carry out any instructions to vote any of the Deposited Securities, or for the manner in which any such vote is cast or the effect of any such vote.

The Depositary shall have no duty to make any determination or provide any information as to the tax status of the Company or any liability for any tax consequences that may be incurred by Owners or Holders as a result of owning or holding American Depositary Shares. The Depositary shall not be liable for the inability or failure of an Owner or Holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

No disclaimer of liability under the United States federal securities laws is intended by any provision of this Deposit Agreement.

SECTION 5.4. Resignation and Removal of the Depositary.

The Depositary may at any time resign as Depositary hereunder by written notice of its election so to do delivered to the Company, to become effective upon the appointment of a successor depositary and its acceptance of that appointment as provided in this Section. The effect of resignation if a successor depositary is not appointed is provided for in Section 6.2.

The Depositary may at any time be removed by the Company by 120 days' prior written notice of that removal, to become effective upon the later of (i) the 120th day after delivery of the notice to the Depositary and (ii) the appointment of a successor depositary and its acceptance of its appointment as provided in this Section.

If the Depositary resigns or is removed, the Company shall use its best efforts to appoint a successor depositary, which shall be a bank or trust company having an office in the Borough of Manhattan, The City of New York. Every successor depositary shall execute and deliver to the Company an instrument in writing accepting its appointment under this Deposit Agreement. If the Depositary receives notice from the Company that a successor depositary has been appointed following its resignation or removal, the Depositary, upon payment of all sums due it from the Company, shall deliver to its successor a register listing all the Owners and their respective holdings of outstanding American Depositary Shares and shall deliver the Deposited Securities to or to the order of its successor. When the Depositary has taken the actions specified in the preceding sentence (i) the successor shall become the Depositary and shall have all the rights and shall assume all the duties of the Depositary under this Deposit Agreement and (ii) the predecessor depositary shall cease to be the Depositary and shall be discharged and released from all obligations under this Deposit Agreement, except for its duties under Section 5.8 with respect to the time before that discharge. A successor Depositary shall notify the Owners of its appointment as soon as practical after assuming the duties of Depositary.

Any corporation or other entity into or with which the Depositary may be merged or consolidated shall be the successor of the Depositary without the execution or filing of any document or any further act.

SECTION 5.5. The Custodians.

The Custodian shall be subject at all times and in all respects to the directions of the Depositary and shall be responsible solely to it. The Depositary in its discretion may at any time appoint a substitute or additional custodian or custodians, each of which shall thereafter be one of the Custodians under this Deposit Agreement. If the Depositary receives notice that a Custodian is resigning and, upon the effectiveness of that resignation there would be no Custodian acting under this Deposit Agreement, the Depositary shall, as promptly as practicable after receiving that notice, appoint a substitute custodian or custodians, each of which shall thereafter be a Custodian under this Deposit Agreement. The Depositary shall require any Custodian that resigns or is removed to deliver all Deposited Securities held by it to another Custodian.

SECTION 5.6. Notices and Reports.

If the Company takes or decides to take any corporate action of a kind that is addressed in Sections 4.1 to 4.4, or 4.6 to 4.8, or that effects or will effect a change of the name or legal structure of the Company, or that effects or will effect a change to the Shares, the Company shall notify the Depositary and the Custodian of that action or decision as soon as it is lawful and practical to give that notice. The notice shall be in English and shall include all details that the Company is required to include in any notice to any governmental or regulatory authority or securities exchange or is required to make available generally to holders of Shares by publication or otherwise.

The Company will arrange for the translation into English, if not already in English, to the extent required pursuant to any regulations of the Commission, and the prompt transmittal by the Company to the Depositary and the Custodian of all notices and any other reports and communications which are made generally available by the Company to holders of its Shares. If requested in writing by the Company, the Depositary will Disseminate, at the Company's expense, those notices, reports and communications to all Owners or otherwise make them available to Owners in a manner that the Company specifies as substantially equivalent to the manner in which those communications are made available to holders of Shares and compliant with the requirements of any securities exchange on which the American Depositary Shares are listed. The Company will timely provide the Depositary with the quantity of such notices, reports, and communications, as requested by the Depositary from time to time, in order for the Depositary to effect that Dissemination.

The Company represents that as of the date of this Deposit Agrement the statements in Article 11 of the form of Receipt appearing as Exhibit A to this Deposit Agreement or, if applicable, most recently filed with the Commission pursuant to Rule 424(b) under the Securities Act with respect to the Company's obligation to file periodic reports under the United States Securities Exchange Act of 1934, as amended, or its qualification for exemption from registration under that Act pursuant to Rule 12g3-2(b) under that Act, as the case may be, are true and correct. The Company agrees to promptly notify the Depositary upon becoming aware of any change in the truth of any of those statements or if there is any change in the Company's status regarding those reporting obligations or that qualification.

SECTION 5.7. Distribution of Additional Shares, Rights, etc.

If the Company or any affiliate of the Company determines to make any issuance or distribution of (1) additional Shares, (2) rights to subscribe for Shares, (3) securities convertible into Shares, or (4) rights to subscribe for such securities (each a "Distribution"), the Company shall notify the Depositary in writing in English as promptly as practicable and in any event before the Distribution starts and, if requested in writing by the Depositary, the Company shall promptly furnish to the Depositary either (i) evidence satisfactory to the Depositary that the Distribution is registered under the Securities Act of 1933 or (ii) a written opinion from U.S. counsel for the Company that is reasonably satisfactory to the Depositary, stating that the Distribution does not require, or, if made in the United States, would not require, registration under the Securities Act of 1933.

The Company agrees with the Depositary that neither the Company nor any company controlled by, controlling or under common control with the Company will at any time deposit any Shares that, at the time of deposit, are Restricted Securities.

SECTION 5.8. Indemnification.

The Company agrees to indemnify the Depositary, its directors, employees, agents and affiliates and each Custodian against, and hold each of them harmless from, any liability or expense (including, but not limited to any fees and expenses incurred in seeking, enforcing or collecting such indemnity and the reasonable and documented fees and expenses of counsel) that may arise out of or in connection with (a) any registration with the Commission of American Depositary Shares or Deposited Securities or the offer or sale thereof or (b) acts performed or omitted, pursuant to the provisions of or in connection with this Deposit Agreement and the American Depositary Shares, as the same may be amended, modified or supplemented from time to time, (i) by either the Depositary or a Custodian or their respective directors, employees, agents and affiliates, except for any liability or expense arising out of the negligence or bad faith of either of them, or (ii) by the Company or any of its directors, employees, agents and affiliates.

The Depositary agrees to indemnify the Company, its directors, employees, agents and affiliates and hold them harmless from any liability or expense (including, but not limited to any fees and expenses incurred in seeking, enforcing or collecting such indemnity and the reasonable and documented fees and expenses of counsel) that may arise out of acts performed or omitted by the Depositary or any Custodian or their respective directors, employees, agents and affiliates due to their negligence or bad faith.

The obligations set forth in this Section 5.8 shall survive the termination of this Deposit Agreement and the succession or substitution of any party hereto.

Any person seeking indemnification hereunder (an "Indemnified Person") shall notify the person from whom it is seeking indemnification (the "Indemnifying Person") of the commencement of any indemnifiable action or claim promptly after such Indemnified Person becomes aware of such commencement and shall consult in good faith with the Indemnifying Person as to the conduct of the defense of such action or claim, which defense shall be reasonable under the circumstances. No Indemnified Person shall compromise or settle any such action or claim without the consent in writing of the Indemnifying Person (which shall not be unreasonably withheld).

SECTION 5.9. Charges of Depositary.

The Company agrees to pay the fees and charges specified in the following paragraph only to the extent the Company is a depositor of Shares or an Owner.

The following charges shall be incurred by any party depositing or withdrawing Shares or by any party surrendering American Depositary Shares or to whom American Depositary Shares are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by the Company or an exchange of stock regarding the American Depositary Shares or Deposited Securities or a delivery of American Depositary Shares pursuant to Section 4.3), or by Owners, as applicable: (1) taxes and other governmental charges, (2) such registration fees as may from time to time be in effect for the registration of transfers of Shares generally on the Share register of the Company or Foreign Registrar and applicable to transfers of Shares to or from the name of the Depositary or its nominee or the Custodian or its nominee on the making of deposits or withdrawals hereunder, (3) such cable (including SWIFT) and facsimile transmission fees and expenses as are expressly provided in this Deposit Agreement, (4) such expenses as are incurred by the Depositary in the conversion of foreign currency pursuant to Section 4.5, (5) a fee of $5.00 or less per 100 American Depositary Shares (or portion thereof) for the delivery of American Depositary Shares pursuant to Section 2.3, 4.3 or 4.4 and the surrender of American Depositary Shares pursuant to Section 2.5 or 6.2, (6) a fee of $.05 or less per American Depositary Share (or portion thereof) for any cash distribution made pursuant to this Deposit Agreement, including, but not limited to Sections 4.1 through 4.4 and Section 4.8, (7) a fee for the distribution of securities pursuant to Section 4.2 or of rights pursuant to Section 4.4 (where the Depositary will not exercise or sell those rights on behalf of Owners), such fee being in an amount equal to the fee for the execution and delivery of American Depositary Shares referred to above which would have been charged as a result of the deposit of such securities under this Deposit Agreement (for purposes of this item 7 treating all such securities as if they were Shares) but which securities are instead distributed by the Depositary to Owners, (8) in addition to any fee charged under item 6 above, a fee of $.05 or less per American Depositary Share (or portion thereof) per annum for depositary services, which will be payable as provided in item 9 below, and (9) any other charges payable by the Depositary or the Custodian, any of the Depositary's or Custodian's agents or the agents of the Depositary's or Custodian's agents, in connection with the servicing of Shares or other Deposited Securities (which charges shall be assessed against Owners as of the date or dates set by the Depositary in accordance with Section 4.6 and shall be payable at the sole discretion of the Depositary by billing those Owners for those charges or by deducting those charges from one or more cash dividends or other cash distributions).

The Depositary may collect any of its fees by deduction from any cash distribution payable, or by selling a portion of any securities to be distributed, to Owners that are obligated to pay those fees.

In performing its duties under this Deposit Agreement, the Depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the Depositary and that may earn or share fees, spreads or commissions.

The Depositary may own and deal in any class of securities of the Company and its affiliates and in American Depositary Shares.

SECTION 5.10. Retention of Depositary Documents.

The Depositary is authorized to destroy those documents, records, bills and other data compiled during the term of this Deposit Agreement at the times permitted by the laws or regulations governing the Depositary.

SECTION 5.11. Exclusivity.

Without prejudice to the Company's rights under Section 5.4, the Company agrees not to appoint any other depositary for issuance of depositary shares, depositary receipts or any similar securities or instruments (for the avoidance of doubt, other than instruments or securities issued directly by the Company) so long as The Bank of New York Mellon is acting as Depositary under this Deposit Agreement.

SECTION 5.12. Information for Regulatory Compliance.

Each of the Company and the Depositary shall provide to the other, as promptly as practicable, information from its records or otherwise available to it that is reasonably requested by the other to permit the other to comply with applicable law or requirements of governmental or regulatory authorities.

ARTICLE 6. AMENDMENT AND TERMINATION

SECTION 6.1. Amendment.

The form of the Receipts and any provisions of this Deposit Agreement may at any time and from time to time be amended by agreement between the Company and the Depositary without the consent of Owners or Holders in any respect that they may deem necessary or desirable. Any amendment that would impose or increase any fees or charges (other than taxes and other governmental charges, registration fees, cable (including SWIFT) or facsimile transmission costs, delivery costs or other such expenses), or that would otherwise prejudice any substantial existing right of Owners, shall, however, not become effective as to outstanding American Depositary Shares until the expiration of 30 days after notice of that amendment has been Disseminated to the Owners of outstanding American Depositary Shares. Every Owner and Holder, at the time any amendment so becomes effective, shall be deemed, by continuing to hold American Depositary Shares or any interest therein, to consent and agree to that amendment and to be bound by this Deposit Agreement as amended thereby. Upon the effectiveness of an amendment to the form of Receipt, including a change in the number of Shares represented by each American Depositary Share, the Depositary may call for surrender of Receipts to be replaced with new Receipts in the amended form or call for surrender of American Depositary Shares to effect that change of ratio. In no event shall any amendment impair the right of the Owner to surrender American Depositary Shares and receive delivery of the Deposited Securities represented thereby, except in order to comply with mandatory provisions of applicable law.

SECTION 6.2. Termination.

(a) The Company may initiate termination of this Deposit Agreement by notice to the Depositary. The Depositary may initiate termination of this Deposit Agreement if (i) at any time 60 days shall have expired after the Depositary delivered to the Company a written resignation notice and a successor depositary has not been appointed and accepted its appointment as provided in Section 5.4 or (ii) a Termination Option Event has occurred or will occur. If termination of this Deposit Agreement is initiated, the Depositary shall Disseminate a notice of termination to the Owners of all American Depositary Shares then outstanding setting a date for termination (the "Termination Date"), which shall be at least 90 days after the date of that notice, and this Deposit Agreement shall terminate on that Termination Date.

(b) After the Termination Date, the Company shall be discharged from all obligations under this Deposit Agreement except for its obligations to the Depositary under Sections 5.8 and 5.9.

(c) At any time after the Termination Date, the Depositary may sell the Deposited Securities then held under this Deposit Agreement and may thereafter hold uninvested the net proceeds of any such sale, together with any other cash then held by it hereunder, unsegregated and without liability for interest, for the pro rata benefit of the Owners of American Depositary Shares that remain outstanding, and those Owners will be general creditors of the Depositary with respect to those net proceeds and that other cash. After making that sale, the Depositary shall be discharged from all obligations under this Deposit Agreement, except (i) to account for the net proceeds and other cash (after deducting, in each case, the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of such American Depositary Shares in accordance with the terms and conditions of this Deposit Agreement and any applicable taxes or governmental charges) and (ii) for its obligations under Section 5.8 and (iii) to act as provided in paragraph (d) below.

(d) After the Termination Date, the Depositary shall continue to receive dividends and other distributions pertaining to Deposited Securities (that have not been sold), may sell rights and other property as provided in this Deposit Agreement and shall deliver Deposited Securities (or sale proceeds) upon surrender of American Depositary Shares (after payment or upon deduction, in each case, of the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of those American Depositary Shares in accordance with the terms and conditions of this Deposit Agreement and any applicable taxes or governmental charges). After the Termination Date, the Depositary shall not accept deposits of Shares or deliver American Depositary Shares. After the Termination Date, (i) the Depositary may refuse to accept surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities (that have not been sold) or reverse previously accepted surrenders of that kind that have not settled if in its judgment the requested withdrawal would interfere with its efforts to sell the Deposited Securities, (ii) the Depositary will not be required to deliver cash proceeds of the sale of Deposited Securities until all Deposited Securities have been sold and (iii) the Depositary may discontinue the registration of transfers of American Depositary Shares and suspend the distribution of dividends and other distributions on Deposited Securities to the Owners and need not give any further notices or perform any further acts under this Deposit Agreement except as provided in this Section.

ARTICLE 7. MISCELLANEOUS

SECTION 7.1. Counterparts; Signatures; Delivery.

This Deposit Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of those counterparts shall constitute one and the same instrument. Copies of this Deposit Agreement shall be filed with the Depositary and the Custodians and shall be open to inspection by any Owner or Holder during regular business hours.

The exchange of copies of this Deposit Agreement and manually-signed signature pages by facsimile, or email attaching a pdf or similar bit-mapped image, shall constitute effective execution and delivery of this Deposit Agreement as to the parties to it; copies and signature pages so exchanged may be used in lieu of the original Deposit Agreement and signature pages for all purposes and shall have the same validity, legal effect and admissibility in evidence as an original manual signature; the parties to this Deposit Agreement hereby agree not to argue to the contrary.

SECTION 7.2. No Third Party Beneficiaries.

This Deposit Agreement is for the exclusive benefit of the Company, the Depositary, the Owners and the Holders and their respective successors and shall not be deemed to give any legal or equitable right, remedy or claim whatsoever to any other person.

SECTION 7.3. Severability.

In case any one or more of the provisions contained in this Deposit Agreement or in a Receipt should be or become invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained in this Deposit Agreement or that Receipt shall in no way be affected, prejudiced or disturbed thereby.

SECTION 7.4. Owners and Holders as Parties; Binding Effect.

The Owners and Holders from time to time shall be parties to this Deposit Agreement and shall be bound by all of the terms and conditions of this Deposit Agreement and of the Receipts by acceptance of American Depositary Shares or any interest therein.

SECTION 7.5. Notices.

Any and all notices to be given to the Company shall be in writing and shall be deemed to have been duly given if personally delivered or sent by domestic first class or international air mail or air courier or sent by facsimile transmission or email attaching a pdf or similar bit-mapped image of a signed writing, addressed to Geneta Science S.p.A., Via Olgettina No. 58, 20132 Milan Italy, Attention: Pierluigi Paracchi, or any other place to which the Company may have transferred its principal office with notice to the Depositary.

Any and all notices to be given to the Depositary shall be in writing and shall be deemed to have been duly given if in English and personally delivered or sent by first class domestic or international air mail or air courier or sent by facsimile transmission or email attaching a pdf or similar bit-mapped image of a signed writing, addressed to The Bank of New York Mellon, 240 Greenwich Street, New York, New York 10286, Attention: Depositary Receipt Administration, or any other place to which the Depositary may have transferred its Office with notice to the Company.

Delivery of a notice to the Company or Depositary by mail or air courier shall be deemed effected when deposited, postage prepaid, in a post-office letter box or received by an air courier service. Delivery of a notice to the Company or Depositary sent by facsimile transmission or email shall be deemed effected when the recipient acknowledges receipt of that notice.

A notice to be given to an Owner shall be deemed to have been duly given when Disseminated to that Owner. Dissemination in paper form will be effective when personally delivered or sent by first class domestic or international air mail or air courier, addressed to that Owner at the address of that Owner as it appears on the transfer books for American Depositary Shares of the Depositary, or, if that Owner has filed with the Depositary a written request that notices intended for that Owner be mailed to some other address, at the address designated in that request. Dissemination in electronic form will be effective when sent in the manner consented to by the Owner to the electronic address most recently provided by the Owner for that purpose.

SECTION 7.6. Appointment of Agent for Service of Process; Submission to Jurisdiction; Jury Trial Waiver.

The Company hereby designates and appoints the person named in Exhibit A to this Deposit Agreement as the Company's authorized agent in the United States upon which process may be served in any suit or proceeding arising out of or relating to the Shares or Deposited Securities, the American Depositary Shares, the Receipts or this Deposit Agreement (a "Proceeding"). Each of the Company and the Depositary consents and submits to the jurisdiction of any state or federal court in the State of New York in which any Proceeding may be instituted. The Company agrees that service of process upon said authorized agent shall be deemed in every respect effective service of process upon the Company in any Proceeding. The Company agrees to deliver to the Depositary, upon the execution and delivery of this Deposit Agreement, a written acceptance by the agent named in Exhibit A to this Deposit Agreement of its appointment as process agent. The Company further agrees to take any and all action, including the filing of any and all such documents and instruments, as may be necessary to continue that designation and appointment in full force and effect, or to appoint and maintain the appointment of another process agent located in the United States as required above, and to deliver to the Depositary a written acceptance by that agent of that appointment, for so long as any American Depositary Shares or Receipts remain outstanding or this Deposit Agreement remains in force. In the event the Company fails to maintain the designation and appointment of a process agent in the United States in full force and effect, the Company hereby waives personal service of process upon it and consents that a service of process in connection with a Proceeding may be made by certified or registered mail, return receipt requested, directed to the Company at its address last specified for notices under this Deposit Agreement, and service so made shall be deemed completed five (5) days after the same shall have been so mailed.

EACH PARTY TO THIS DEPOSIT AGREEMENT (INCLUDING, FOR AVOIDANCE OF DOUBT, EACH OWNER AND HOLDER) HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING AGAINST THE COMPANY AND/OR THE DEPOSITARY DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THE SHARES OR OTHER DEPOSITED SECURITIES, THE AMERICAN DEPOSITARY SHARES OR THE RECEIPTS, THIS DEPOSIT AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREIN OR THEREIN, OR THE BREACH HEREOF OR THEREOF, INCLUDING, WITHOUT LIMITATION, ANY QUESTION REGARDING EXISTENCE, VALIDITY OR TERMINATION (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY).

SECTION 7.7. Waiver of Immunities.

To the extent that the Company or any of its properties, assets or revenues may have or may hereafter become entitled to, or have attributed to it, any right of immunity, on the grounds of sovereignty or otherwise, from any legal action, suit or proceeding, from the giving of any relief in any respect thereof, from setoff or counterclaim, from the jurisdiction of any court, from service of process, from attachment upon or prior to judgment, from attachment in aid of execution or judgment, or from execution of judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of any judgment, in any jurisdiction in which proceedings may at any time be commenced, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with the Shares or Deposited Securities, the American Depositary Shares, the Receipts or this Deposit Agreement, the Company, to the fullest extent permitted by law, hereby irrevocably and unconditionally waives, and agrees not to plead or claim, any immunity of that kind and consents to relief and enforcement as provided above.

SECTION 7.8. Governing Law.

This Deposit Agreement and the Receipts shall be interpreted in accordance with and all rights hereunder and thereunder and provisions hereof and thereof shall be governed by the laws of the State of New York.

IN WITNESS WHEREOF, GENETA SCIENCE S.P.A. and THE BANK OF NEW YORK MELLON have duly executed this Deposit Agreement as of the day and year first set forth above and all Owners and Holders shall become parties hereto upon acceptance by them of American Depositary Shares or any interest therein.

GENETA SCIENCE S.P.A.

By: _____
Name: Pierluigi Paracchi
Title: Chief Executive Officer

THE BANK OF NEW YORK MELLON,
as Depositary

By: _____
Name:
Title:

EXHIBIT A

AMERICAN DEPOSITARY SHARES
(Each American Depositary Share represents
One deposited Share)

THE BANK OF NEW YORK MELLON
AMERICAN DEPOSITARY RECEIPT
FOR ORDINARY SHARES OF
GENETA SCIENCE S.P.A.
(INCORPORATED UNDER THE LAWS OF ITALY)

The Bank of New York Mellon, as depositary (hereinafter called the "Depositary"), hereby certifies that_____, or registered assigns IS THE OWNER OF _____

AMERICAN DEPOSITARY SHARES

representing deposited ordinary shares (herein called "Shares") of Geneta Science S.p.A., incorporated under the laws of Italy (herein called the "Company"). At the date hereof, each American Depositary Share represents one Share deposited or subject to deposit under the Deposit Agreement (as such term is hereinafter defined) with a custodian for the Depositary (herein called the "Custodian") that, as of the date of the Deposit Agreement, was The Bank of New York Mellon, acting through an office located in the United Kingdom. The Depositary's Office and its principal executive office are located at 240 Greenwich Street, New York, N.Y. 10286.

THE DEPOSITARY'S OFFICE ADDRESS IS
240 GREENWICH STREET, NEW YORK, N.Y. 10286

1. THE DEPOSIT AGREEMENT.

This American Depositary Receipt is one of an issue (herein called "Receipts"), all issued and to be issued upon the terms and conditions set forth in the Deposit Agreement dated as of _____, 2021 (herein called the "Deposit Agreement") among the Company, the Depositary, and all Owners and Holders from time to time of American Depositary Shares issued thereunder, each of whom by accepting American Depositary Shares agrees to become a party thereto and become bound by all the terms and conditions thereof. The Deposit Agreement sets forth the rights of Owners and Holders and the rights and duties of the Depositary in respect of the Shares deposited thereunder and any and all other securities, property and cash from time to time received in respect of those Shares and held thereunder (those Shares, securities, property, and cash are herein called "Deposited Securities"). Copies of the Deposit Agreement are on file at the Depositary's Office in New York City and at the office of the Custodian.

The statements made on the face and reverse of this Receipt are summaries of certain provisions of the Deposit Agreement and are qualified by and subject to the detailed provisions of the Deposit Agreement, to which reference is hereby made. Capitalized terms defined in the Deposit Agreement and not defined herein shall have the meanings set forth in the Deposit Agreement.

2. SURRENDER OF AMERICAN DEPOSITARY SHARES AND WITHDRAWAL OF SHARES.

Upon surrender of American Depositary Shares for the purpose of withdrawal of the Deposited Securities represented thereby and payment of the fee of the Depositary for the surrender of American Depositary Shares as provided in Section 5.9 of the Deposit Agreement and payment of all taxes and governmental charges payable in connection with that surrender and withdrawal of the Deposited Securities, and subject to the terms and conditions of the Deposit Agreement, the Owner of those American Depositary Shares shall be entitled to delivery (to the extent delivery can then be lawfully and practicably made), to or as instructed by that Owner, of the amount of Deposited Securities at the time represented by those American Depositary Shares, but not any money or other property as to which a record date for distribution to Owners has passed (since money or other property of that kind will be delivered or paid on the scheduled payment date to the Owner as of that record date), and except that the Depositary shall not be required to accept surrender of American Depositary Shares for the purpose of withdrawal to the extent it would require delivery of a fraction of a Deposited Security. The Depositary shall direct the Custodian with respect to delivery of Deposited Securities and may charge the surrendering Owner a fee and its expenses for giving that direction by cable (including SWIFT) or facsimile transmission. If Deposited Securities are delivered physically upon surrender of American Depositary Shares for the purpose of withdrawal, that delivery will be made at the Custodian's office, except that, at the request, risk and expense of the surrendering Owner, and for the account of that Owner, the Depositary shall direct the Custodian to forward any cash or other property comprising, and forward a certificate or certificates, if applicable, and other proper documents of title, if any, for, the Deposited Securities represented by the surrendered American Depositary Shares to the Depositary for delivery at the Depositary's Office or to another address specified in the order received from the surrendering Owner.

3. REGISTRATION OF TRANSFER OF AMERICAN DEPOSITARY SHARES; COMBINATION AND SPLIT-UP OF RECEIPTS; INTERCHANGE OF CERTIFICATED AND UNCERTIFICATED AMERICAN DEPOSITARY SHARES.

The Depositary, subject to the terms and conditions of the Deposit Agreement, shall register a transfer of American Depositary Shares on its transfer books upon (i) in the case of certificated American Depositary Shares, surrender of the Receipt evidencing those American Depositary Shares, by the Owner or by a duly authorized attorney, properly endorsed or accompanied by proper instruments of transfer or (ii) in the case of uncertificated American Depositary Shares, receipt from the Owner of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9 of that Agreement), and, in either case, duly stamped as may be required by the laws of the State of New York and of the United States of America. Upon registration of a transfer, the Depositary shall deliver the transferred American Depositary Shares to or upon the order of the person entitled thereto.

The Depositary, subject to the terms and conditions of the Deposit Agreement, shall upon surrender of a Receipt or Receipts for the purpose of effecting a split-up or combination of such Receipt or Receipts, execute and deliver a new Receipt or Receipts for any authorized number of American Depositary Shares requested, evidencing the same aggregate number of American Depositary Shares as the Receipt or Receipts surrendered.

The Depositary, upon surrender of certificated American Depositary Shares for the purpose of exchanging for uncertificated American Depositary Shares, shall cancel the Receipt evidencing those certificated American Depositary Shares and send the Owner a statement confirming that the Owner is the owner of the same number of uncertificated American Depositary Shares. The Depositary, upon receipt of a proper instruction (including, for the avoidance of doubt, instructions through DRS and Profile as provided in Section 2.9 of the Deposit Agreement) from the Owner of uncertificated American Depositary Shares for the purpose of exchanging for certificated American Depositary Shares, shall cancel those uncertificated American Depositary Shares and register and deliver to the Owner a Receipt evidencing the same number of certificated American Depositary Shares.

As a condition precedent to the delivery, registration of transfer, or surrender of any American Depositary Shares or split-up or combination of any Receipt or withdrawal of any Deposited Securities, the Depositary, the Custodian, or Registrar may require payment from the depositor of the Shares or the presenter of the Receipt or instruction for registration of transfer or surrender of American Depositary Shares not evidenced by a Receipt of a sum sufficient to reimburse it for any tax or other governmental charge and any stock transfer or registration fee with respect thereto (including any such tax or charge and fee with respect to Shares being deposited or withdrawn) and payment of any applicable fees as provided in the Deposit Agreement, may require the production of proof satisfactory to it as to the identity and genuineness of any signature and may also require compliance with any regulations the Depositary may establish consistent with the provisions of the Deposit Agreement.

The Depositary may refuse to accept deposits of Shares for delivery of American Depositary Shares or to register transfers of American Depositary Shares in particular instances, or may suspend deposits of Shares or registration of transfer generally, whenever it or the Company considers it necessary or advisable to do so. The Depositary may refuse surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities in particular instances, or may suspend surrenders for the purpose of withdrawal generally, but, notwithstanding anything to the contrary in the Deposit Agreement, only for (i) temporary delays caused by closing of the Depositary's register or the register of holders of Shares maintained by the Company or the Foreign Registrar, or the deposit of Shares, in connection with voting at a shareholders' meeting or the payment of dividends, (ii) the payment of fees, taxes and similar charges, (iii) compliance with any U.S. or foreign laws or governmental regulations relating to the American Depositary Shares or to the withdrawal of the Deposited Securities or (iv) any other reason that, at the time, is permitted under paragraph I(A)(1) of the General Instructions to Form F-6 under the Securities Act of 1933 or any successor to that provision; in each case, the Depositary shall notify the Company as promptly as practicable of any suspension of that kind of that is outside the ordinary course of business.

The Depositary shall not knowingly accept for deposit under the Deposit Agreement any Shares that, at the time of deposit, are Restricted Securities.

4. LIABILITY OF OWNER FOR TAXES.

If any tax or other governmental charge shall become payable by the Custodian or the Depositary with respect to or in connection with any American Depositary Shares or any Deposited Securities represented by any American Depositary Shares or in connection with a transaction to which Section 4.8 of the Deposit Agreement applies, that tax or other governmental charge shall be payable by the Owner of those American Depositary Shares to the Depositary. The Depositary may refuse to register any transfer of those American Depositary Shares or any withdrawal of Deposited Securities represented by those American Depositary Shares until that payment is made, and may withhold any dividends or other distributions or the proceeds thereof, or may sell for the account of the Owner any part or all of the Deposited Securities represented by those American Depositary Shares, and may apply those dividends or other distributions or the net proceeds of any sale of that kind in payment of that tax or other governmental charge but, even after a sale of that kind, the Owner shall remain liable for any deficiency. The Depositary shall distribute any net proceeds of a sale made under Section 3.2 of the Deposit Agreement that are not used to pay taxes or governmental charges to the Owners entitled to them in accordance with Section 4.1 of the Deposit Agreement. If the number of Shares represented by each American Depositary Share decreases as a result of a sale of Deposited Securities under Section 3.2 of the Deposit Agreement, the Depositary may call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares and may sell American Depositary Shares to the extent necessary to avoid distributing fractions of American Depositary Shares in that exchange and distribute the net proceeds of that sale to the Owners entitled to them.

5. WARRANTIES ON DEPOSIT OF SHARES.

Every person depositing Shares under the Deposit Agreement shall be deemed thereby to represent and warrant that those Shares and each certificate therefor, if applicable, are validly issued, fully paid and nonassessable and were not issued in violation of any preemptive or similar rights of the holders of outstanding securities of the Company and that the person making that deposit is duly authorized so to do. Every depositing person shall also be deemed to represent that the Shares, at the time of deposit, are not Restricted Securities. All representations and warranties deemed made under Section 3.3 of the Deposit Agreement shall survive the deposit of Shares and delivery of American Depositary Shares.

6. FILING PROOFS, CERTIFICATES, AND OTHER INFORMATION.

Any person presenting Shares for deposit or any Owner or Holder may be required from time to time to file with the Depositary or the Custodian such proof of citizenship or residence, exchange control approval, or such information relating to the registration on the books of the Company or the Foreign Registrar, if applicable, to execute such certificates and to make such representations and warranties, as the Depositary may deem necessary or proper. The Depositary may withhold the delivery or registration of transfer of any American Depositary Shares, the distribution of any dividend or other distribution or of the proceeds thereof or the delivery of any Deposited Securities until that proof or other information is filed or those certificates are executed or those representations and warranties are made. As conditions of accepting Shares for deposit, the Depositary may require (i) any certification required by the Depositary or the Custodian in accordance with the provisions of the Deposit Agreement, (ii) a written order directing the Depositary to deliver to, or upon the written order of, the person or persons stated in that order, the number of American Depositary Shares representing those Deposited Shares, (iii) evidence satisfactory to the Depositary that those Shares have been re-registered in the books of the Company or the Foreign Registrar in the name of the Depositary, a Custodian or a nominee of the Depositary or a Custodian, (iv) evidence satisfactory to the Depositary that any necessary approval has been granted by any governmental body in each applicable jurisdiction and (v) an agreement or assignment, or other instrument satisfactory to the Depositary, that provides for the prompt transfer to the Custodian of any dividend, or right to subscribe for additional Shares or to receive other property, that any person in whose name those Shares are or have been recorded may thereafter receive upon or in respect of those Shares, or, in lieu thereof, such agreement of indemnity or other agreement as shall be satisfactory to the Depositary.

Owners and Holders shall comply with requests from the Depositary or the Custodian for proofs, certificates, representations and warranties under the preceding paragraph.

7. CHARGES OF DEPOSITARY.

The following charges shall be incurred by any party depositing or withdrawing Shares or by any party surrendering American Depositary Shares or to whom American Depositary Shares are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by the Company or an exchange of stock regarding the American Depositary Shares or Deposited Securities or a delivery of American Depositary Shares pursuant to Section 4.3 of the Deposit Agreement), or by Owners, as applicable: (1) taxes and other governmental charges, (2) such registration fees as may from time to time be in effect for the registration of transfers of Shares generally on the Share register of the Company or Foreign Registrar and applicable to transfers of Shares to or from the name of the Depositary or its nominee or the Custodian or its nominee on the making of deposits or withdrawals hereunder, (3) such cable (including SWIFT) and facsimile transmission fees and expenses as are expressly provided in the Deposit Agreement, (4) such expenses as are incurred by the Depositary in the conversion of foreign currency pursuant to Section 4.5 of the Deposit Agreement, (5) a fee of $5.00 or less per 100 American Depositary Shares (or portion thereof) for the delivery of American Depositary Shares pursuant to Section 2.3, 4.3 or 4.4 of the Deposit Agreement and the surrender of American Depositary Shares pursuant to Section 2.5 or 6.2 of the Deposit Agreement, (6) a fee of $.05 or less per American Depositary Share (or portion thereof) for any cash distribution made pursuant to the Deposit Agreement, including, but not limited to Sections 4.1 through 4.4 and 4.8 of the Deposit Agreement, (7) a fee for the distribution of securities pursuant to Section 4.2 of the Deposit Agreement or of rights pursuant to Section 4.4 of that Agreement (where the Depositary will not exercise or sell those rights on behalf of Owners), such fee being in an amount equal to the fee for the execution and delivery of American Depositary Shares referred to above which would have been charged as a result of the deposit of such securities under the Deposit Agreement (for purposes of this item 7 treating all such securities as if they were Shares) but which securities are instead distributed by the Depositary to Owners, (8) in addition to any fee charged under item 6, a fee of $.05 or less per American Depositary Share (or portion thereof) per annum for depositary services, which will be payable as provided in item 9 below, and (9) any other charges payable by the Depositary or the Custodian, any of the Depositary's or Custodian's agents or the agents of the Depositary's or Custodian's agents, in connection with the servicing of Shares or other Deposited Securities (which charges shall be assessed against Owners as of the date or dates set by the Depositary in accordance with Section 4.6 of the Deposit Agreement and shall be payable at the sole discretion of the Depositary by billing those Owners for those charges or by deducting those charges from one or more cash dividends or other cash distributions).

The Depositary may collect any of its fees by deduction from any cash distribution payable, or by selling a portion of any securities to be distributed, to Owners that are obligated to pay those fees.

The Depositary may own and deal in any class of securities of the Company and its affiliates and in American Depositary Shares.

From time to time, the Depositary may make payments to the Company to reimburse the Company for costs and expenses generally arising out of establishment and maintenance of the American Depositary Shares program, waive fees and expenses for services provided by the Depositary or share revenue from the fees collected from Owners or Holders. In performing its duties under the Deposit Agreement, the Depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the Depositary and that may earn or share fees, spreads or commissions.

8. DISCLOSURE OF INTERESTS.

When required in order to comply with applicable laws and regulations or the articles of association or similar document of the Company, the Company may from time to time request each Owner and Holder to provide to the Depositary information relating to: (a) the capacity in which it holds American Depositary Shares, (b) the identity of any Holders or other persons or entities then or previously interested in those American Depositary Shares and the nature of those interests and (c) any other matter where disclosure of such matter is required for that compliance. Each Owner and Holder agrees to provide all information known to it in response to a request made pursuant to Section 3.4 of the Deposit Agreement. Each Holder consents to the disclosure by the Depositary and the Owner or other Holder through which it holds American Depositary Shares, directly or indirectly, of all information responsive to a request made pursuant to that Section relating to that Holder that is known to that Owner or other Holder.

9. TITLE TO AMERICAN DEPOSITARY SHARES.

It is a condition of the American Depositary Shares, and every successive Owner and Holder of American Depositary Shares, by accepting or holding the same, consents and agrees that American Depositary Shares evidenced by a Receipt, when the Receipt is properly endorsed or accompanied by proper instruments of transfer, shall be transferable as certificated registered securities under the laws of the State of New York, and that American Depositary Shares not evidenced by Receipts shall be transferable as uncertificated registered securities under the laws of the State of New York. The Depositary, notwithstanding any notice to the contrary, may treat the Owner of American Depositary Shares as the absolute owner thereof for the purpose of determining the person entitled to distribution of dividends or other distributions or to any notice provided for in the Deposit Agreement and for all other purposes, and neither the Depositary nor the Company shall have any obligation or be subject to any liability under the Deposit Agreement to any Holder of American Depositary Shares, but only to the Owner.

10. VALIDITY OF RECEIPT.

This Receipt shall not be entitled to any benefits under the Deposit Agreement or be valid or obligatory for any purpose, unless this Receipt shall have been (i) executed by the Depositary by the manual signature of a duly authorized officer of the Depositary or (ii) executed by the facsimile signature of a duly authorized officer of the Depositary and countersigned by the manual signature of a duly authorized signatory of the Depositary or the Registrar or a co-registrar.

11. REPORTS; INSPECTION OF TRANSFER BOOKS.

The Company is subject to the periodic reporting requirements of the Securities Exchange Act of 1934 and, accordingly, files certain reports with the Securities and Exchange Commission. Those reports will be available for inspection and copying through the Commission's EDGAR system or at public reference facilities maintained by the Commission in Washington, D.C.

The Depositary will make available for inspection by Owners at its Office any reports, notices and other communications, including any proxy soliciting material, received from the Company which are both (a) received by the Depositary as the holder of the Deposited Securities and (b) made generally available to the holders of those Deposited Securities by the Company. The Company shall furnish reports and communications, including any proxy soliciting material to which Section 4.9 of the Deposit Agreement applies, to the Depositary in English, to the extent such materials are required to be translated into English pursuant to any regulations of the Commission.

The Depositary will maintain a register of American Depositary Shares and transfers of American Depositary Shares, which shall be open for inspection by the Owners at the Depositary's Office during regular business hours, but only for the purpose of communicating with Owners regarding the business of the Company or a matter related to this Deposit Agreement or the American Depositary Shares.

12. DIVIDENDS AND DISTRIBUTIONS.

Whenever the Depositary receives any cash dividend or other cash distribution on Deposited Securities, the Depositary will, if at the time of receipt thereof any amounts received in a foreign currency can in the judgment of the Depositary be converted on a reasonable basis into Dollars transferable to the United States, and subject to the Deposit Agreement, convert that dividend or other cash distribution into Dollars and distribute the amount thus received (net of the fees and expenses of the Depositary as provided in Article 7 hereof and Section 5.9 of the Deposit Agreement) to the Owners entitled thereto; provided, however, that if the Custodian or the Depositary is required to withhold and does withhold from that cash dividend or other cash distribution an amount on account of taxes or other governmental charges, the amount distributed to the Owners of the American Depositary Shares representing those Deposited Securities shall be reduced accordingly.

If a cash distribution would represent a return of all or substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may:

(i) require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that cash distribution; or

(ii) sell all Deposited Securities other than the subject cash distribution and add any net cash proceeds of that sale to the cash distribution, call for surrender of all those American Depositary Shares and require that surrender as a condition of making that cash distribution.

If the Depositary acts under this paragraph, that action shall also be a Termination Option Event.

Subject to the provisions of Section 4.11 and 5.9 of the Deposit Agreement, whenever the Depositary receives any distribution other than a distribution described in Section 4.1, 4.3 or 4.4 of the Deposit Agreement on Deposited Securities (but not in exchange for or in conversion or in lieu of Deposited Securities), the Depositary will cause the securities or property received by it to be distributed to the Owners entitled thereto, after deduction or upon payment of any fees and expenses of the Depositary and any taxes or other governmental charges, in any manner that the Depositary deems equitable and practicable for accomplishing that distribution (which may be a distribution of depositary shares representing the securities received); provided, however, that if in the opinion of the Depositary such distribution cannot be made proportionately among the Owners entitled thereto, or if for any other reason the Depositary deems such distribution not to be lawful and feasible, the Depositary may adopt such other method as it may deem equitable and practicable for the purpose of effecting such distribution, including, but not limited to, the public or private sale of the securities or property thus received, or any part thereof, and distribution of the net proceeds of any such sale (net of the fees and expenses of the Depositary as provided in Article 7 hereof and Section 5.9 of the Deposit Agreement) to the Owners entitled thereto all in the manner and subject to the conditions set forth in Section 4.1 of the Deposit Agreement. The Depositary may withhold any distribution of securities under Section 4.2 of the Deposit Agreement if it has not received satisfactory assurances from the Company that the distribution does not require registration under the Securities Act of 1933. The Depositary may sell, by public or private sale, an amount of securities or other property it would otherwise distribute under this Article that is sufficient to pay its fees and expenses in respect of that distribution.

If a distribution to be made under Section 4.2 of the Deposit Agreement would represent a return of all or substantially all the value of the Deposited Securities underlying American Depositary Shares, the Depositary may:

(i) require payment of or deduct the fee for surrender of American Depositary Shares (whether or not it is also requiring surrender of American Depositary Shares) as a condition of making that distribution; or

(ii) sell all Deposited Securities other than the subject distribution and add any net cash proceeds of that sale to the distribution, call for surrender of all those American Depositary Shares and require that surrender as a condition of making that distribution.

If the Depositary acts under this paragraph, that action shall also be a Termination Option Event.

Whenever the Depositary receives any distribution consisting of a dividend in, or free distribution of, Shares, the Depositary may deliver to the Owners entitled thereto, an aggregate number of American Depositary Shares representing the amount of Shares received as that dividend or free distribution, subject to the terms and conditions of the Deposit Agreement with respect to the deposit of Shares and issuance of American Depositary Shares, including the withholding of any tax or other governmental charge as provided in Section 4.11 of the Deposit Agreement and the payment of the fees and expenses of the Depositary as provided in Article 7 hereof and Section 5.9 of the Deposit Agreement (and the Depositary may sell, by public or private sale, an amount of Shares received (or American Depositary Shares representing those Shares) sufficient to pay its fees and expenses in respect of that distribution). In lieu of delivering fractional American Depositary Shares, the Depositary may sell the amount of Shares represented by the aggregate of those fractions (or American Depositary Shares representing those Shares) and distribute the net proceeds, all in the manner and subject to the conditions described in Section 4.1of the Deposit Agreement. If and to the extent that additional American Depositary Shares are not delivered and Shares or American Depositary Shares are not sold, each American Depositary Share shall thenceforth also represent the additional Shares distributed on the Deposited Securities represented thereby.

If the Company declares a distribution in which holders of Deposited Securities have a right to elect whether to receive cash, Shares or other securities or a combination of those things, or a right to elect to have a distribution sold on their behalf, the Depositary may, after consultation with the Company, make that right of election available for exercise by Owners in any manner the Depositary considers to be lawful and practical. As a condition of making a distribution election right available to Owners, the Depositary may require satisfactory assurances from the Company that doing so does not require registration of any securities under the Securities Act of 1933 that has not been effected.

If the Depositary determines that any distribution received or to be made by the Depositary (including Shares and rights to subscribe therefor) is subject to any tax or other governmental charge that the Depositary is obligated to withhold, the Depositary may sell, by public or private sale, all or a portion of the distributed property (including Shares and rights to subscribe therefor) in the amounts and manner the Depositary deems necessary and practicable to pay those taxes or charges, and the Depositary shall distribute the net proceeds of that sale, after deduction of those taxes or charges, to the Owners entitled thereto in proportion to the number of American Depositary Shares held by them respectively.

Each Owner and Holder agrees to indemnify the Company, the Depositary, the Custodian and their respective directors, employees, agents and affiliates for, and hold each of them harmless against, any claim by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced withholding at source or other tax benefit received by it. The obligations of Owners and Holders under the preceding sentence shall survive any transfer of American Depositary Shares or surrender of American Depositary Shares and withdrawal of Deposited Securities and the termination of the Deposit Agreement. Services for Owners and Holders that may permit them to obtain reduced rates of tax withholding at source or reclaim excess tax withheld, and the fees and costs associated with using services of that kind, are not provided under, and are outside the scope of, the Deposit Agreement.

13. RIGHTS.

(a) If rights are granted to the Depositary in respect of deposited Shares to purchase additional Shares or other securities, the Company and the Depositary shall endeavor to consult as to the actions, if any, the Depositary should take in connection with that grant of rights. The Depositary may, to the extent deemed by it to be lawful and practical (i) if requested in writing by the Company, grant to all or certain Owners rights to instruct the Depositary to purchase the securities to which the rights relate and deliver those securities or American Depositary Shares representing those securities to Owners, (ii) if requested in writing by the Company, deliver the rights to or to the order of certain Owners, or (iii) sell the rights to the extent practicable and distribute the net proceeds of that sale to Owners entitled to those proceeds. To the extent rights are not exercised, delivered or disposed of under (i), (ii) or (iii) above, the Depositary shall permit the rights to lapse unexercised.

(b) If the Depositary will act under (a)(i) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon instruction from an applicable Owner in the form the Depositary specified and upon payment by that Owner to the Depositary of an amount equal to the purchase price of the securities to be received upon the exercise of the rights, the Depositary shall, on behalf of that Owner, exercise the rights and purchase the securities. The purchased securities shall be delivered to, or as instructed by, the Depositary. The Depositary shall (i) deposit the purchased Shares under the Deposit Agreement and deliver American Depositary Shares representing those Shares to that Owner or (ii) deliver or cause the purchased Shares or other securities to be delivered to or to the order of that Owner. The Depositary will not act under (a)(i) above unless the offer and sale of the securities to which the rights relate are registered under the Securities Act of 1933 or the Depositary has received an opinion of United States counsel that is satisfactory to it to the effect that those securities may be sold and delivered to the applicable Owners without registration under the Securities Act of 1933.

(c) If the Depositary will act under (a)(ii) above, the Company and the Depositary will enter into a separate agreement setting forth the conditions and procedures applicable to the particular offering. Upon (i) the request of an applicable Owner to deliver the rights allocable to the American Depositary Shares of that Owner to an account specified by that Owner to which the rights can be delivered and (ii) receipt of such documents as the Company and the Depositary agreed to require to comply with applicable law, the Depositary will deliver those rights as requested by that Owner.

(d) If the Depositary will act under (a)(iii) above, the Depositary will use reasonable efforts to sell the rights in proportion to the number of American Depositary Shares held by the applicable Owners and pay the net proceeds to the Owners otherwise entitled to the rights that were sold, upon an averaged or other practical basis without regard to any distinctions among such Owners because of exchange restrictions or the date of delivery of any American Depositary Shares or otherwise.

(e) Payment or deduction of the fees of the Depositary as provided in Section 5.9 of the Deposit Agreement and payment or deduction of the expenses of the Depositary and any applicable taxes or other governmental charges shall be conditions of any delivery of securities or payment of cash proceeds under Section 4.4 of that Agreement.

(f) The Depositary shall not be responsible for any failure to determine that it may be lawful or feasible to make rights available to or exercise rights on behalf of Owners in general or any Owner in particular , or to sell rights.

14. CONVERSION OF FOREIGN CURRENCY.

Whenever the Depositary or the Custodian receives foreign currency, by way of dividends or other distributions or the net proceeds from the sale of securities, property or rights, and if at the time of the receipt thereof the foreign currency so received can in the judgment of the Depositary be converted on a reasonable basis into Dollars and the resulting Dollars transferred to the United States, the Depositary or one of its agents or affiliates or the Custodian shall convert or cause to be converted by sale or in any other manner that it may determine that foreign currency into Dollars, and those Dollars shall be distributed to the Owners entitled thereto. A cash distribution may be made upon an averaged or other practicable basis without regard to any distinctions among Owners based on exchange restrictions, the date of delivery of any American Depositary Shares or otherwise and shall be net of any expenses of conversion into Dollars incurred by the Depositary as provided in Section 5.9 of the Deposit Agreement.

If a conversion of foreign currency or the repatriation or distribution of Dollars can be effected only with the approval or license of any government or agency thereof, the Depositary may, but will not be required to, file an application for that approval or license.

If the Depositary, after consultation with the Company to the extent practicable, determines that in its judgment any foreign currency received by the Depositary or the Custodian is not convertible on a reasonable basis into Dollars transferable to the United States, or if any approval or license of any government or agency thereof that is required for such conversion is not filed or sought by the Depositary or is not obtained within a reasonable period as determined by the Depositary, the Depositary may distribute the foreign currency received by the Depositary to, or in its discretion may hold such foreign currency uninvested and without liability for interest thereon for the respective accounts of, the Owners entitled to receive the same.

If any conversion of foreign currency, in whole or in part, cannot be effected for distribution to some of the Owners entitled thereto, the Depositary may in its discretion make that conversion and distribution in Dollars to the extent practicable and permissible to the Owners entitled thereto and may distribute the balance of the foreign currency received by the Depositary to, or hold that balance uninvested and without liability for interest thereon for the account of, the Owners entitled thereto.

The Depositary may convert currency itself or through any of its affiliates, or the Custodian or the Company may convert currency and pay Dollars to the Depositary. Where the Depositary converts currency itself or through any of its affiliates, the Depositary acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the Deposit Agreement and the rate that the Depositary or its affiliate receives when buying or selling foreign currency for its own account. The Depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under the Deposit Agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to Owners, subject to the Depositary's obligations under Section 5.3 of that Agreement. The methodology used to determine exchange rates used in currency conversions made by the Depositary is available upon request. Where the Custodian converts currency, the Custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to Owners, and the Depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the Depositary may receive dividends or other distributions from the Company in Dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by or on behalf of the Company and, in such cases, the Depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor the Company makes any representation that the rate obtained or determined by the Company is the most favorable rate and neither it nor the Company will be liable for any direct or indirect losses associated with the rate.

15. RECORD DATES.

Whenever a cash dividend, cash distribution or any other distribution is made on Deposited Securities or rights to purchase Shares or other securities are issued with respect to Deposited Securities (which rights will be delivered to or exercised or sold on behalf of Owners in accordance with Section 4.4 of the Deposit Agreement) or the Depositary receives notice that a distribution or issuance of that kind will be made, or whenever the Depositary receives notice that a meeting of holders of Shares will be held in respect of which the Company has requested the Depositary to send a notice under Section 4.7 of the Deposit Agreement, or whenever the Depositary will assess a fee or charge against the Owners, or whenever the Depositary causes a change in the number of Shares that are represented by each American Depositary Share, or whenever the Depositary otherwise finds it necessary or convenient, the Depositary shall fix a record date, which shall be the same as, or as near as practicable to, any corresponding record date set by the Company with respect to Shares, (a) for the determination of the Owners (i) who shall be entitled to receive the benefit of that dividend or other distribution or those rights, (ii) who shall be entitled to give instructions for the exercise of voting rights at that meeting, (iii) who shall be responsible for that fee or charge or (iv) for any other purpose for which the record date was set, or (b) on or after which each American Depositary Share will represent the changed number of Shares. Subject to the provisions of Sections 4.1 through 4.5 of the Deposit Agreement and to the other terms and conditions of the Deposit Agreement, the Owners on a record date fixed by the Depositary shall be entitled to receive the amount distributable by the Depositary with respect to that dividend or other distribution or those rights or the net proceeds of sale thereof in proportion to the number of American Depositary Shares held by them respectively, to give voting instructions or to act in respect of the other matter for which that record date was fixed, or be responsible for that fee or charge, as the case may be.

16. VOTING OF DEPOSITED SHARES.

(a) Upon receipt of notice of any meeting of holders of Shares at which holders of Shares will be entitled to vote, if requested in writing by the Company, the Depositary shall, as soon as practicable thereafter, Disseminate to the Owners a notice, the form of which shall be in the sole discretion of the Depositary, that shall contain (i) the information contained in the notice of meeting received by the Depositary, (ii) a statement that the Owners as of the close of business on a specified record date will be entitled, subject to any applicable provision of Italian law and of the articles of association or similar documents of the Company, to instruct the Depositary as to the exercise of the voting rights pertaining to the amount of Shares represented by their respective American Depositary Shares, (iii) a statement as to the manner in which those instructions may be given and (iv) the last date on which the Depositary will accept instructions (the "Instruction Cutoff Date").

(b) Upon the written request of an Owner of American Depositary Shares, as of the date of the request or, if a record date was specified by the Depositary, as of that record date, received on or before any Instruction Cutoff Date established by the Depositary, the Depositary may, and if the Depositary sent a notice under the preceding paragraph shall, endeavor, in so far as practicable, to vote or cause to be voted the amount of deposited Shares represented by those American Depositary Shares in accordance with the instructions set forth in that request. The Depositary shall not vote or attempt to exercise the right to vote that attaches to the deposited Shares other than in accordance with instructions given by Owners and received by the Depositary.

(c) There can be no assurance that Owners generally or any Owner in particular will receive the notice described in paragraph (a) above in time to enable Owners to give instructions to the Depositary prior to the Instruction Cutoff Date.

(d) In order to give Owners a reasonable opportunity to instruct the Depositary as to the exercise of voting rights relating to Shares, if the Company will request the Depositary to Disseminate a notice under paragraph (a) above, the Company shall give the Depositary notice of the meeting, details concerning the matters to be voted upon and copies of materials to be made available to holders of Shares in connection with the meeting not less than 45 days prior to the meeting date.

Notwithstanding anything in Section 4.7 of the Deposit Agreement to the contrary, the Depositary and the Company may modify, amend or adopt additional procedures with respect to voting Deposited Securities from time to time as they determine may be necessary or appropriate to comply with applicable laws and regulations.

17. TENDER AND EXCHANGE OFFERS; REDEMPTION, REPLACEMENT OR CANCELLATION OF DEPOSITED SECURITIES.

(a) The Depositary shall not tender any Deposited Securities in response to any voluntary cash tender offer, exchange offer or similar offer made to holders of Deposited Securities (a "Voluntary Offer"), except when instructed in writing to do so by an Owner surrendering American Depositary Shares and subject to any conditions or procedures the Depositary may require.

(b) If the Depositary receives a written notice that Deposited Securities have been redeemed for cash or otherwise purchased for cash in a transaction that is mandatory and binding on the Depositary as a holder of those Deposited Securities (a "Redemption"), the Depositary, at the expense of the Company, shall (i) if required, surrender Deposited Securities that have been redeemed to the issuer of those securities or its agent on the redemption date, (ii) Disseminate a notice to Owners (A) notifying them of that Redemption, (B) calling for surrender of a corresponding number of American Depositary Shares and (C) notifying them that the called American Depositary Shares have been converted into a right only to receive the money received by the Depositary upon that Redemption and those net proceeds shall be the Deposited Securities to which Owners of those converted American Depositary Shares shall be entitled upon surrenders of those American Depositary Shares in accordance with Section 2.5 or 6.2 of the Deposit Agreement and (iii) distribute the money received upon that Redemption to the Owners entitled to it upon surrender by them of called American Depositary Shares in accordance with Section 2.5 of that Agreement (and, for the avoidance of doubt, Owners shall not be entitled to receive that money under Section 4.1 of that Agreement). If the Redemption affects less than all the Deposited Securities, the Depositary shall call for surrender a corresponding portion of the outstanding American Depositary Shares and only those American Depositary Shares will automatically be converted into a right to receive the net proceeds of the Redemption. The Depositary shall allocate the American Depositary Shares converted under the preceding sentence among the Owners pro-rata to their respective holdings of American Depositary Shares immediately prior to the Redemption, except that the allocations may be adjusted so that no fraction of a converted American Depositary Share is allocated to any Owner. A Redemption of all or substantially all of the Deposited Securities shall be a Termination Option Event.

(c) If the Depositary is notified of or there occurs any change in nominal value or any subdivision, combination or any other reclassification of the Deposited Securities or any recapitalization, reorganization, sale of assets substantially as an entirety, merger or consolidation affecting the issuer of the Deposited Securities or to which it is a party that is mandatory and binding on the Depositary as a holder of Deposited Securities and, as a result, securities or other property have been or will be delivered in exchange, conversion, replacement or in lieu of, Deposited Securities (a "Replacement"), the Depositary shall, if required, surrender the old Deposited Securities affected by that Replacement of Shares and hold, as new Deposited Securities under the Deposit Agreement, the new securities or other property delivered to it in that Replacement. However, the Depositary may elect to sell those new Deposited Securities if in the opinion of the Depositary, after consultation with the Company to the extent practicable, it is not lawful or not practical for it to hold those new Deposited Securities under the Deposit Agreement because those new Deposited Securities may not be distributed to Owners without registration under the Securities Act of 1933 or for any other reason, at public or private sale, at such places and on such terms as it deems proper and proceed as if those new Deposited Securities had been Redeemed under paragraph (b) above. A Replacement shall be a Termination Option Event.

(d) In the case of a Replacement where the new Deposited Securities will continue to be held under the Deposit Agreement, the Depositary may call for the surrender of outstanding Receipts to be exchanged for new Receipts specifically describing the new Deposited Securities and the number of those new Deposited Securities represented by each American Depositary Share. If the number of Shares represented by each American Depositary Share decreases as a result of a Replacement, the Depositary may, after consultation with the Company to the extent practicable, call for surrender of the American Depositary Shares to be exchanged on a mandatory basis for a lesser number of American Depositary Shares and may sell American Depositary Shares to the extent necessary to avoid distributing fractions of American Depositary Shares in that exchange and distribute the net proceeds of that sale to the Owners entitled to them.

(e) If there are no Deposited Securities with respect to American Depositary Shares, including if the Deposited Securities are cancelled, or the Deposited Securities with respect to American Depositary Shares become apparently worthless, the Depositary may call for surrender of those American Depositary Shares or may cancel those American Depositary Shares, upon notice to Owners, and that condition shall be a Termination Option Event.

18. LIABILITY OF THE COMPANY AND DEPOSITARY.

Neither the Depositary nor the Company nor any of their respective directors, employees, agents or affiliates shall incur any liability to any Owner or Holder:

(i) if by reason of (A) any provision of any present or future law or regulation or other act of the government of the United States, any State of the United States or any other state or jurisdiction, or of any governmental or regulatory authority or stock exchange; (B) (in the case of the Depositary only) any provision, present or future, of the articles of association or similar document of the Company, or by reason of any provision of any securities issued or distributed by the Company, or any offering or distribution thereof; or (C) any event or circumstance, whether natural or caused by a person or persons, that is beyond the ability of the Depositary or the Company, as the case may be, to prevent or counteract by reasonable care or effort (including, but not limited to earthquakes, floods, severe storms, fires, explosions, war, terrorism, civil unrest, labor disputes, criminal acts or outbreaks of infectious disease; interruptions or malfunctions of utility services, Internet or other communications lines or systems; unauthorized access to or attacks on computer systems or websites; or other failures or malfunctions of computer hardware or software or other systems or equipment), the Depositary or the Company is, directly or indirectly, prevented from, forbidden to or delayed in, or could be subject to any civil or criminal penalty on account of doing or performing and therefore does not do or perform, any act or thing that, by the terms of the Deposit Agreement or the Deposited Securities, it is provided shall be done or performed;

(ii) for any exercise of, or failure to exercise, any discretion provided for in the Deposit Agreement (including any determination by the Depositary to take, or not take, any action that the Deposit Agreement provides the Depositary may take);

(iii) for the inability of any Owner or Holder to benefit from any distribution, offering, right or other benefit that is made available to holders of Deposited Securities but is not, under the terms of the Deposit Agreement, made available to Owners or Holders; or

(iv) for any special, consequential or punitive damages for any breach of the terms of the Deposit Agreement.

Where, by the terms of a distribution to which Section 4.1, 4.2 or 4.3 of the Deposit Agreement applies, or an offering to which Section 4.4 of that Agreement applies, or for any other reason, that distribution or offering may not be made available to Owners, and the Depositary may not dispose of that distribution or offering on behalf of Owners and make the net proceeds available to Owners, then the Depositary shall not make that distribution or offering available to Owners, and shall allow any rights, if applicable, to lapse.

Neither the Company nor the Depositary assumes any obligation or shall be subject to any liability under the Deposit Agreement to Owners or Holders, except that they agree to perform their obligations specifically set forth in the Deposit Agreement without negligence or bad faith. The Depositary shall not be a fiduciary or have any fiduciary duty to Owners or Holders. The Depositary shall not be subject to any liability with respect to the validity or worth of the Deposited Securities. Neither the Depositary nor the Company shall be under any obligation to appear in, prosecute or defend any action, suit, or other proceeding in respect of any Deposited Securities or in respect of the American Depositary Shares, on behalf of any Owner or Holder or other person. Neither the Depositary nor the Company shall be liable for any action or non-action by it in reliance upon the advice of or information from legal counsel, accountants, any person presenting Shares for deposit, any Owner or Holder, or any other person believed by it in good faith to be competent to give such advice or information. Each of the Depositary and the Company may rely, and shall be protected in relying upon, any written notice, request, direction or other document believed by it to be genuine and to have been signed or presented by the proper party or parties. The Depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the Depositary or in connection with a matter arising wholly after the removal or resignation of the Depositary, provided that in connection with the issue out of which such potential liability arises, the Depositary performed its obligations without negligence or bad faith while it acted as Depositary. The Depositary shall not be liable for the acts or omissions of any securities depository, clearing agency or settlement system in connection with or arising out of book-entry settlement of American Depositary Shares or Deposited Securities or otherwise. In the absence of bad faith on its part, the Depositary shall not be responsible for any failure to carry out any instructions to vote any of the Deposited Securities or for the manner in which any such vote is cast or the effect of any such vote. The Depositary shall have no duty to make any determination or provide any information as to the tax status of the Company or any liability for any tax consequences that may be incurred by Owners or Holders as a result of owning or holding American Depositary Shares. The Depositary shall not be liable for the inability or failure of an Owner or Holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit. No disclaimer of liability under the United States federal securities laws is intended by any provision of the Deposit Agreement.

19. RESIGNATION AND REMOVAL OF THE DEPOSITARY; APPOINTMENT OF SUCCESSOR CUSTODIAN.

The Depositary may at any time resign as Depositary under the Deposit Agreement by written notice of its election so to do delivered to the Company, to become effective upon the appointment of a successor depositary and its acceptance of such appointment as provided in the Deposit Agreement. The Depositary may at any time be removed by the Company by 120 days' prior written notice of that removal, to become effective upon the later of (i) the 120th day after delivery of the notice to the Depositary and (ii) the appointment of a successor depositary and its acceptance of its appointment as provided in the Deposit Agreement. The Depositary in its discretion may at any time appoint a substitute or additional custodian or custodians.

20. AMENDMENT.

The form of the Receipts and any provisions of the Deposit Agreement may at any time and from time to time be amended by agreement between the Company and the Depositary without the consent of Owners or Holders in any respect which they may deem necessary or desirable. Any amendment that would impose or increase any fees or charges (other than taxes and other governmental charges, registration fees, cable (including SWIFT) or facsimile transmission costs, delivery costs or other such expenses), or that would otherwise prejudice any substantial existing right of Owners, shall, however, not become effective as to outstanding American Depositary Shares until the expiration of 30 days after notice of that amendment has been Disseminated to the Owners of outstanding American Depositary Shares. Every Owner and Holder, at the time any amendment so becomes effective, shall be deemed, by continuing to hold American Depositary Shares or any interest therein, to consent and agree to that amendment and to be bound by the Deposit Agreement as amended thereby. Upon the effectiveness of an amendment to the form of Receipt, including a change in the number of Shares represented by each American Depositary Share, the Depositary may call for surrender of Receipts to be replaced with new Receipts in the amended form or call for surrender of American Depositary Shares to effect that change of ratio. In no event shall any amendment impair the right of the Owner to surrender American Depositary Shares and receive delivery of the Deposited Securities represented thereby, except in order to comply with mandatory provisions of applicable law.

21. TERMINATION OF DEPOSIT AGREEMENT.

(a) The Company may initiate termination of the Deposit Agreement by notice to the Depositary. The Depositary may initiate termination of the Deposit Agreement if (i) at any time 60 days shall have expired after the Depositary delivered to the Company a written resignation notice and a successor depositary has not been appointed and accepted its appointment as provided in Section 5.4 of that Agreement or (ii) a Termination Option Event has occurred. If termination of the Deposit Agreement is initiated, the Depositary shall Disseminate a notice of termination to the Owners of all American Depositary Shares then outstanding setting a date for termination (the "Termination Date"), which shall be at least 90 days after the date of that notice, and the Deposit Agreement shall terminate on that Termination Date.

(b) After the Termination Date, the Company shall be discharged from all obligations under the Deposit Agreement except for its obligations to the Depositary under Sections 5.8 and 5.9 of that Agreement.

(c) At any time after the Termination Date, the Depositary may sell the Deposited Securities then held under the Deposit Agreement and may thereafter hold uninvested the net proceeds of any such sale, together with any other cash then held by it hereunder, unsegregated and without liability for interest, for the pro rata benefit of the Owners of American Depositary Shares that remain outstanding, and those Owners will be general creditors of the Depositary with respect to those net proceeds and that other cash. After making that sale, the Depositary shall be discharged from all obligations under the Deposit Agreement, except (i) to account for the net proceeds and other cash (after deducting, in each case, the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of such American Depositary Shares in accordance with the terms and conditions of the Deposit Agreement and any applicable taxes or governmental charges) and (ii) for its obligations under Section 5.8 of that Agreement and (iii) to act as provided in paragraph (d) below.

(d) After the Termination Date, the Depositary shall continue to receive dividends and other distributions pertaining to Deposited Securities (that have not been sold), may sell rights and other property as provided in the Deposit Agreement and shall deliver Deposited Securities (or sale proceeds) upon surrender of American Depositary Shares (after payment or upon deduction, in each case, of the fee of the Depositary for the surrender of American Depositary Shares, any expenses for the account of the Owner of those American Depositary Shares in accordance with the terms and conditions of the Deposit Agreement and any applicable taxes or governmental charges). After the Termination Date, the Depositary shall not accept deposits of Shares or deliver American Depositary Shares. After the Termination Date, (i) the Depositary may refuse to accept surrenders of American Depositary Shares for the purpose of withdrawal of Deposited Securities (that have not been sold) or reverse previously accepted surrenders of that kind that have not settled if in its judgment the requested withdrawal would interfere with its efforts to sell the Deposited Securities, (ii) the Depositary will not be required to deliver cash proceeds of the sale of Deposited Securities until all Deposited Securities have been sold and (iii) the Depositary may discontinue the registration of transfers of American Depositary Shares and suspend the distribution of dividends and other distributions on Deposited Securities to the Owners and need not give any further notices or perform any further acts under the Deposit Agreement except as provided in Section 6.2 of that Agreement.

22. DTC DIRECT REGISTRATION SYSTEM AND PROFILE MODIFICATION SYSTEM.

(a) Notwithstanding the provisions of Section 2.4 of the Deposit Agreement, the parties acknowledge that DTC's Direct Registration System ("DRS") and Profile Modification System ("Profile") apply to the American Depositary Shares upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC that facilitates interchange between registered holding of uncertificated securities and holding of security entitlements in those securities through DTC and a DTC participant. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of an Owner of American Depositary Shares, to direct the Depositary to register a transfer of those American Depositary Shares to DTC or its nominee and to deliver those American Depositary Shares to the DTC account of that DTC participant without receipt by the Depositary of prior authorization from the Owner to register that transfer.

(b) In connection with DRS/Profile, the parties acknowledge that the Depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an Owner in requesting registration of transfer and delivery as described in paragraph (a) above has the actual authority to act on behalf of that Owner (notwithstanding any requirements under the Uniform Commercial Code). For the avoidance of doubt, the provisions of Sections 5.3 and 5.8 of the Deposit Agreement apply to the matters arising from the use of the DRS/Profile. The parties agree that the Depositary's reliance on and compliance with instructions received by the Depositary through the DRS/Profile system and otherwise in accordance with the Deposit Agreement, shall not constitute negligence or bad faith on the part of the Depositary.

23. APPOINTMENT OF AGENT FOR SERVICE OF PROCESS; SUBMISSION TO JURISDICTION; JURY TRIAL WAIVER; WAIVER OF IMMUNITIES.

The Company has (i) appointed Cogency Global Inc., 122 East 42nd Street, 18th Floor New York, NY 10168 as the Company's authorized agent in the United States upon which process may be served in any suit or proceeding arising out of or relating to the Shares or Deposited Securities, the American Depositary Shares, the Receipts or this Agreement, (ii) consented and submitted to the jurisdiction of any state or federal court in the State of New York in which any such suit or proceeding may be instituted, and (iii) agreed that service of process upon said authorized agent shall be deemed in every respect effective service of process upon the Company in any such suit or proceeding.

EACH PARTY TO THE DEPOSIT AGREEMENT (INCLUDING, FOR AVOIDANCE OF DOUBT, EACH OWNER AND HOLDER) THEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING AGAINST THE COMPANY AND/OR THE DEPOSITARY DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THE SHARES OR OTHER DEPOSITED SECURITIES, THE AMERICAN DEPOSITARY SHARES OR THE RECEIPTS, THE DEPOSIT AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREIN OR THEREIN, OR THE BREACH HEREOF OR THEREOF, INCLUDING, WITHOUT LIMITATION, ANY QUESTION REGARDING EXISTENCE, VALIDITY OR TERMINATION (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY).

To the extent that the Company or any of its properties, assets or revenues may have or hereafter become entitled to, or have attributed to it, any right of immunity, on the grounds of sovereignty or otherwise, from any legal action, suit or proceeding, from the giving of any relief in any respect thereof, from setoff or counterclaim, from the jurisdiction of any court, from service of process, from attachment upon or prior to judgment, from attachment in aid of execution or judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of any judgment, in any jurisdiction in which proceedings may at any time be commenced, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with the Shares or Deposited Securities, the American Depositary Shares, the Receipts or the Deposit Agreement, the Company, to the fullest extent permitted by law, hereby irrevocably and unconditionally waives, and agrees not to plead or claim, any such immunity and consents to such relief and enforcement.

Exhibit 10.1

LICENSE AGREEMENT

Between

Ospedale San Raffaele S.r.l.

And

Genenta Science S.r.l.

Milan, December 15, 2014

LICENSE AGREEMENT

This LICENSE AGREEMENT (the "**License Agreement**" or, briefly, the "**Agreement**") dated as of December 15, 2014 (the "**Effective Date**"), is entered into in Milan

By and between

Ospedale San Raffaele S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 07636600962, duly represented for the purposes hereof by its Managing Director, Mr. Nicola Bedin ("**OSR**")

- *on the one side* -

And

Genenta Science S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 08738490963, duly represented for the purposes hereof by its Managing Directors, Ms. Anna Flavia d'Amelio Einaudi and Mr. Pierluigi Paracchi ("**Genenta**")

- *on the other side* -

(OSR and Genenta shall be, collectively but not jointly, defined as the "**Parties**" and, severally, a "**Party**").

WHEREAS:

(A) On June 19, 2013, Fondazione Telethon, having its principal seat in Rome, via Carlo Spinola No. 16 ("**Telethon**") and OSR stipulated a co-operation agreement (the "**OSR-Telethon Cooperation Agreement**"), for the carrying out of basic, translational and clinical research relating to diagnosis and therapy of certain diseases through the establishment of the so-called "*San Raffaele Telethon Institute for Gene Therapy*" (the "**TIGET Institute**");

(B) For what matters for the purposes of this License Agreement, the OSR-Telethon Cooperation Agreement sets forth: *(i)* the joint ownership on any intellectual property rights arising out from the research activities jointly carried out through the TIGET Institute (a) in the specific field consisting in the diagnosis, physiopathology and therapy of hereditary genetic diseases, including diagnostic and prognostic applications, the development and clinical trial of strategy and technological platform for the gene and cells therapy, the identification, characterization, manipulation and transplant of stem or differentiated cells relevant for regenerating medicine, cell therapy and modulation of immunological reaction and (b) outside the field mentioned in letter *(i)*(a) above; and *(ii)* the granting of a world-wide exclusive license by Telethon to OSR, bearing the right to sub-license to third party, on the intellectual property rights jointly held by Telethon and OSR

and arising out from the research activities carried out outside the field indicated in letter *(i)*(a) above;

(C) On the basis of the OSR-Telethon Cooperation Agreement, the TIGET Institute has carried out certain pre-clinical studies on a specific gene therapy approach compound (as identified below) to be further developed and assessed on human clinical trials based on the use of Interferon (IFN) gene therapy by lentiviral based-HSPC gene transfer with respect to lympho-hematopoietic indication and/or solid cancer indication and, therefore, OSR owns and, for the quota held by Telethon, has the right to license, the intellectual property rights accrued up to the Effective Date on the know-how developed as of the Effective Date, it being understood that the know-how in possession of OSR as of the Effective Date that is reasonably necessary to research, develop, manufacture or commercialize the Licensed Products in the Field of Use is identified (along with the relevant limitations) in Exhibit (C) to this License Agreement (the **"Existing Know-How"**);

(D) On July 24, 2014, OSR, [redacted], [redacted] and [redacted] incorporated Genenta;

(E) On July 24, 2014, OSR, [redacted], [redacted] and [redacted] entered into an investment and shareholders' agreement for the regulation of the common investment in Genenta as well as to regulate certain governance prerogatives on the management of the said company (the **"Genenta Investment Agreement"**);

(F) Based on the Genenta Investment Agreement, Genenta shall operate in the development and subsequently exploitation of a project for the research and development of a treatment of cancer through genetic therapy and, specifically, for the inhibition of cancer through the genetic engineering of hematopoietic stem cells used as carrier of alpha-interferon through monocytes (the **"Genenta Project"**);

(G) For what matters for the purposes of this License Agreement, the Parties hereby acknowledge that:

(a) on December 12, 2015, OSR, in accordance to the terms of the OSR-Telethon Cooperation Agreement, notified Telethon its intention to license the patents and the relevant Existing Know-How in the field covered by the Genenta Project and requested Telethon the authorization to further sub-license the Telethon's quota of the said patents and know-how in the field covered by the Genenta Project;

(b) on the very same date, Telethon acknowledged the communication mentioned under letter (a) above and agreed to amend the OSR-Telethon Cooperation Agreement so that the right to further sub-license the Telethon's quota of the said patents and Know-How in the field covered by the Genenta Project is now expressly set forth by the OSR-Telethon Cooperation Agreement.

(H) In furtherance of the Genenta Investment Agreement, OSR is willing to grant to Genenta, who is willing to accept, a license under the Licensed Technology in the Field of Use (each as defined below), under the terms and conditions set forth below and the Parties hereby acknowledge that, through the entering of this License Agreement, the condition precedent set forth by letter a) of Article 3.1 of the Investment Agreement is met.

* * *

NOW, THEREFORE, also in consideration of the foregoing premises, which together with the Exhibits herein appended form an integral and substantial part of this Agreement, and the mutual covenants herein contained, the **PARTIES HEREBY AGREE AS FOLLOWS.**

1. DEFINITIONS

In addition to the other terms and expressions elsewhere defined in this Agreement, or purposes hereof, the terms and expressions defined in this Section 1, whether used in singular or plural, shall have the respective meanings set forth below.

1.1 **"Additional Patents"** shall mean the patents and patent applications identified in Exhibit 1.1 to this License Agreement.

1.2 **"Affiliate"** shall mean, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct (or cause the direction of) the management and policies of the other Person by any means whatsoever; provided that, for the purposes of this License Agreement, (a) in no case may Genenta be regarded as, or considered, an Affiliate of OSR and *vice-versa* and (b) in no case a shareholder of Genenta, whether controlling or not such company, shall be considered an Affiliate of Genenta.

1.3 **"Applicable Regulation"** shall mean any applicable federal, state, local or foreign law, statute, ordinance, principle of common law, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license or permit of any Governmental Authority, including, for the avoidance of doubt, cGCP, cGLP and cGMP.

1.4 **"Best Standards"** means, with respect to a specific Party's obligation, that the relevant specific obligation shall be considered, qualified and construed as requiring the maximum degree of due diligence and care under the Applicable Regulations and this Agreement and, as such, the relevant obligor shall be exempted from liability only if, and to the extent that, (a) a force majeure event has occurred and is ongoing or (b) is able to demonstrate that all efforts necessary to perform such obligation were timely and correctly made by such obligor and, despite that, the

relevant result was not achieved. Given the nature of this License Agreement, Best Standards shall not however mean the achievement of the specific results (endpoints) of each phase of the research and development activities regarding each Licensed Product.

1.5 **"Business Day"** shall mean any day, excluding Saturday, Sunday and any day which shall be in Milan, Italy a day on which banking institutions are not open for their business activity.

1.6 **"Calendar Quarter"** shall mean the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on the last day of March, June, September, or December, respectively; provided that, the final Calendar Quarter shall end on the last day of the Term.

1.7 **"Calendar Year"** shall mean the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) consecutive calendar months beginning on January 1 and ending on December 31; provided that, the final Calendar Year shall end on the last day of the Term.

1.8 **"cGCP"** means the then-current standards, practices and procedures set forth in the International Conference on Harmonization (ICH) guidelines entitled "*Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance*" including related requirements promulgated by the FDA, and equivalent foreign regulations or standards, as applicable, as such standards, practices, procedures, requirements and regulations may be amended from time to time.

1.9 **"cGLP"** means the then-current good laboratory practice regulations promulgated by the FDA, published at 21 C.F.R. § 58, and equivalent foreign regulations or standards, as applicable, as such current laboratory practices, regulations and equivalent foreign regulations or standards may be amended from time to time.

1.10 **"cGMP"** means the then-current good manufacturing practices that apply to the manufacturing practices for fine chemicals, intermediates, bulk products and/or finished medicinal products, including the regulations promulgated by the FDA, published at 21 C.F.R. Parts 210 and 211, and equivalent foreign regulations or standards, as applicable, including The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products, as current good manufacturing practices, regulations and equivalent foreign regulations or standards may be amended from time to time.

1.11 **"Combination Product"** means a product that contains a Licensed Product and another component, including other active ingredients, delivery devices and adjuvants which are themselves not Licensed Products.

1.12 **"Commercial Exclusivity"** means, with respect to each Licensed Product in each of the countries included in the Territory, that, alternatively: (a) at least one Valid Claim of each of the Licensed Patents covers the composition of matter, formulation, manufacture, use, sale, offer for sale or importation of such Licensed Product in such country; or (b) *(i)* Genenta or any of its Sublicensees has been granted and continues to enjoy the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of the Applicable Regulation) in such country to market and sell the Licensed Product in such country, or *(ii)* the data and information submitted by (or on behalf and in the interest of) Genenta or any of its Sublicensees to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval may not, as a matter of legal right or under Applicable Regulations, be disclosed, referenced or relied upon in any way by any other applicant or by such Regulatory Authority (including by relying upon the Regulatory Authority's previous findings regarding the safety or effectiveness of the Licensed Product) to support the Regulatory Approval or marketing of any product by a Third Party in such country.

1.13 **"Commercially Reasonable Efforts"** shall mean, with respect to any obligation or task of Genenta under this Agreement, the application by Genenta or its Sublicensees, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources then used to fulfil the obligation in issue, consistent with the level of efforts that Genenta (or the applicable Sublicensee) would devote to research, develop, manufacture or commercialize a medicinal product owned by it (or to which it has rights) having profit potential and strategic value comparable to that of the Licensed Product and in any case in compliance with the Applicable Regulations.

1.14 **"Competing Product"** shall mean any product consisting of, or containing, any viral vector regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of anti-cancer proteins other than IFN under the control of a Tie2 promoter and/or IFN under the control of any promoter other than Tie2for any Lympho-Hematopoietic Indication and/or Solid Cancer Indication.

1.15 **"Effective Date"** shall mean the date of signature of this License Agreement.

1.16 **"EMA"** shall mean the European Medicines Agency of the European Union, or the successor thereto.

1.17 **"FDA"** shall mean the Food and Drug Administration of the United States of America, or the successor thereto.

1.18 **"Field of Use"** shall mean the use of Interferon (IFN) gene therapy by lentiviral based-HSPC gene transfer with respect to (a) any Lympho-Hematopoietic

Indication and/or (b) any Solid Cancer Indication had Genenta exercised the option set forth in Section 2.2(c) below.

1.19 **"First Commercial Sale"** shall mean, with respect to any Licensed Product, the first sale of such Licensed Product in any country included in the Territory after all applicable marketing and pricing approvals (if any) have been granted by the applicable Regulatory Authority in such country.

1.20 **"Genenta Product Improvements"** shall mean any modification, enhancement, improvement, invention, discovery, idea, know-how, data or information (whether patentable or not) that (a) relate to the Licensed Products and the Licensed Technology, and (b) is generated by Genenta during the Term in the exercise of the rights granted to it under Section 2.1.

1.21 **"Generic Product"** shall mean a gene therapy product that (a) obtained a Regulatory Approval by means of establishing equivalence to a Licensed Product in a particular country and in the same Field of Use, and (b) is legally marketed in such country by an entity other than Genenta or its Sublicensees.

1.22 **"Governmental Authority"** means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court, tribunal or other entity), including a Regulatory Authority.

1.23 **"IND"** means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto. References herein to IND shall include, to the extent applicable (but, in no case, under Section 10.4 below), any comparable filing(s) outside the United Stated of America for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application, or CTA, in the European Union).

1.24 **"Investment Threshold"** shall mean the overall amount of Euro [redacted] duly paid to Genenta through, subscription of share capital increases and bonds, as set forth and in accordance with the Genenta Investment Agreement.

1.25 **"Licensed Know-How"** shall mean (a) the Existing Know-How; and (b) upon exercise by Genenta of the option set forth in Section 2.2(b), the OSR Product Improvements, which are necessary or useful to develop, manufacture and/or commercialize the Licensed Products in the Field of Use, whether patentable (but not patented) or not, as indicated by the scientific advisory board of Genenta.

1.26 **"Licensed Patents"** shall mean: (a) the patents and patent applications identified in Exhibit 1.26 to this License Agreement; (b) upon exercise by Genenta of the option set forth in Section 2.2(a), the Additional Patents; (c) upon exercise by Genenta of the option set forth in Section 2.2(b), the patents and patent

applications, if any, covering the OSR Product Improvements; (d) all divisions, continuations, continuations-in-part, that claim priority to, or common priority with, any of the patent applications described in letters from (a) through (d) above; and (e) all patents that have issued or in the future issue from any of the foregoing patent applications, being it understood that letters (a) through (e) above shall always include any reissues, renewals, extensions, supplemental protection certificates, and additions to any thereof.

1.27 **"Licensed Product"** shall mean any product developed during the Term consisting of, or containing, any lentivirals vector regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter.

1.28 **"Licensed Technology"** shall mean, collectively, the Licensed Patents and the Licensed Know-How.

1.29 **"Lympho-Hematopoietic Indication"** shall mean any indication related to lympho-hematopoietic malignancies.

1.30 **"MAA"** shall mean a marketing authorization application or equivalent application filed with the applicable Regulatory Authority in the Territory.

1.31 **"MAA Approval"** shall mean the approval of a MAA by the applicable Regulatory Authority to market a Licensed Product in the Field of Use in a country or region in the Territory.

1.32 **"Major EU Countries"** shall mean any of the following countries: France, Germany, Italy, Spain and United Kingdom.

1.33 **"NDA"** shall mean a New Drug Application, or similar application for marketing approval of a Licensed Product in the Field of Use filed with the FDA.

1.34 **"Net Sales"** shall mean the gross invoiced amount of any Licensed Products sold by Genenta or its Sublicensees to any Third Party in a transaction after deducting, if not previously deducted, from the amount invoiced or received:

(i) value added taxes, sales taxes, or similar taxes;

(ii) amounts actually credited or allowed for rejections or returns of the relevant Licensed Products actually accepted by Genenta and/or its Sublicensees;

(iii) rebates, chargebacks, retroactive price reductions and other sales allowances that are actually allowed or granted, including rebates, reductions and allowances mandated by Regulatory Authorities;

(iv) early payment cash discounts, bad debt expense, amounts written off by reason of uncollectible debt; and

(v) insurance, customs duties, freight, postage, shipping, handling, and other transportation costs incurred by the Genenta or its Sublicensees in shipping the Licensed Products to a Third Party,

It being understood and further agreed that:

(a) the adjustments and reductions of the "*Net Sales*" indicated by letters (ii), (iii) and (iv) above shall not be in excess of [redacted] of the Net Sales during each Net Sales reporting period;

(b) in the case of any sale of the Licensed Products which is not invoiced or is delivered before invoicing, Net Sales shall be calculated at the time all revenue recognition criteria are met, irrespective of when the actual payment for such sale is received by Genenta or its Sublicensees;

(c) in the case of any sale or other disposal of a Licensed Products between or among Genenta and/or its Sublicensees for resale, Net Sales shall be calculated as above, only on the value charged or invoiced on the first sale by such Sublicensee to any Third Party;

(d) any nominal consideration received in exchange for the transfer of Licensed Products for use in clinical trials, sampling compassionate or promotional use, free of charge, shall not be included in Net Sales;

(e) Net Sales for Combination Products shall be determined as follows:

(i) In the event one or more Licensed Products are sold as part of a Combination Product in a particular country, and all Licensed Products contained in the Combination Product are also sold separately in such country, the Net Sales of such Licensed Product(s), for the purposes of determining payments based on the Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country, during the applicable Net Sales reporting period, by the fraction A/(A+B), where:

"*A*" is the average weighted (by sales volume, on a quarterly basis) sale price of the Licensed Product(s) contained in such Combination Product when sold separately in finished form in such country; and

"*B*" is the average weighted (by sales volume, on a quarterly basis) purchase price paid by Genenta or its Sublicensees

for the other component(s) included in the Combination Product,

in each case during the applicable Net Sales reporting period.

(ii) In the event one or more Licensed Products are sold as part of a Combination Product and are sold separately in finished form in such country, but the other medicinal Licensed Product(s) included in the Combination Product are not sold separately in finished form in such country, the Net Sales of the Licensed Product, for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country by the fraction C/D where:

"*C*" is the average weighted (by sales volume, on a quarterly basis) sale price of the Licensed Product(s) contained in such Combination Product when sold separately in finished form in such country; and

"*D*" is the average weighted (by sales volume, on a quarterly basis) sale price of the Combination Product sold in such country,

in each case during the applicable Net Sales reporting period.

(iii) In the event that the Net Sales of the Licensed Product(s) when included in a Combination Product cannot be determined by using the methods indicated in letters (i) and (ii) above, the Net Sales for the purposes of determining payments based on the Net Sales shall be agreed upon in good faith by the Parties, on the basis of the respective fair market values of the Licensed Product(s) and all other medicinal Licensed Products included in such Combination Product.

1.35 "**Net Sublicensing Income**" shall mean, with respect to any Licensed Product, any cash amounts received by Genenta in consideration for any sublicense under the Licensed Technology granted by Genenta or its Sublicensees (other than distributors) with respect to such Licensed Product, including any upfront payment, and (to the extent they exceed the amounts of the Milestone Payment A or Milestone Payment B, as set forth in Section 4.6 below) any milestone payments, but excluding the following amounts: royalties, amounts received to reimburse Genenta's costs to perform research, development or similar services conducted for such Licensed Product after signing the agreement with the Third Party, or in reimbursement of patent expenses or other out-of-pocket expenses relating to such Licensed Product.

1.36 **"Option Period"** shall mean the period that commences on the Effective Date and ends on January 31, 2019, as eventually extended pursuant to Section 2.2(c) below.

1.37 **"OSR Product Improvements"** shall mean any modification, enhancement, improvement, invention, discovery, idea, know-how, data or information (whether patentable or not) relating to the Licensed Products (as well as to the Genenta Product Improvements) in the Field of Use generated after the Effective Date and during the Term by scientists or other personnel working at the TIGET Institute or at OSR and owned, controlled by, or for which OSR has the right to license, under the terms and conditions of the OSR-Telethon Cooperation Agreement.

1.38 **"OSR-Genenta Scientific Collaboration Agreement"** means that certain Scientific Collaboration Agreement entered into between OSR and Genenta on the Effective Date, as such agreement may be amended or extended from time to time by the Parties during the Term.

1.39 **"Person"** shall mean an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.40 **"Phase I/II Clinical Trial"** shall mean a human clinical trial in any country that is intended to evaluate the safety and effectiveness of a Licensed Product in the Field of Use and satisfies the requirements of 21 CFR 312.21(a/b), or its foreign equivalent.

1.41 **"Phase III Clinical Trial"** shall mean a human clinical trial in any country, the results of which could be used to establish safety and efficacy of a Licensed Product in the Field as a basis for an NDA, or its foreign equivalent, and satisfies the requirements of 21 CFR 312.21(c), or its foreign equivalent.

1.42 **"Regulatory Authority(ies)"** shall mean, collectively (a) the governmental entities in each country or supranational organization that is responsible for the regulation of any Licensed Product intended for use in the Field of Use or the establishment, maintenance and/or protection of rights related to the Licensed Technology (including the FDA and the EMA), or (b) any other applicable regulatory or administrative agency in any country or supranational organization that is comparable to, or a counterpart of, the foregoing.

1.43 **"Registration(s)"** shall mean any and all permits, licenses, authorizations, registrations or regulatory approvals (including NDAs) required and/or granted by any Regulatory Authority as a prerequisite to the development, manufacturing, packaging, marketing and selling of any Licensed Product.

1.44 **"Royalty Term"** shall mean, with respect to each Licensed Product in each country included in the Territory, on a country-by-country basis, the period of time

commencing on the First Commercial Sale of such Licensed Product in such country and ending upon the later of: (a) the expiration of Commercial Exclusivity with respect to that Licensed Product in that country; and (b) ten (10) years from the First Commercial Sale of that Licensed Product in such country.

1.45 **"Solid Cancer Indication"** means any solid cancer indication (*e.g.*, without limitation, breast, pancreas, colon cancer), it being understood that each affected human organ shall count as a specific Solid Cancer Indication.

1.46 **"Sublicensee"** means any Person to whom Genenta has granted a sublicense under the Licensed Technology: (a) subject to the previous approval of the scientific advisory board of Genenta, to research and develop and (b) to make, have made, use, offer for sale, sell and import the Licensed Products in the Territory in the Field of Use in accordance with Section 2.6 of this License Agreement. For the sake of clarity, any Affiliate of Genenta and/or any shareholder of Genenta shall not (solely by virtue of being an Affiliate or shareholder, as applicable) be included in the definition of Sublicensee. In addition, any distributor, reseller or similar channel partner that is not granted rights under the Licensed Technology, other than the right to market and/or sell the Licensed Products in the Territory in the Field of Use shall not be included in the definition of Sublicensee.

1.47 **"Territory"** shall mean worldwide.

1.48 **"Third Party"** shall mean any Person other than OSR, Genenta and their respective Affiliates and, for the purposes of the calculation of the Net Sales, shall exclude, for the avoidance of doubt, any Sublicensee of Genenta.

1.49 **"Valid Claim"** shall mean a claim of (a) an issued and unexpired patent included within the Licensed Patents, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or (b) a pending patent application that has not been finally abandoned or finally rejected or expired and which has been pending for no more than eight (8) years from the date of filing of such application as a utility, non-provisional application, provided that if such patent application is subsequently granted, such claim(s) shall again be considered Valid Claim(s) once such patent application is granted.

2. LICENSES

2.1 **License grant.** Subject to the terms and conditions of this Agreement, OSR hereby grants to Genenta an exclusive (which is also exclusive with respect to OSR and its Affiliates, but, to such an extent subject to Section 2.10), royalty-bearing, non-transferrable license (except in connection with a permitted assignment of the

Agreement in accordance with Section 15.2), under the Licensed Technology, to conduct research and to develop, make, have made, use, offer for sale, sell and import the Licensed Products in the Territory in the Field of Use, with the right to sublicense, also on multiple-tier basis, (a) subject however to the prior approval of the scientific advisory board of Genenta and without prejudice to Section 7.8 below, the right to research, develop, make, have made, use and (b) the right to offer for sale, sell and import, that Licensed Products in the Territory in the Field of Use, to the Sublicensees pursuant to the terms of Section 2.6 below.

2.2 **Option.** Subject to the terms and conditions of this Agreement, OSR hereby grants to Genenta an exclusive option, which may be exercised by Genenta at any time during the Option Period upon written notice to OSR (the "**Notice**") to:

(a) include the Additional Patents as part of the Licensed Patents licensed to Genenta under Section 2.1 above, at no additional cost, upon the advice of the Genenta's scientific advisory board, according to which the use of the Additional Patents could be useful for the development and/or commercialization of Licensed Products in the Territory and in the Field of Use; and/or

(b) include a specific OSR Product Improvement as part of the Licensed Know-How licensed to Genenta under Section 2.1 above, at no additional cost, subject to Genenta's scientific advisory board resolving that the specific OSR Product Improvement is useful or necessary of the development and/or commercialization of the Licensed Products in the Territory and in the Field of Use; and/or

(c) include any Solid Cancer Indication as part of the Field of Use, on an indication-by-indication basis, subject to the payment of (i) the Option Fee (as defined below) and (ii) the milestones payments for each Solid Cancer Indication as set forth in Section 4.6 of this Agreement. In the event that Genenta exercises the option set forth under this Section 2.2(c) with respect to any Solid Cancer Indication, the Option Period for any other Solid Cancer Indication shall be extended for twenty-four (24) months as from February 1st 2019.

2.3 **Option Fee and Additional Milestones.** Further to the exercise of the Option set forth by Section 2.2(c) above, the Field of Use of this License shall be (and shall be considered) extended so as to include the relevant Solid Cancer Indication, only upon effective receipt by OSR of the following amounts: (a) Euro [redacted] for the first Solid Cancer Indication; (b) Euro [redacted] for the second Solid Cancer Indication; and Euro [redacted] for the third Solid Cancer Indication. The foregoing amounts shall become due and payable upon receipt of the Notice. No Option Fee shall be due for the 4th (fourth) and following Solid Cancer Indications. For clarity, should Genenta exercise the option granted under Section 2.2(c), the Milestones Payment B shall become effective and due upon occurrence of the

relevant Milestone Event with respect to such Solid Cancer Indication, as set forth in Section 4.6 of this License Agreement and the other financial terms and conditions set forth by this License Agreement shall apply, *mutatis mutandis*, to the sale of any Licensed Products for such Solid Cancer Indication.

2.4 **Exclusivity of the Option.** During the Option Period, as eventually extended pursuant to Section 2.2(c) above, OSR may not grant or transfer to any Third party any rights that are covered by the options granted to Genenta under Section 2.2(a) and (c) above.

2.5 **License non-transferrable.** The license granted by OSR under this Agreement is non-transferable, except in connection with a permitted assignment of the Agreement in accordance with Section 15.2 below.

2.6 **Sublicense.** Subject to the terms and condition of this Agreement, OSR hereby grants Genenta, under the Licensed Technology, the right to sublicense, where permissible also on a multiple-tier basis, the following: (a) subject however to the prior approval of the scientific advisory board of Genenta and without prejudice to Section 7.8 below, the right to research, develop, make, have made, use; and (b) the right to offer for sale, sell and import the Licensed Products in the Territory in the Field of Use as granted to Genenta under Section 2.1 above, to any Sublicensee, provided that Genenta:

(i) before the signature of any sublicense agreement notifies to OSR the corporate name and details of the relevant Sublicensee, the scope of the prospective sublicense agreement and, should such Sublicensee be granted with any of the rights mentioned under letter (a) of this Section 2.6, the advice of the scientific advisory board approving the involvement of such Sublicensee;

(ii) ensures that the applicable sublicense agreement entered into with each Sublicensee be consistent with (and do not exceed) the scope of the licenses granted under this Agreement;

(iii) is and remains fully responsible and liable towards OSR for the actions or omissions of each Sublicensee which result in a breach of the terms and conditions of this License Agreement.

2.7 **Distributors and Third Parties' suppliers.** Subject to the terms and conditions of this Agreement, Genenta shall be (and keeps) full responsibility towards OSR for any act and/or omission of any distributors of the Licensed Products as well as of any Third Party suppliers engaged in connection with the activities covered by this License Agreement, to the extent that such act or omission results in a breach of the terms and conditions of this License Agreement and/or in the prejudice of OSR's interests under this License Agreement.

2.8 **No other right.** Genenta hereby expressly agrees and acknowledges that the rights granted under the Licensed Technology pursuant to this Agreement concern only the Licensed Products in the Field of Use, and that no rights or licenses are hereby granted to Genenta and/or its Affiliates and/or its Sublicensees by OSR under this Agreement with respect to any active pharmaceutical ingredient or therapeutic agent or field of use other than those expressly stated in this License Agreement. Neither Party grants to the other Party any rights, licenses or covenants in or to any intellectual property, whether by implication, estoppels, or otherwise, other than the license rights that are expressly granted under this Agreement.

2.9 **OSR license to the Genenta Product Improvements.** Subject to the terms and conditions of this License Agreement, Genenta hereby grants to OSR during the Term a perpetual, worldwide, royalty-free, non-exclusive license under the Genenta Product Improvements as follows: (a) subject to Section 3 below, to carry out internal research in the Field of Use directly or in or with the collaboration of any Third Party; and (b) for any use outside the Field of Use, in which case the license shall be sublicenseable, also on a multiple-tier basis, provided however that each sublicensee of OSR shall be subject to non-disclosure obligations with respect to the Genenta Product Improvements at least compatable to those set forth in Section 8 below.

2.10 **OSR's retained rights.** OSR and the relevant Affiliates shall retain the right to use the Licensed Technology as follows: (a) subject to Section 3 below, for internal research use only, either founded by OSR and/or its Affiliates or by any Third Party, including through the TIGET Institute, in the Field of Use; and (b) for any use or exploitation outside the Field of Use, without any limitation of right, and including the right to grant sublicense, also on a multiple tier level; provided that, for clarity, OSR may not during the Term grant or transfer any rights to, or deliver to any person or entity any Licensed Technology for use in the Field of Use (and, subject to the exercise of the option set forth by Section 2.2(b) above, any OSR Product Improvement for use in the Field of Use).

2.11 **Availability of Existing Know-how.** OSR shall provide Genenta with a copy of all information available to OSR incorporating the Existing Know-How, relating to the Field of Use, including without limitation, listings and tables of results from the pre-clinical studies within sixty (60) Business Days following the achievement of the Investment Threshold. Thereafter, OSR shall deliver to Genenta the OSR Product Improvements, during the Term, subject to the exercise of the option set forth by Section 2 2b) above.

2.12 **Registrations.** Subject to the terms and conditions of this Agreement and the reaching by Genenta of the Investment Threshold, OSR acknowledges and agrees that Genenta shall own (or be transferred if already issued) all Registrations for Licensed Products for use in the Field of Use in each country in the Territory. Upon (and subject to the) reaching by Genenta of the Investment Threshold, OSR hereby grants to Genenta a free-of-charge, sublicenseable right to reference and

have access to all Registrations and all other regulatory documents that relate to the Licensed Technology, including INDs, BLAs, NDAs and DMFs, and any supplements, amendments or updates to the foregoing, all of the above provided that these Registrations and other regulatory documents concern the use of the Licensed Product in the Field of Use. OSR shall promptly notify Genenta of any written or oral notices received from, or inspections by any Regulatory Authority relating to any such Registrations, and shall promptly inform Genenta of any responses to such written notices or inspections and the resolution of any issue raised by such Regulatory Authority.

3. NON-COMPETE

3.1 **Non-compete.** Notwithstanding anything to the contrary in this Agreement, OSR may not: (A) grant any license to any Third Party to commercialize a Competing Product, in each case until the earlier of (a) 5 (five) years as from the Effective Date or (b) the completion of the first Phase I/II Clinical Trial of the Licensed Product; and (B) grant any option to any Third Party to commercialize a Competing Product for the initial two (2) year-period as from the Effective Date. Notwithstanding the foregoing, OSR shall be free to grant any Third Party the right to research and develop any such Competing Product at any time during the Term as well as to grant any other right upon the expiry of the terms set forth by letters (A) and (B) above.

3.2 **Sufficient consideration.** The Parties acknowledge and agree that the economic terms and conditions set forth by this License Agreement have been assess and agreed also as consideration, and in the light, of the non-compete undertakings set forth by Section 3.1 above.

4. FINANCIAL CONSIDERATIONS

4.1 **Upfront Fee.** Genenta shall pay to OSR an amount equal of Euro [redacted] (the "**Upfront Fee**"), which shall be due upon achievement by Genenta of the Investment Threshold.

4.2 **Royalties.** Subject to Sections 4.3 and 4.4, Genenta shall pay to OSR royalties equal to [redacted] of Net Sales of each Licensed Product (the "**Royalties**"). It is understood and agreed that the amount of the Royalties shall be due and payable with respect to each Licensed Product regardless of how many Valid Claims cover such Licensed Product.

4.3 **Generic competition.** Subject to Section 4.4 below, upon commencement of Generic Competition with respect to a Licensed Product in a country included in the Territory, and thereafter for so long as such Generic Competition persists, the

Royalties payable thereafter under Section 4.2 above with respect to such Licensed Product sold in such country shall be reduced by:

(a) [redacted] percent [redacted] if such Generic Product(s) represent(s) a total quantity sold of at least [redacted] percent [redacted] of the total quantity sold of such Licensed Product and such Generic Product(s), in the aggregate, in such country in such Calendar Year, as determined by the number of unit equivalents for such Licensed Product and such Generic Product(s), in the aggregate, during such Calendar Year (as measured by an IMS audit or other mechanism selected by Genenta and accepted by OSR);

or, as the case may be,

(b) [redacted] percent [redacted] if such Generic Product(s) represent(s) a total quantity sold of at least [redacted] percent [redacted] of the total quantity sold of such Licensed Product and such Generic Product(s), in the aggregate, in such country in such Calendar Year, as determined by the number of unit equivalents for such Licensed Product and such Generic Product(s), in the aggregate, during such calendar year (measured as described in letter (a) above).

4.4 **Royalty floor.** In no event shall the amount of the Royalties due and payable by Genenta to OSR in accordance with Section 4.2 be reduced by (a) reason of Generic Competition as set forth by Sections 4.3(a) and 4.3(b) above or (b) any Licensing Necessity as set forth by Section 4.7 below, whether alone or in combination, to less than [redacted] of the Royalties that would otherwise (*i.e.* without applying the mentioned reductions) be due under Section 4.2 above for each Calendar Quarter.

4.5 **Net Sublicensing Income Sharing.** In addition to the Royalties set forth by Section 4.2 above and to the Milestone Payments set forth by Section 4.6 below, Genenta shall pay to OSR an amount equal to [redacted] of Net Sublicensing Income for each Licensed Product (the "**OSR Sublicensing Income**").

4.6 **Milestones.** In addition to the Royalties set forth by Section 4.2 above and to the OSR Sublicensing Income set forth by Section 4.5 above, Genenta shall pay to OSR:

(a) for each Lympho Hematopoietic Indication of each Licensed Product, on a Licensed Product-by-Licensed Product basis and on an Indication-by-Indication basis, and within thirty (30) Business Days as of the occurrence applicable milestone event indicated in the table below (each a "**Milestone Event**"), the amount indicated in the said table with respect to such Milestone Event (each "**Milestone Payment A**");

(b) subject to the exercise of the option granted to Genenta under Section 2.2(c) above, for each Solid Cancer Indication of each Licensed Product, on a Licensed Product-by-Licensed Product basis and on an Indication-by-Indication basis, and within thirty (30) Business Days as of the occurrence a Milestone Event, the amount indicated in the said table with respect to such Milestone Event (each "**Milestone Payment B**" and, together with the Milestone Payments A, the "**Milestone Payments**"), it being understood that starting from the fifth (5th) Solid Cancer Indication (included) onwards, the amount of first two (2) Milestone Payments B shall be reduced by [redacted]. In addition, if clinical proof of concept (*PoC*) is not achieved in the first Solid Cancer Indication, and Genenta exercises the option set forth by Section 2.2(c) with respect to a second Solid Cancer Indication, then the first two (2) Milestone Payments B will be reduced by [redacted] for such second Solid Cancer Indication. For clarity, for the purposes of determining milestone payments under this Section 4.6, a given Licensed Product includes all dosage strengths and formulations of such Licensed Product.

Milestone Event	Milestone Payment A	Milestone Payment B
First patient dosed with a Licensed Product in Phase I/II Clinical Trial	[redacted]	[redacted]
First patient dosed with such Licensed Product in a Phase III Clinical Trial	[redacted]	[redacted]
MAA Approval for such Licensed Product in the first Major EU Country	[redacted]	[redacted]
NDA acceptance for such Licensed Product (United States of America)	[redacted]	[redacted]
First Commercial Sale of such Licensed Product in the United States of America	[redacted]	[redacted]
First Commercial Sale of such Licensed Product in	[redacted]	[redacted]

three (3) out of 5 Major EU Countries		
Aggregated Net Sales in the Territory during a single Calendar Year firstly exceeding Euro [redacted]	[redacted]	[redacted]

4.7 **Anti-stacking.** If:

(a) in order to avoid infringement of any claim of any Third Party's patent and/or know-how by any Licensed Product, it is reasonably necessary to: (x) obtain a license from such Third Party in order to secure Genenta's rights and licenses to develop and commercialize such Licensed Product, as it has been developed by (or on behalf of) OSR as at the Effective Date (such necessity to obtain a Third Party-license, the **"Licensing Necessity"**); and (y) pay a royalty or other amounts under such license (including, without limitation, in connection with settlement of a patent infringement claim); or

(b) Genenta shall be subject to any enforceable order or ruling of any court of competent jurisdiction, requiring the payment of a royalty or other similar payment or compensation or indemnification to a Third Party patent or know-how holder with respect to the development, marketing, manufacture or commercialization of the Licensed Product, as it has been developed by (or on behalf) of OSR as of the Effective Date,

Then, in the case of each of letters (a) and (b) above, and provided that Genenta has previously informed of, and reasonably consulted with, OSR on the Licensing Necessity, [redacted] of the royalty or other payment or compensation or indemnification which is owed and paid to such Third Party will be fully offset against the Milestone Payments and/or the Royalties otherwise owed to OSR under this Section 4; provided further that: (a) in the event that Genenta is entitled to seek and actually obtains a stay of application of such order or ruling, Genenta shall not be entitled to offset any such Milestone Payments and/or Royalties, as the case may be, while such stay is in effect or is not requested by Genenta; and (b) in the event that such order or ruling is reversed upon appeal and Genenta obtains reimbursement of the sums taken to offset Milestone Payments and/or the Royalties hereunder, such sums shall be promptly reimbursed to OSR by Genenta.

4.8 **Disagreement on the Licensing Necessity.** If OSR disagrees with Genenta's view that there is a Licensing Necessity, Genenta may, at its own costs and expense, request a written opinion on the Licensing Necessity from an independent

law firm which is internationally recognized in intellectual property matters (the "**Independent Law Firm**"). If the Independent Law Firm confirms that there is no Licensing Necessity or is unable to provide such confirmation, then the costs of the Independent Law Firm shall be paid solely by Genenta. If the Independent Law Firm confirms that there is a Licensing Necessity, the costs of the Independent Law Firm shall be paid by OSR. The Parties agree that the determination of the Independent Law Firm as to whether or not a Licensing Necessity exists shall be final and binding on the Parties.

4.9 **VAT.** Each of the payment due to OSR from Genenta under this Agreement are exclusive of applicable value added tax to be charged to Genenta under any applicable law ("**VAT**") and, accordingly, all applicable VAT shall be added to the above payments and paid by Genenta to OSR.

5. ROYALTY REPORTS AND ACCOUNTING

5.1 **Royalty reports.** Within forty-five (45) Business Days after the end of each Calendar Quarter during the Term of this Agreement, Genenta shall furnish to OSR a quarterly written report showing in reasonably specific details the following: (a) the calculation of Net Sales during such Calendar Quarter; (b) the calculation of Net Sublicensing Income for such Calendar Quarter; (c) the calculation of the royalties, if any, that shall have accrued based upon such Net Sales and Net Sublicensing Income; (d) the withholding taxes, if any, required by law to be deducted with respect to such sales; and (e) the exchange rates, if any, used in determining the amount of Euro. With respect to sales of Licensed Products invoiced in Euros, the gross sales, Net Sales and royalties payable shall be expressed in Euro. With respect to (i) the Net Sales invoiced in a currency other than Euro and (ii) any cash consideration paid by the Sublicensees in a currency other than Euro, all such amounts shall be expressed both in the currency in which the distribution is invoiced and in the United States dollar equivalent. The Euro equivalent shall be calculated using the average of the exchange rate (local currency per Euro 1) published in The Wall Street Journal, Western Edition, under the heading "*Currency Trading*" on the last Business Day of each month during the applicable Calendar Quarter.

5.2 **Audits.** Upon written request of OSR and not more than twice in each Calendar Year (except for just cause), Genenta shall permit an independent certified public accounting firm of nationally recognized standing selected by OSR, at OSR's expense, to have access during normal business hours to such of the financial records of Genenta as may be reasonably necessary to verify the accuracy of the payment reports hereunder for the twelve (12) Calendar Quarters immediately prior to the date of such request. If such accounting firm concludes that additional amounts were owed during the audited period, Genenta shall pay such additional amounts within twenty (20) Business Days after the date OSR delivers to Genenta such accounting firm's written report so concluding. The fees charged by such

accounting firm shall be paid by OSR; provided, however, if the audit discloses that the overall amounts actually paid by Genenta for such audited period are lower by more than [redacted] than the amount payable and due for such period as evidenced by the report of the accounting firm, then Genenta shall pay the reasonable fees and expenses charged by such accounting firm. OSR shall cause its accounting firm to retain all financial information subject to review under this Section 5.2 in strict confidence; provided, however, that Genenta shall have the right to require that such accounting firm, prior to conducting such audit, enters into an appropriate non-disclosure agreement with Genenta regarding such financial information. OSR shall treat all such financial information as Genenta's Confidential Information.

6. PAYMENTS

6.1 **Payment terms.** (a) The Upfront Fee shall be paid by Genenta to OSR by and not later than June 30, 2015. (b) All Royalties and OSR Sublicensing Income payable and due in accordance to this License Agreement shall be paid by Genenta to OSR by forty-five (45) Business Days as of the end of each Calendar Quarter, irrespective of the receipt of the report provided by Genenta in accordance with Section 5.1 above. (c) All Milestone Payments payable and due in accordance to this License Agreement shall be paid by and not later than thirty (30) Business Days as from the day on which the relevant Milestone Event occurs, irrespective of the receipt of the report prepared by Genenta in accordance with Section 5.1.

6.2 **Exchange control.** If at any time legal restrictions prevent the prompt remittance of part or all Royalties with respect to any country in the Territory where the Licensed Product is sold, Genenta shall have the right, in its sole discretion, to make such payments by depositing the amount thereof in local currency to OSR's account in a bank or other depository institution in such country. If the royalty rate specified in this Agreement should exceed the permissible rate established in any country, the royalty rate for sales in such country shall be adjusted to the highest legally permissible or government-approved rate.

6.3 **Withholding taxes.** Genenta shall be entitled to deduct the amount of any withholding taxes, value-added taxes or other taxes, levies or charges with respect to such amounts, payable by Genenta or its Sublicensees, or any taxes required to be withheld by Genenta or its Sublicensees, to the extent Genenta or its Sublicensees pay to the appropriate governmental authority on behalf of OSR such taxes, levies or charges. Genenta shall use reasonable efforts to secure an exemption or a reduction in any withholding taxes and minimize any such taxes, levies or charges required to be withheld on behalf of OSR by Genenta or its Sublicensees. Genenta shall promptly deliver to OSR proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

6.4 **Late payment interest rate.** Without prejudice to Section 6.5 below and to Section 10.3 below, any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interests at a rate equal to the thirty (30) day "*euribor*" rate, divisor 365, effective for the date that payment was due, as reported by "*Il Sole 24 Ore*" plus [redacted]

6.5 **Late payment interest rate for Milestone Payment.** Without prejudice to Section 10.3 below, the Parties agree that, with regard to the payments of the Milestone Payments, late payment interests shall accrue at an overall rate of [redacted] on a yearly basis, divisor 365, from the date on which the said Milestone Payment was payable and due until the date on which each of the aforementioned payments was effectively made.

6.6 **Bank transfer.** All payments set forth by this Agreement shall be made through bank transfer to the bank account indicated by OSR in writing.

7. GENENTA'S DEVELOPMENT, PHARMACOVIGILANCE, MANUFACTURE AND MARKETING OBLIGATIONS

7.1 **Development of the Licensed Products.** Genenta shall carry out and perform, under its own responsibility and at its own risk, all development activities necessary and/or useful so that at least one Licensed Product reach filing of the NDA with the FDA and of the MAA with the EMA, respectively, in the United States of America and in the European Union. Consistently with the above: (a) Genenta shall carry out these activities in accordance with (i) the terms of this Agreement; (ii) the Applicable Regulations, the cGCP, the cGLP and the cGMP, as applicable, and (iii) the Best Standards (it being agreed that, to the extent it is not imputable to Genenta, the refusal or rejection of the NDA by the FDA and/or of the MAA by the EMA shall not trigger a breach of this License Agreement); and (b) OSR covenants that it shall not withheld and/or delay any approval, delivery of document or information which may be reasonably required in carrying out the development activities. Genenta hereby commits to carry out the development activities through highly skilled professionals and sufficient level of resources and, in any case, to invest in activities related to Licensed Product(s) in the Field of Use the following amounts: (a) at least [redacted] with respect to the development of such Licensed Product(s), (b) at least [redacted] with respect to the manufacturing of such Licensed Product(s) (it being understood that such amount may be lower in the event Genenta is able to obtain from the applicable supplier(s) pricing terms that are more favorable than estimated as of the Effective Date, and/or Genenta's requirements of Licensed Product(s) are lower than estimated as of the Effective Date), and, for clarity, (c) the Upfront Fee in accordance with Section 4.1.

7.2 **Resources.** Consistently with the above, Genenta shall: (a) maintain and utilize highly qualified and experienced scientific staff, sufficient facilities as may be

reasonably needed to perform the development activities in accordance to this Agreement; and (b) use personnel and/or consultants with sufficient skills and experience as may be reasonably required to accomplish efficiently and expeditiously the development activities in a good scientific manner and in compliance in all material respects with all Applicable Regulations, cGCP and cGLP standards, as applicable.

7.3 **Records.** Genenta shall maintain records, in sufficient details and in good scientific manner, which shall reflect all work done and results achieved in the performance of its research and development regarding any Licensed Products.

7.4 **Reports.** Within sixty (60) Business Days following the end of each Calendar Year during the Term of this Agreement, Genenta shall prepare and deliver to OSR a written summary report which shall describe: (a) the research performed to date by employing the Licensed Technology, (b) the progress of the development, and testing of any Licensed Products in clinical trials, and (c) the status of obtaining regulatory approvals to market any Licensed Products.

7.5 **Regulatory.** During the Term of this Agreement, as between the Parties and towards the Regulatory Authorities, Genenta shall be responsible for preparing all filings of the MAA and NDA of each Licensed Product in the Field of Use. Genenta shall be responsible to deploy Best Standards in the filing of such MAA and NDA with the Regulatory Authorities as well as for any interaction with these Authorities in relation to the MAA Approvals requested, until the said Approvals are achieved.

7.6 **Pharmacovigilance.** Genenta will manage, at its own costs and expense, all pharmacovigilance requirements for each Licensed Products in the Field of Use in any country in the Territory and shall serve as the holder of the world-wide pharmacovigilance database for the Licensed Products in the Field of Use.

7.7 **Pharmacovigilance records and cooperation by OSR.** Genenta shall maintain accurate records of all non-medical and medical Licensed Product-related complaints and reports of adverse events with respect to any Licensed Product in the Field of Use in the Territory. Genenta shall be responsible for meeting regulatory safety reporting obligations in compliance with the requirements of the FDCA, 21 U.S.C. § 321 et seq., the Directive 2001/20/EC, the regulations promulgated thereunder, and equivalent Applicable Regulations in each case with respect to any Licensed Product in the Field of Use in the Territory. As soon as the Parties will enter a clinical trial agreement, they shall also enter into a pharmacovigilance agreement, which shall specify all relevant undertakings to conduct a clinical trial and to report serious adverse events, which agreement shall be consistent with Sections 7.6 and 7.7 hereunder and shall additionally set forth, among other things, provisions for the mutual reporting of serious adverse events.

7.8 **Clinical trial primary site**. For the Term of this License Agreement, Genenta hereby elects OSR as primary site in any pre-clinical study or clinical trial (including all phases thereof) relating to any Licensed Products in the Field of Use (as eventually extended in accordance with Section 2.2. above), subject to OSR (b) maintaining at all times any required quality standards and otherwise complying with the OSR-Genenta Scientific Collaboration Agreement and (b) providing its services on customary and reasonable terms and consistent with then-applicable market standards.

7.9 **Manufacturing**. As between the Parties and their Affiliates and Sublicensees, Genenta will be responsible for the manufacturing and supply of any Licensed Products in the Territory (including, for clarity, through Sublicensees in accordance to the terms of this Agreement), at Genenta's sole expense. This obligation includes responsibility for managing all aspects of the supply chain, to be used for the commercialization of any Licensed Products. In manufacturing, supplying and marketing each Licensed Products Genenta will comply with all Applicable Regulations, including cGMP.

7.10 **Promotion and marketing**. As between the Parties and their Affiliates and Sublicensees, Genenta shall use its Commercially Reasonable Efforts to promote, advertise and market each Licensed Product in the Field of Use and in the Territory (including, for clarity, through Sublicensees in accordance to the terms of this Agreement), at its own cost and expense. In no case shall OSR be responsible for, or liable to, any Third Party, to the extent that such liability derives from any inaccurate or misleading statements in Genenta's promotional and sales literature.

8. CONFIDENTIALITY

8.1 **Confidential Information.** During the Term of this Agreement, and until (a) five (5) years following the expiry of this Agreement or (b), in any case of early termination or withdrawal, for as long as and to the extent the Confidential Information are covered by an MAA Approval in any of the country in the Territory, each Party shall (1) maintain in strict confidence all information of the other Party that is disclosed by the other Party and/or is identified as, or acknowledged to be, confidential at the time of disclosure, including, for the avoidance of doubts, the Existing Know-How, the Genenta Product Improvements and the OSR Product Improvements (the "**Confidential Information**"), it being understood that the Existing Know-How and OSR Product Improvements shall also be protected under this Article 8 as OSR's Confidential Information, and the Genenta Product Improvements as Genenta's Confidential Information, and (2) not use, disclose or grant the use of the Confidential Information, except on a need-to-know basis to those directors, officers, affiliates, employees, permitted licensees, permitted assignees and agents, consultants, clinical investigators or contractors, to the extent that such disclosure is reasonably necessary in connection with performing its obligations or exercising its

rights under this Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, each Party hereto shall obtain agreement of any such Person to hold in strict confidence and not to use the Confidential Information for any purpose other than those permitted by this Agreement. Each Party shall notify the other Party promptly upon discovery of any unauthorized use or disclosure of the other Party's Confidential Information.

8.2 **Permitted disclosures.** The confidentiality obligations contained in Section 8.1 shall not apply to the extent that:

(a) any receiving Party (the "**Recipient**") is required: (i) to disclose information by law, regulation or order of a Governmental Authority, or (ii) to disclose information to any Governmental Authority for purposes of obtaining approval to test or market the Licensed Product, provided in either case that the Recipient shall provide written notice thereof to the other Party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof; or

(b) the Recipient can demonstrate that: (i) the disclosed information was public knowledge at the time of such disclosure to the Recipient, or thereafter became public knowledge, other than as a result of actions of the Recipient in violation hereof; (ii) the disclosed information was rightfully known by the Recipient (as shown by its written records) prior to the date of disclosure to the Recipient by the other Party hereunder; (iii) the disclosed information was disclosed to the Recipient on an unrestricted basis from a source not under a duty of confidentiality to the other Party; or (iv) the disclosed information was independently developed by the Recipient without use of the Confidential Information disclosed by the other Party.

In addition, Genenta may disclose Confidential Information regarding the Licensed Know-How for the following purposes: (a) regulatory filings and other filings with Governmental Authorities, including filings with the FDA, as necessary for the development or commercialization of Licensed Technology and the Licensed Products; (b) prosecuting or defending litigation; (c) complying with Applicable Regulations, including regulations promulgated by securities exchanges, (d) disclosures to its employees, agents, independent contractors, and Sublicensees only on a need-to-know basis and solely in connection with the performance of this Agreement, provided that each disclosee must be bound by obligations of confidentiality and non-use consistent and at least comparable to those set forth in this Section 8; (e) disclosure of the stage of data regarding the development and commercialization of Licensed Products under this Agreement to any *bona fide* potential or actual investor, stockholder, investment banker, acquirer, merger partner or other potential or actual financial partner, provided that each disclosee must be bound by obligations of confidentiality and non-use consistent and at least comparable to those set forth in this Section 8.

8.3 **Terms of this Agreement.** OSR and Genenta shall not disclose any terms or conditions of this Agreement to any Third Party, without the prior consent of the other Party, except as set forth in Section 8.2 above or to any *bona fide* potential or actual investor, stockholder, investment banker, acquirer, merger partner or other potential or actual financial partner or Sublicensee; provided however that each disclosee must be bound by obligations of confidentiality and non-use consistent and at least comparable with those under this Section 8.

8.4 **Press releases; public filings.** Neither Party shall issue any press release or other public announcement disclosing the existence of this Agreement or any of the terms or conditions of this Agreement or the transaction contemplated by this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Notwithstanding the above, each Party may file a copy of this Agreement or portions thereof with any Government Authorities to the extent required under Applicable Law.

9. IP RIGHTS

9.1 **Patents' prosecution and maintenance.** OSR shall have the right and obligation to control the preparation, filing, prosecution and maintenance of all patents and patent applications within the Licensed Patents. The costs of the foregoing activities shall be borne by OSR prior to the achievement of the Investment Threshold, and, following, such achievement by Genenta, who, for the avoidance of doubt, shall reimburse all costs borne by OSR in accordance with this Section 9.1 from the Effective Date to the date on which the Investment Threshold is met, provided however that should other licensees benefit from the preparation, filing, prosecution and maintenance of the said patents and patents applications, such costs shall be allocated on a *pro-rata* basis based on the number of licensees, to the extent such licensees are contractually obligated to bear such costs, on a country-by-country basis. If OSR elects not to file any such patent application in any country, or decides to abandon any such pending application or issued patent in any country, OSR shall promptly provide written notice to Genenta, and Genenta shall have the right, at its sole expense and notwithstanding the above, to assume control of the preparation, filing, prosecution and maintenance of such patent application or patent in its name at its own expense.

9.2 **Notification of infringement.** Each Party shall (and shall procure that its own Affiliates and/or Sublicensees) notify the other Party of any infringement in the Territory known to such Party of any Licensed Technology and shall provide the other Party with the available evidence, if any, of such infringement.

9.3 **Enforcement of IP rights.** OSR shall have the right at its sole expense and in its sole discretion to control the enforcement of the Licensed Technology against any infringers. If, within two (2) months of receipt of written notice by Genenta that a Third Party is marketing in the Field of Use a product that infringes the Licensed

Technology, OSR fails to file suit to enforce such Licensed Technology against the infringing party in the Field of Use, then Genenta shall have the right to take whatever action it deems appropriate in its own name and, if required by law and in any case after written notice to OSR, in the name of OSR to enforce such Licensed Technology in the Field of Use, and OSR shall reasonably cooperate with Genenta in the planning and execution of any such action to enforce such Licensed Technology in the Field of Use. The Party controlling any such enforcement action may not settle, or otherwise consent to an adverse judgment in, such action, without the prior express written consent of the non-controlling Party. All monies recovered upon the final judgment or settlement of such action shall be shared, after reimbursement of expenses, in relation to the damages suffered by each Party or, failing a *bona fide* agreement between the Parties, on a 50%-50% basis.

9.4 **Cooperation.** In any suit to enforce and/or defend the Licensed Technology pursuant to this Section 9, the Party not in control of such suit shall, at the request and expense of the controlling Party, reasonably cooperate and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like, in any case in compliance with Section 8 above and to the extent that such cooperation is not precluded by any agreements executed by such cooperating Party with any Third Party.

10. TERMINATION

10.1 **Expiration.** Unless terminated earlier as set forth below, this Agreement shall expire upon expiry of the Royalty Term for all Licensed Products and all countries in the Territory (the "**Term**").

10.2 **Termination for breach.** Without prejudice to Sections 10.3 and 10.4 below, should one Party materially breaches any obligations set forth by this License Agreement, then the non-breaching Party may deliver notice of such breach to the other Party, in accordance to Section 15.1 below, along with a warning to cure the breach and granting the non-breaching Party a sixty (60) Business Days deadline to cure the breach. Should the breaching Party fail to cure the breach within the aforementioned deadline, this Agreement shall be terminated by law, without prejudice to any further right or remedy accruing to the benefit of the non-breaching Party pursuant to the applicable law.

10.3 **Termination for failure to pay.** Should Genenta fail to pay the Upfront Fee and/or any Royalty and/or any Milestone Payment and/or any OSR Sublicensing Income payable and due under Sections 4.1, 4.2, 4.5 and 4.6 hereunder, in each case within thirty (30) days following the expiration of the applicable deadlines as indicated, respectively, in letters (a), (b) or (c) of Section 6.1 above, as the case may be, then OSR shall have right to terminate this License Agreement forthwith, by sending a written notice to Genenta in accordance to Section 15.1 below.

10.4 **Termination for failure to develop.** OSR may terminate this Agreement upon sixty (60) Business Days prior written notice to Genenta, to be sent in accordance to Section 15.1 below, subject in each case to OSR's compliance with the OSR-Genenta Scientific Collaboration Agreement, in the event that:

(a) Genenta has exercised the option set forth in Section 2.2(c) above with respect to one or more Solid Cancer Indications and Genenta (or a Sublicensee) has not filed an IND with respect to the applicable Solid Cancer Indication for which the option was exercised (the "**Terminated Solid Cancer Indication**"), within three (3) years from the date of the exercise of the option, it being understood that in such case: (a) the termination rights shall be limited to the Terminated Solid Cancer Indication; (b) any further activity on the said Terminated Solid Cancer Indication shall be immediately discontinued by Genenta; and (c) the provisions of Section 10.9 below shall apply only with respect to that Terminated Solid Cancer Indication; or

(b) Genenta has exercised the option set forth in Section 2.2(c) above with respect to three (3) Solid Cancer Indications and Genenta (or a Sublicensee) has not filed an IND with respect to any such Solid Cancer Indications for which the option was exercised, within three (3) years as of the date on which the relevant option was exercised, it being understood that in such case: (a) the termination rights shall be apply to all Solid Cancer Indications (but not to any Lympho-Hematopoietic Indications, to the extent it shall be included under this License Agreement, for which the provisions of this License Agreement shall survive); (b) any further activity on all Solid Cancer Indications shall be immediately discontinued by Genenta; and (c) the provisions of Section 10.9 below shall apply to all Solid Cancer Indications.

(c) no patient has been dosed with a Licensed Product in a Phase III Clinical Trial for a Lympho-Hematopoietic Indication by the seventh (7^{th}) anniversary of the Effective Date, it being understood that in such case: (a) the termination rights shall be limited to all Lympho-Hematopoietic Indications (but not to any Solid Cancer Indication, to the extent it shall be included under this License Agreement, for which the provisions of this License Agreement shall survive); (b) any further activity on all Lympho-Hematopoietic Indications shall be immediately discontinued by Genenta; and (c) the provisions of Section 10.9 below shall apply to all Lympho-Hematopoietic Indications.

10.5 **Termination of the Investment Agreement.** OSR may withdraw from this Agreement, at no costs and with no indemnification, immediately upon written notice to Genenta, to be sent in accordance to Section 15.1 below, in any case of termination of the Investment Agreement other than a "*Disinvestimento*" (as defined in the Investment Agreement).

10.6 **Withdrawal of OSR.** The Parties hereby agree that OSR shall have the right to withdraw from this License Agreement forthwith, through written notice to Genenta, to be sent in accordance to Section 15.1 below, and with no compensation to Genenta, in the event the Investment Threshold is not reached by June 30, 2015.

10.7 **Termination for winding-up of Genenta.** OSR may withdraw from this Agreement, at no costs and with no indemnification, immediately upon written notice to Genenta, to be sent in accordance to Section 15.1 below, should Genenta (a) resolves its voluntary liquidation (also in accordance with the provisions of the Genenta Investment Agreement) or (b) be liquidated by in accordance with the Applicable Regulations.

10.8 **Termination by Genenta.** In the event that, upon the advice of Genenta's scientific advisory board, no Licensed Product in the Field can be successfully developed by Genenta under the Licensed Technology due to critical and objective technical or scientific reasons concerning the safety or efficacy of such Licensed Products, then Genenta may terminate this Agreement, upon one-hundred twenty (120) Business Days prior written notice to OSR, to be sent in accordance to Section 15.1 below. In such case, Section 10.9 shall apply as well.

10.9 **Effect of expiration or termination.** In any case of expiration of termination of this Agreement,

(a) All licenses granted to Genenta in this License Agreement under the Licensed Technology and the OSR Product Improvements shall immediately terminate without any monetary consideration by OSR to Genenta;

(b) Genenta shall assign to OSR, at no costs, all trademarks relating to the Licensed Products indicated in the NDA filed by Genenta with the FDA and in the MAA filed with the EMA;

(c) The Parties shall not be relieved of any obligation accruing prior to such expiration or termination, and the provisions of Sections 2.8, 4, 6, 8, 10.9, 13, 14, 15 and 16 shall survive the expiration or termination of this Agreement, it being understood that only in case of expiration of each Royalty Term, on a country-by-country, with respect to the applicable country the license on the Licensed Know-How shall survive for the marketing and commercialization of the Licensed Products in the Field of Use;

(d) Genenta and its Sublicensee, as applicable, shall be permitted to distribute and sell all Licensed Products that were in inventory or in production on the date of such expiration or termination, for a period of twelve (12)

months following the effective expiration or termination date, in accordance with the terms of this Agreement.

(e) OSR shall assume any sublicense entered into by Genenta with its Sublicensees, provided that and subject to: (i) such sublicense complies with letters (i) and (ii) of Section 2.6 above; (ii) Genenta has first represented and warranted in writing to OSR that as of the effective date of such expiration or termination, such Sublicensee is then in full compliance with all terms and conditions of its sublicense; and (iii) such Sublicensee agrees in writing to assume all applicable obligations of Genenta under this Agreement with respect to the scope of the sublicense, it being understood and agreed that should even only one of the conditions and requirements set forth by letters (i), (ii) and (iii) above is not met and fulfilled, the relevant sublicense shall be and remain without effects as between Genenta and/or OSR and the relevant Sublicensee.

(f) Within thirty (30) Business Days following the effective date of expiration or termination of this Agreement, Genenta shall transfer and assign to OSR all tangible embodiments of the Genenta Product Improvements generated by Genenta as of the time of such expiration or termination without any compensation to be paid by OSR as well as all MAA Approvals related to each Licensed Products in the Territory, all data and information relating to each Licensed Products, including the relevant drug master file, as well as all intellectual property rights relating to the Licensed Products accrued to the benefit of Genenta in accordance with this License Agreement, including all patents and patents applications registered in the name of Genenta and covering the Licensed Products and/or the Genenta Product Improvements, by also executing and timely providing all approvals, documents and deeds which may be necessary to notify such assignment and transfer to the Regulatory Authorities and to all Third Parties;

(g) OSR, or its designee, shall have the right (but not the obligation) to assume and take over all then-existing and ongoing contracts and contractual arrangements eventually entered into by Genenta with any Third Parties other than Sublicensees, related in any manner whatsoever to the ongoing development of the Licensed Product (including but not limited to all research contracts) for which assignment is possible, and the Parties shall cooperate to promptly transfer or assign to OSR, or its designee, all such contracts and arrangements, in each case, at Genenta's cost and expense. To facilitate the assumption and taking over of any and/or all such existing and ongoing contracts or contractual arrangements as set forth above, Genenta agrees to provide a detailed list of such contracts and contractual arrangements to OSR within twenty (20) Business Days as of the effective date of such expiration or termination. OSR will then have one hundred forty-five (145) days from the receipt of that list (the "**Election Period**") to

make its election as to whether to assume and take-over any or all of the contracts and contractual arrangements.

11. REPRESENTATIONS AND WARRANTIES

11.1 **Mutual representations and warranties.** Each Party hereby represents and warrants to the other Party as follows:

(a) Such Party is a corporation duly organized, validly existing and in good standing under the laws of the State or country in which it is incorporated;

(b) Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

(c) All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained;

(d) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of the Applicable Regulations, and (b) do not conflict with, or constitute a default under, any contractual obligation of it.

11.2 **OSR additional representations and warranties.** OSR hereby represents and warrants to Genenta that at the Effective Date, except as set forth in Exhibit 11.2, in the Field of Use:

(a) OSR is the sole and exclusive owner of the Licensed Technology, or has the right to grant the licenses granted under Section 2 above with respect to the Licensed Technology based, *inter alia*, on the OSR-Telethon Cooperation Agreement;

(b) OSR has not granted to any Third Party any license or other interest in the Licensed Technology.

(c) OSR does not own or control any patent or patent application other than the Licensed Patents (including, where applicable, the Additional Patents) that are required or useful for the development, manufacturing or commercialization of the Licensed Products.

(d) To the best knowledge of OSR, there are no pending or threatened claims, judgments or settlements against OSR relating to the Licensed Technology.

(e) To the best of OSR's knowledge, no Third Party has infringed or is infringing any Licensed Technology.

(f) Without limiting letter (c) of Section 11.1 above, OSR hereby represents and Genenta hereby acknowledges that OSR has received from Molmed S.p.A., with registered offices in Milano, via Olgettina No. 58, Fiscal Code 11887610159, a notice that it is not willing to exercise the option rights on the exploitation of the certain patents necessary for the carrying out of the Genenta Project.

11.3 **Genenta Additional Representations and Warranties.** Genenta hereby represents and warrants to Genenta that:

(a) The development of the Licensed Products under the Licensed Technology and this Agreement shall be conducted in accordance with the Applicable Regulations, including the cGCP and cGLP, as applicable, it being understood that this Section 11.3(a) shall not be applicable to the extent that any breach is imputable to OSR under the OSR-Genenta Scientific Collaboration Agreement;

(b) The manufacturing of the Licensed Products shall be conducted in accordance with the Applicable Regulations, including the cGMP, cGLP, as applicable.

12. INDEMNIFICATION

12.1 **Indemnification.** Each Party (the "**Indemnitor**") shall defend, indemnify and hold the other Party (the "**Indemnitee**") harmless from all losses, liabilities, damages and expenses (including attorneys' fees and costs) incurred as a result of any claim, demand, action or proceeding arising out of any breach by the Indemnitor and/or its Affiliates and/or its Sublicenses and/or its distributors and Third Parties suppliers, of the representations and warranties under Section 11 above. Genenta shall defend, indemnify and hold OSR harmless from any claim, demand, action or proceeding arising out of the infringement of Third-Party intellectual property rights by the Genenta Product Improvements or the Licensed Products, except to the extent such claim, demand, action or proceeding to the extent arising from (a) the Licensed Technology as existing as of the Effective Date, and/or (b) activities conducted by or on behalf of OSR under the OSR-Genenta Scientific Collaboration Agreement.

12.2 **Procedure.** The Indemnitee shall promptly notify the Indemnitor of any liability or action in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the right to assume the defense thereof with counsel selected by the Indemnitor. The indemnity agreement in this Section 12 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve the Indemnitor of any liability to the Indemnitee under this Section 12, but the omission so to deliver notice to the Indemnitor will not relieve it of any liability that it may have to the Indemnitee otherwise than under this Section 12. The Indemnitee under this Section 12, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any action, claim or liability covered by this indemnification.

13. LIMITATION OF LIABILITY

13.1 **Limitation of liability.** Except for breaches of Section 8 above, neither Party shall be liable under this Agreement for any indirect, incidental, punitive, exemplary, special or consequential damages of any kind, which may be awarded by any judge or authority of competent jurisdiction, except in case of willful misconduct (*dolo*) or serious negligence (*colpa grave*).

14. *FORCE MAJEURE*

14.1 **Limitation of liability.** Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected party including but not limited to fire, floods, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party.

15. MISCELLANEOUS

15.1 **Notices.** Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other Party shall be in writing, delivered by any lawful means to such other Party at its address indicated below (where the Party hereby elect domicile for the purposes of servicing legal pleadings or arbitration requests), or to such other address as the addressee shall

have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to OSR, to:
Ospedale San Raffaele S.r.l.
via Olgettina No. 60
20132, Milan, Italy

Attention: Mr. Nicola Bedin

If to Genenta, to:
Genenta Science S.r.l.
via Olgettina No. 60
20132, Milan, Italy

Attention: Ms. Anna Flavia d'Amelio Einaudi and Mr. Luigi Paracchi

15.2 **Assignment.** Without the prior written consent of OSR, not to be unreasonably withheld or delayed, Genenta shall not assign its rights or obligations under this Agreement, including (a) to any Affiliate or shareholder, or (b) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or (c) in the event of any merger, demerger, consolidation, change in control or other similar corporate transaction. Notwithstanding the above, an assignment of the Agreement by Genenta in connection with any "*Disinvestimento*", as such term is defined in the Genenta Investment Agreement, shall not require OSR's consent.

15.3 **Waivers and amendments.** No change, modification, extension, termination or waiver of this Agreement, or any of the provisions herein contained, shall be valid unless made in writing and signed by duly authorized representatives of the parties hereto.

15.4 **Entire agreement.** This Agreement embodies the entire agreement between the parties and supersedes any prior representations, understandings and agreements between the parties regarding the subject matter hereof. There are no representations, understandings or agreements, oral or written, between the parties regarding the subject matter hereof that are not fully expressed herein.

15.5 **Severability.** Any of the provisions of this Agreement which are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof and without affecting the validity or enforceability of any of the terms of this Agreement in any other jurisdiction.

15.6 **Waiver.** The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other party shall not be deemed a waiver of any other

right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

15.7 **Exhibits.** The following Exhibits are an integral and substantial part of this Agreement:

Exhibit C	Existing Know-How;
Exhibit 1.1	Additional Patents;
Exhibit 1.24	Licensed Patents;
Exhibit 11.2	Exceptions to OSR's additional representations and warranties.

15.8 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

16. GOVERNING LAW AND ARBITRATION

16.1 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of Italy, without regard to the conflicts of law principles thereof.

16.2 **Arbitration.** Any dispute, controversy or claim initiated by either Party arising out of or relating to this Agreement, its negotiations, execution or interpretation, or the performance by either Party of its obligations under this Agreement (other than (a) any dispute, controversy or claim regarding the validity, enforceability, claim construction or infringement of any patent rights, or defenses to any of the foregoing), shall be finally resolved through arbitration by a panel of three (3) arbitrators appointed under the Rules of the International Court of Arbitration of the International Chamber of Commerce of Paris (the "**Rules**"), which both Parties declare to know and accept. Each Party shall appoint one arbitrator and the two thus-appointed arbitrators shall appoint the third arbitrator, who shall act as chairman of the panel. In case of disagreement, the third arbitrator shall be appointed by the Chairman of the International Chamber of Commerce, in accordance with the provisions of the Rules. Where necessary the Chairman of the International Chamber of Commerce shall also appoint an arbitrator on behalf of the Party that has failed to appoint its arbitrator within the deadline set forth by the Rules The seat of the arbitration shall be Milan, Italy. Any such arbitration shall be conducted in the Italian language, without prejudice to the Parties right to file documents in the English or other foreign language, along with the relevant certified translation into Italian English or to hear witness in languages other than Italian provided that a simultaneous translation is offered to the panel. Any award issued by the arbitration panel shall binding upon the Parties and the arbitration shall be "*rituale*" in its nature. The arbitration shall be conducted in accordance with the Rules and the Parties hereby declare that the Emergency Arbitrators Provisions

shall not apply between them. The award rendered by the arbitrators may be challenged on the grounds of breach of rules of law (*impugnazione per violazione delle regole di diritto*) pursuant to Article 829 (*Casi di nullità*), third paragraph, of the Italian Code of Civil Procedure.

16.3 **Residual jurisdiction.** Any other dispute which may not be submitted to the arbitration proceeding pursuant to Section 16.2 above, including those relating to injunctive reliefs and provisional and/or urgent measures and payment injunctions (*decreto ingiuntivo*) shall be devoted to the exclusive jurisdiction and venue of Tribunal of Milan.

* * *

IN WITNESS WHEREOF, the Parties have executed this Agreement effective as of the Effective Date.

Ospedale San Raffaele S.r.l.

By:

Name: Mr. Nicola Bedin

Title: Chief Executive Officer

Genenta Science S.r.l.

By:

Name: Ms. Anna Flavia d'Amelio Einaudi and Mr. Pierluigi Paracchi

Title: Managing Directors

EXHIBIT C

EXISTING KNOW-HOW

Without prejudice to the other definitions indicated in this Exhibit, the words and expressions in capital letters set forth in this Exhibit C shall have the meaning provided for by the License Agreement.

1. **Lentigen know-how**

Know How Sublicense Agreement by and between GlaxoSmithKline Intellectual Property Development Limited and Ospedale San Raffaele and Fondazione Telethon dated July 18, 2014. Under such agreement, OSR is willing to grant, and does hereby grant, to Genenta a non-exclusive, worldwide sublicense to use the "*Lentigen know how*" in the Field of Use for the Term. Such know how is not sublicensable by Genenta to any third party.

2. **Other Existing Know-How**

The following is a list of the publications as at the Effective Date relating to the Genenta Project. The Existing Know-How shall also include any underlying raw data, copies of pre-clinical studies (including study reports, development reports and safety reports, if any), lab notebooks, and analytical methods, in each case to the extent (a) in possession of OSR as of the Effective Date and (b) reasonably necessary to research, develop, manufacture or commercialize Licensed Products in the Field of Use.

1. *Escobar G, Gentner B, Naldini L, Mazzieri R.*, Engineered tumor-infiltrating macrophages as gene delivery vehicles for interferon-α activates immunity and inhibits breast cancer progression. Oncoimmunology. 2014 Apr 29;3:e28696. eCollection 2014.

2. *Escobar G, Moi D, Ranghetti A, Ozkal-Baydin P, Squadrito ML, Kajaste-Rudnitski A, Bondanza A, Gentner B, De Palma M, Mazzieri R, Naldini L.*, Genetic engineering of hematopoiesis for targeted IFN-α delivery inhibits breast cancer progression. Sci Transl Med. 2014 Jan 1;6(217):217ra3.

3. *Chiriaco M, Farinelli G, Capo V, Zonari E, Scaramuzza S, Di Matteo G, Sergi LS, Migliavacca M, Hernandez RJ, Bombelli F, Giorda E, Kajaste-Rudnitski A, Trono D, Grez M, Rossi P, Finocchi A, Naldini L, Gentner B, Aiuti A*, Dual-regulated lentiviral vector for gene therapy of X-linked chronic granulomatosis. Mol Ther. 2014 Aug;22(8):1472-83.

4. *Gentner B, Visigalli I, Hiramatsu H, Lechman E, Ungari S, Giustacchini A, Schira G, Amendola M, Quattrini A, Martino S, Orlacchio A, Dick JE, Biffi A, Naldini L.*, Identification of hematopoietic stem cell-specific miRNAs enables gene therapy of globoid cell leukodystrophy. Sci Transl Med. 2010 Nov 17;2(58):58ra84.

5. *De Palma M, Mazzieri R, Politi LS, Pucci F, Zonari E, Sitia G, Mazzoleni S, Moi D, Venneri MA, Indraccolo S, Falini A, Guidotti LG, Galli R, Naldini L.*, Tumor-targeted interferon-alpha delivery by Tie2-expressing monocytes inhibits tumor growth and metastasis. Cancer Cell. 2008 Oct 7;14(4):299-311.

3. Presentations

1. Abstract (the relevant publication is ongoing)

Engineering Hematopoiesis for Tumor-Targeted Interferon-Alpha Delivery
Giulia Escobar, Anna Ranghetti, Luigi Barbarossa, Silvia Nucera, Cristiana Fanciullo, Fabio Ciceri, Bernhard Gentner, Luigi Naldini

"Tumor immunotherapy is a promising approach for cancer treatment, but the immunosuppressive tumor microenvironment represents a major hurdle to its efficacy. To overcome this immunosuppression, we developed an approach based on genetic engineering of hematopoietic stem and progenitor cells (HSPC). Using lentiviral vectors, we introduced a transcriptionally and post-transcriptionally regulated Interferon-alpha (IFNa) cassette targeting IFNa expression to tumor-infiltrating monocytes/macrophages originating from a gene-modified HSPC graft (IFNa cell therapy). When applying our strategy to spontaneous breast cancer mouse models we observed tumor-targeted activation of type I IFN response, accompanied by strong infiltration of the tumors by activated CD4 and CD8 T cells and resulting in sustained inhibition of primary breast cancer and its metastases. We then developed a spontaneous B-ALL mouse model based on onco-mir expression and showed that IFNa cell therapy significantly reduced leukemic burden. We have now derived leukemic subclones engineered with model antigens (e.g. huCD20) to test combination of IFNa cell therapy with monoclonal antibodies or adoptive immunotherapy. To move toward clinical application, we humanized the vector and exploited the myeloid progeny of huHSPC generated in hematochimeric mice as therapeutic vehicle to deliver IFNa into human breast cancer and multiple myeloma xenografts. IFNa cell therapy promoted immune-mediated clearance of breast tumors and tumoristatic effects associated with prolonged survival in myeloma xenografts. IFNa cell therapy also inhibited human Ph+ primary B-ALL growth, and we are testing its combination with Imatinib. These results pave the way for a phase I/II trial testing IFNa cell therapy in patients with multiple myeloma and lymphoid malignancies undergoing autologous transplant".

2. Presentation (at the congress ASGCT held in Washington DC on May 21-24, 2014)

Inhibition of Solid and Hematologic Tumors by Engineering Human Hematopoiesis for Tumor-Targeted IFNa Delivery

Giulia Escobar

Angiogenesis & Tumor Targeting Unit San Raffaele TIGET Institute

EXHIBIT 1.1

ADDITIONAL PATENTS

1. Patent Number US7833789

Title: MONOGYPE GENE Applicants: Ospedale San Raffaele S.r.l. 50% - Fondazione Telethon 50% Inventors: Luigi Naldini, Michele De Palma, Mary Anna Lucia Venneri					
STATUS	COUNTRY	APPLICATION NUMBER	FILING DATE	PUBLICATION NUMBER (PUBLICATION DATE)	PATENT NUMBER (ISSUE DATE)
Expired	US	US provisional: N. 60/821,059	Aug 1, 2006		
Granted	US	11/831,248	July 31, 2007	US2008057043 (March 6, 2008)	US7833789 (16.11.2010)

2. Patent Family of PCT/IB2014/065594

Title: METHOD Applicants: Ospedale San Raffaele S.r.l. 50% - Fondazione Telethon 50% Inventors: Luigi Naldini, Gentner Bernhard, Zonari Erika, Boccalatte Francesco					
STATUS	COUNTRY	APPLICATION NUMBER	FILING DATE	PUBLICATION NUMBER (PUBLICATION DATE)	PATENT NUMBER (ISSUE DATE)
Expired	UK	1318830.5	24.10.2013		
Expired	UK	1409067.4	21.05.2014		
Pending	PCT	PCT/IB2014/065594	24.10.2014		

3. Patent Family of UK appl. No. 1412494.5

Title: VECTOR PRODUCTION Applicants: Ospedale San Raffaele S.r.l. 50% - Fondazione Telethon 50% Inventors: Alessio Cantore, Angelo Peone Lombardo, Luigi Naldini					
STATUS	COUNTRY	APPLICATION NUMBER	FILING DATE	PUBLICATION NUMBER (PUBLICATION DATE)	PATENT NUMBER (ISSUE DATE)
Pending	UK	1412494.5	14.07.2014		

EXHIBIT 1.24

LICENSED PATENTS

1. Patent Family of WO2007000668

Title: GENE VECTOR Applicants: Ospedale San Raffaele S.r.l. 50% - Fondazione Telethon 50% Inventors: Luigi Naldini, Brian David Brown					
STATUS	COUNTRY	APPLICATION NUMBER	FILING DATE	PUBLICATION NUMBER (PUBLICATION DATE)	PATENT NUMBER (ISSUE DATE)
Expired	US	US provisional N. 60/684,954	May 27, 2005		
Expired	PCT	PCT/IB2006/002266	May 26, 2006	WO2007000668 (Jan 4, 2007)	
Pending	Europe	N.06795291.1	May 26, 2006	EP2002003 (Dec 17, 2008)	
Granted	S. Korea	20077030594	May 26, 2006	KR20080041601 (May 13, 2008)	10-1373548 (06.03.2014)
Abandoned	S. Korea	10-2013-7025874 divisional	May 26, 2006		
Pending	India	5430/CHENP/2007	May 26, 2006		
Pending	Singapore	200718092-0	May 26, 2006		
Pending	Singapore	SG201003686-1 divisional	May 26, 2006	SG162726 (July 29, 2010)	
Pending	Israel	187679	May 26, 2006		
Pending	Canada	20062609142	May 26, 2006	CA2609142 (Jan 4, 2007)	
Pending	USA	11/921,140	May 26, 2006	US2010041737 (Feb 18, 2010)	
Pending	USA	14/332,222 divisional	May 26, 2006		
Pending	Japan	2013-098229 divisional	May 26, 2006	JP2013226139 (Nov 7, 2013)	
Pending	Japan	2008-512952	May 26, 2006	JP2008545406 (Dec 18, 2008)	
Pending	China	200680027591.5	May 26, 2006	CN101287834 (Oct 15, 2008)	

2. Patent Family of WO2010125471

Title: GRNE VECTOR Applicants: Ospedale San Raffaele S.r.l. 50% - Fondazione Telethon 50% Inventors: Alessandra Biffi; Bernhard Rudolf Gentner; Luigi Naldini					
STATUS	COUNTRY	APPLICATION NUMBER	FILING DATE	PUBLICATION NUMBER (PUBLICATION DATE)	PATENT NUMBER (ISSUE DATE)
Expired	US	US provisional N. 61/174,124	April 30, 2009		
Expired	PCT	PCT/IB2010/001166	April 30, 2010	WO2010125471 (04.11. 2010)	
Pending	Europe	10723305.8	April 30, 2010	EP2424571 (07.03.2012)	
Pending	USA	13/266,381	April 30, 2010	US 2012/0128643 (24.05.2012)	
Pending	China	201080030337.7	April 30, 2010	CN102596255 (18.07.2012)	
Pending	Japan	2012-507847	April 30, 2010	JP2012525141 (22.10.2012)	
Pending	Canada	2,759,438	April 30, 2010	CA2759438 (04.11.2010)	
Pending	Australia	AU2010243276	April 30, 2010	AU2010243276 (17.11.2011)	
Pending	Brazil	PI1010873-4	April 30, 2010		
Pending	Eurasia	201171335	April 30, 2010	EA201171335 (30.05.2012)	
Pending	India	7894/CHENP/2011	April 30, 2010	7894/CHENP/2011 (21.12.2012)	
Pending	Israel	215804	April 30, 2010		
Pending	S. Korea	10-2011-7028569	April 30, 2010	KR20120038403 (23.04.2012)	
Granted	S. Africa	2011/07625	April 30, 2010		2011/07625 (27.12.2012)
Pending	Singapore	201108000-9	April 30, 2010	SG175839 (29.12.2011)	
Pending	Mexico	MX/A/2011/011508	April 30, 2010	MX2011011508 (13.02.2012)	

EXHIBIT 11.2

EXCEPTIONS TO OSR'S ADDITIONAL REPRESENTATIONS AND WARRANTIES

The following are the exceptions to the representations and warranties set forth by Section 11.2 of the License Agreement.

* * *

Section 11.2(a)

1. **Lentigen know-how**

Know How Sublicense Agreement by and between GlaxoSmithKline Intellectual Property Development Limited and Ospedale San Raffaele and Fondazione Telethon dated July 18, 2014. Under such agreement, OSR is willing to grant Genenta a non-exclusive, worldwide sublicense to use the "*Lentigen know how*" in the Field of Use for the Term. Such know how is not be sublicensable by Genenta to any third party.

Please note that GlaxoSmithKline Intellectual Property Development Limited *(i)* shall have no ownership rights to the improvements made to the Lentigen Know How to the extent that such improvements have are not jointly created by Telethon-OSR and GlaxoSmithKline Intellectual Property Development Limited; *(ii)* shall have a non-exclusive, sublicensable, perpetual, royalty-free, fully paid-up right and license under Telethon-OSR improvements to the Lentigen Know-How to use such Telethon-OSR's improvements in connection with the GSK Alliance and for internal research and development activities.

Section 11.2(b)

None.

Section 11.2(c)

None.

Section 11.2(d)

None.

Section 11.2(e)

None.

AMENDMENT NO. 1 TO LICENSE AGREEMENT

This **AMENDMENT NO. 1 TO LICENSE AGREEMENT** ("**Amendment**") is entered into as of March 16, 2017 (the "**Amendment Effective Date**")

Between

Ospedale San Raffaele S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 07636600962, duly represented for the purposes hereof by its Chief Executive Officer, Mr. Nicola Bedin ("**OSR**")

- *on the one side* -

And

Genenta Science S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 08738490963, duly represented for the purposes hereof by its Chief Executive Officer, Mr. Pierluigi Paracchi ("**Genenta**")

- *on the other side* -

(OSR and Genenta shall be, collectively but not jointly, defined as the "**Parties**" and, severally, a "**Party**").

WHEREAS:

(A) OSR and Genenta entered into that certain license agreement dated December 15, 2014 ("**License Agreement**");

(B) OSR, Genenta and Amgen Inc. entered into that certain research agreement dated September 14, 2016 ("**Research Agreement**") with respect to a research project ("**Research Project**"). The Research Project contemplates, among other things, conducting by OSR and Amgen certain experiments regarding the use of lentiviral based-HSPC gene therapy platform under the License Agreement with both Interferon (IFN) ("**Current Payload**": i.e. the IFN under the License Agreement) and Tumor Necrosis Factor (TNF) ("**Alternative Payload**").

(C) Given the Research Agreement and also considering that the product incorporating the Alternative Payload will be a Competing Product (as defined in the License Agreement), the Parties wish to amend the License Agreement under the terms set forth below.

* * *

NOW, THEREFORE, also in consideration of the foregoing premises, which form an integral and substantial part of this Amendment, and the mutual covenants herein contained, the **PARTIES HEREBY AGREE AS FOLLOWS.**

1. **Definitions**. Capitalized terms not defined herein have the meaning set forth in the License Agreement.

2. **Non-compete**. Section 3.1 of the License Agreement shall automatically be replaced in its entirety with the following (where "Competing Product" shall have the meaning set forth in the License Agreement, as amended, if applicable, pursuant to Sections 3.2(a) and/or 3.2(b) of this Amendment):

"3.1 **Non-compete**. Notwithstanding anything to the contrary in this Agreement, OSR may not, during the Competing Product Option Period (as defined in Section 3.1 of Amendment No.1 to the License Agreement, dated December 15, 2014, grant to any Third Party any license or any option right to commercialize a Competing Product. This Section 3.1 shall not be construed to restrict OSR's ability to conduct research and development activities with respect to any Competing Product, whether on its own or in collaboration with any Third Party (non-profit or for-profit), provided that (i) OSR shall provide prompt notice to Genenta upon entering into any agreement with a for-profit Third Party respect to such research and development activities (any such agreement, "R&D Agreement"), (ii) OSR shall retain all right, title an interest to any invention, discovery, idea, know-how, data or information, or other intellectual property developed by OSR with respect to the applicable Competing Product in connection with such research and development activities. In addition, this Section 3.1 shall not be construed to restrict OSR's ability to manufacture and supply Competing Product to Third Parties (within the scope of permitted R&D Agreements under the terms above), including Amgen as required for OSR to comply with the Research Agreement.

3. **Competing Product Option.**

3.1 Additionally, Genenta shall have the exclusive option to expand the license granted under Section 2.1 of the License Agreement to include:

(a) the use of the Alternative Payload in addition or in alternative to the Current Payload, in compliance with art. 7 of the Research Agreement;

(b) one or more additional (i.e., if applicable, in addition to the product incorporating the Alternative Payload) Competing Products;

in each case, in the event Genenta's Scientific Advisory Board deems scientifically reasonable to develop one or more products incorporating the Alternative Payload and/or other Competing Product(s) ("**Competing Product Option**").

3.2 Genenta may exercise the Competing Product Option by written notice to OSR ("**Competing Product Notice**") within forty-eight (48) months following the Amendment Effective Date but in any event prior to commencing any clinical development activities involving the applicable Alternative Payload and/or Competing Product ("**Competing Product Option Period**"), provided, however, that in the event Genenta exercises the Competing Product Option at any time during the forty-eight (48) month-period following the Amendment Effective Date, the Competing Product Option Period shall be deemed extended only once for a period of eighteen (18) months (i.e., for a total of sixty six (66)] months from the Amendment Effective Date. Each Competing Product Notice shall identify the Alternative Payload and/or Competing Product(s) for which Genenta intends to exercise the Competing Product Option. With regard to each Competing Product identified in each Competing Product Notice, OSR will confirm in writing the possibility to carry out the relevant research and

development activities and the ability to expand the rights granted under the License Agreement in accordance with Section 3.1 of this Amendment ("**OSR Confirmation**"), provided, however, that (for clarity, without limiting OSR's covenants under Section 3.1 of the License Agreement), OSR may withhold the OSR Confirmation only in the event that, prior to the receipt of the Competing Product Notice, OSR granted to one or more Third Parties any rights with respect to the applicable Competing Product that are inconsistent with an expansion of Genenta's license grant in accordance with Section 3.1 of this Amendment. Upon OSR Confirmation, Genenta shall pay to OSR the following amounts: (a) Euro [redacted] for the first product for which Genenta exercises its option under this Section 3.2, (b) Euro [redacted] for the second product and (c) Euro [redacted] for the third and following products. Notwithstanding the above, in the event Genenta exercises the Competing Product Option for the use of the Alternative Payload in alternative to the Current Payload no payment under the above mentioned letter (a) shall be due to OSR. In addition, in the event the Competing Product Option is first exercised for a Solid Cancer Indication, Genenta shall pay to OSR (in lieu of the amount set forth under Section 2.3(a) of the License Agreement): (i) Euro [redacted] upon exercise by Genenta of such Competing Product Option, and (ii) the remaining [redacted] upon the earlier of (1) the first anniversary of Genenta's exercise of the Competing Product Option and (2) dosing of the first patient with such Competing Product in such Solid Cancer Indication in a Phase I/II Clinical Trial. Upon OSR Confirmation of each Competing Product Notice:

(a) in the event such OSR Confirmation is related to the Alternative Payload to be used in addition to the Current Payload and/or other Competing Product(s), the definitions of "Licensed Product" and "Field of Use" shall be deemed amended to include the applicable Alternative Payload and/or Competing Product(s), and the definition of "Competing Product" shall be deemed amended to exclude such Alternative Payload and/or Competing Product(s).

(b) In the event such OSR Confirmation is related to the Alternative Payload to be used in alternative to the Current Payload, the definitions of "Licensed Product" and "Field of Use" shall be deemed amended to include such Alternative Payload and exclude the Current Payload and the definition of "Competing Product" shall be deemed amended to exclude such Alternative Payload. It is understood that in such case: (i) any further activity on the Current Payload shall be immediately discontinued by Genenta; (ii) any right granted by OSR to Genenta in relation to the Current Payload shall revert to OSR; (iii) Genenta shall assign and transfer to OSR, without any monetary consideration by OSR, any right, title and interest to Genenta Product Improvements and all tangible materials related to the Current Payload.

(c) Without limiting Genenta's obligations under the License Agreement, Genenta shall commit to spend at least [redacted] in the twenty-four (24) month-period following such OSR Confirmation to conduct research and development activities regarding each Competing Product (including the Alternative Payload) for which Genenta exercises its option under this Section 3.2.

4. **Termination for failure to develop.** Sections 10.4(a) and 10.4(b) of the License Agreement are hereby replaced in their entirety with the following (it being understood that Section 10.4(c) shall remain unchanged):

(a) Genenta has exercised the option set forth in Section 2.2(c) above with respect to a Licensed Product in a Solid Cancer Indication and Genenta (or a Sublicensee) has not filed an IND with respect to such Solid Cancer Indication (the **"Terminated Solid Cancer Indication"**), within three (3) years from the date of the exercise of the option, it being understood that in such case: (a) the termination rights shall be limited to such Licensed Product in the Terminated Solid Cancer Indication, (b) any further activity on such Licensed Product in the Terminated Solid Cancer Indication shall be immediately discontinued by Genenta; and (c) the provisions of Section 10.9 (as applicable) below shall apply only with respect to such Licensed Product in such Terminated Solid Cancer Indication; or

(b) Genenta has exercised the option set forth in Section 2.2(c) above with respect to a Licensed Product in three (3) Solid Cancer Indications and Genenta (or a Sublicensee) has not filed an IND with respect to any such Solid Cancer Indications for which the option was exercised, within three (3) years as of the date on which the relevant option was exercised, it being understood that in such case: (a) the termination rights shall apply to such Licensed Product in all Solid Cancer Indications (but not to any Lympho-Hematopoietic Indications, to the extent it shall be included under this License Agreement, for which the provisions of this License Agreement shall survive); (b) any further activity on such Licensed Product in all Solid Cancer Indications shall be immediately discontinued by Genenta; and (c) the provisions of Section 10.9 (as applicable) below shall apply to such Licensed Product in all Solid Cancer Indications.

5. **Certain Matters Related to the Research Agreement.**

5.1 For clarity, any invention, discovery, idea, know-how, data or information, or other intellectual property, developed by or on behalf of OSR in connection with the Research Project shall be deemed OSR Product Improvements to the extent related to the Licensed Product (where "Licensed Product" shall have the meaning set forth in the License Agreement, as amended, if applicable, pursuant to Sections 3.2(a) and/or 3.2(b) of this Amendment).

5.2 OSR will be the sole and exclusive owner of Study Report (as defined in the Research Agreement) and any related data, result, conclusion, know-how and other information included therein. For clarity, as between OSR and Genenta (i) inventions or discoveries made solely by OSR in the performance of the Research Plan (as defined in the Research Agreement) shall be owned solely by OSR, (ii) inventions or discoveries made solely by Genenta in the performance of the Research Plan shall be owned solely by Genenta and (iii) inventions or discoveries made jointly made by OSR and Genenta in the performance of the Research Plan shall be jointly owned by OSR and Genenta, and each Party may exploit such joint inventions or discoveries (without any duty to account

or consent requirement) subject to (if applicable), in the case of OSR's joint interest, the License Agreement.

5.3 During the Competing Product Option Period:

(a) Genenta may use the Study Report, under confidentiality and in compliance with the Evaluation Period (as defined in the Research Agreement), for internal research purposes only, including in order to assess the use of the Alternative Payload in addition or in alternative to the Current Payload;

(b) additionally, after the end of the Evaluation Period (as defined in the Research Agreement), Genenta may disclose the Study Report only to current or prospective investors or collaborators, in each case under confidentiality and without granting any rights to any third party (other than the right to internally evaluate the Study Report), unless otherwise agreed upon in writing among Amgen, OSR and Genenta.

(c) OSR shall not disclose the Study Report or any portion thereof to any Third Party (except [redacted], under the terms and conditions of the Research Agreement) without Genenta's prior written consent. Notwithstanding the above, during the Competing Product Option Period, OSR (a) shall be free to make any publication, whether oral or in writing, with respect to the Research Plan, the Study Report, and the data and/or results contained in the Study Report, upon Genenta's prior written consent (which shall not be unreasonably withheld) and in compliance with the Research Agreement, following the procedure set out under Section 5.4 of the Scientific Collaboration Agreement between OSR and Genenta dated December 15, 2014 ("**Scientific Collaboration Agreement**"); (b) shall be free to discuss under confidentiality the content of the Research Plan and the Study Report among its research staff and during internal research meetings (where "internal" may include San Raffaele Telethon Institute for Gene Therapy).

5.4 After the Competing Product Option Period, in the event Genenta did not exercise the Competing Product Option in relation to the Alternative Payload (to be used in alternative or in addition to the Current Payload), Genenta may no longer disclose to any third party the Study Report (to the extent not publicly available at that time), but may continue to use the Study Report for purposes of internal research uses only; and OSR shall be free to disclose and use the Study Report for any purpose.

5.5 With reference to Section 8 of the Research Agreement, as between OSR and Genenta, Genenta shall bear all costs due under the Research Agreement in connection with the preparation, filing, prosecution, defence, enforcement (including the Joint Invention Actions) of any Joint Inventions, Joint Platform Inventions and Joint Inventions Patents (as defined in the Research Agreement), and including the cost of damages awarded against OSR in connection with such action.

6. **Materials Transfer.** During the term of the Research Agreement, Genenta shall provide OSR with any material under Genenta's control (by ownership, license or

otherwise, including any vector or cell manufactured on behalf of Genenta by third parties) necessary or useful to conduct the research activities under the Research Plan as mutually agreed upon by the Parties, and agrees to indemnify, defend (including attorneys' fees) and hold harmless OSR from any liability resulting from any third party claim or demand arising from the use and/or storage of such material, except to the extent such claim results from any negligent or wilful act of OSR and/or its subcontractors. It is understood that OSR shall bear the costs related to the manufacturing (on behalf of Genenta by third parties) of any vector and cell necessary or useful to carry out the research activities under the Research Plan, provided that OSR shall be the sole and exclusive owner of such vectors and cells.

7. **Entire License Agreement.** This Amendment embodies the entire agreement between the Parties and supersedes any prior representations, understandings and agreements between the Parties regarding the subject matter hereof. There are no representations, understandings or agreements, oral or written, between the Parties regarding the subject matter hereof that are not fully expressed herein. Except as amended by this Amendment, the License Agreement shall remain in full force and effect. For clarity, the Research Agreement and the Scientific Collaboration Agreement shall also remain in full force and effect between the Parties.

IN WITNESS WHEREOF, the Parties have executed this Amendment effective as of the Amendment Effective Date.

Ospedale San Raffaele S.r.l.

By:

Name: Mr. Nicola Bedin

Title: Chief Executive Officer

Genenta Science S.r.l.

By:

Name: Mr. Pierluigi Paracchi

Title: Chief Executive Officer

AMENDMENT NO. 2 TO LICENSE AGREEMENT

AND AMENDMENT NO. 4 TO SCIENTIFIC COLLABORATION AGREEMENT

These **AMENDMENT NO. 2 TO LICENSE AGREEMENT** (**"Amendment"**) and **AMENDMENT NO. 4 TO SCIENTIFIC COLLABORATION AGREEMENT** are entered into as of February 1st, 2019 (for both agreements the **"Amendment Effective Date"**)

Between

Ospedale San Raffaele S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 07636600962, duly represented for the purposes hereof by its Chief Executive Officer, Msr. Elena Angela Maria Bottinelli (**"OSR"**)

- on the one side -

And

Genenta Science S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 08738490963, duly represented for the purposes hereof by its Chief Executive Officer, Mr. Pierluigi Paracchi (**"Genenta"**)

- on the other side -

(OSR and Genenta shall be, collectively but not jointly, defined as the **"Parties"** and, severally, a **"Party"**).

WHEREAS:

(A) OSR and Genenta entered into that certain license agreement dated December 15, 2014, as amended by Amendment No.1 dated March 16, 2017 (**"Amendment No.1"**) (such agreement, as amended, **"License Agreement"**), as well as into certain Scientific Collaboration Agreement (such agreement, together with its amendments No. 1, 2 and 3, the **"Collaboration Agreement"**);

(B) During the execution of the above mentioned agreements the Parties have decided to conduct a clinical trial according to a protocol (and any related amendments) no. TEM-GMB_001 and no. EudraCT 2018-001404-11, entitled *"Sperimentazione Clinica di fase I/IIa atta a valutare la sicurezza e l'efficacia di dosi crescenti di cellule staminali ematopoietiche autologhe CD34+ geneticamente modificate con un vettore lentivirale codificante per il gene umano dell'interferone-alfa2 in pazienti affetti da Glioblastoma Multiforme con promotore del gene MGMT non metilato"*.

(C) Considering the above, the Parties now wish to expand the License Agreement and further amend the License Agreement and the Collaboration Agreement under the terms set forth below.

* * *

NOW, THEREFORE, also in consideration of the foregoing premises, which form an integral and substantial part of this Amendment, and the mutual covenants herein contained, the **PARTIES HEREBY AGREE AS FOLLOWS.**

1. **Definitions** Capitalized terms not defined herein have the meaning set forth in the License Agreement or in the Collaboration Agreement (the latter in relation to Section 11 of this amendment only)

2. Section 1.36 of the License Agreement is hereby replaced in its entirety by the following.

   1.36 **"Option Period"** shall mean the period that commences on the Effective Date and ends on the second (2nd) anniversary of the initiation (first patient dosed) of the first human clinical trial for a Licensed Product in any Lympho Hematopoietic Indication or Solid Cancer Indication and, in any case, if earlier, on September 30, 2021, as eventually extended pursuant to Section 2.2(c).

3. Section 1.40 of the License Agreement is hereby replaced in its entirety by the following.

   1.40 **"Phase III Clinical Trial"** shall mean a human clinical trial in any country, the results of which could be used to establish safety and efficacy of a Licensed Product in the Field as a basis for an NDA, or its foreign equivalent, and satisfies the requirements of 21 CFR 312 21(c), or its foreign equivalent, or that is otherwise sufficient to enable submission of an NDA to the FDA (or its foreign equivalent), regardless of whether the sponsor of such trial characterizes or refers to such trial as a "Phase 3," "Phase 2b" or "Phase 2b/3" trial (or otherwise) in the applicable protocol, on clinicaltrials.gov, or in any other context. If a human clinical trial does not constitute a Phase III Clinical Trial at the time of first dosing of the first patient in such trial, but is later determined by the applicable Regulatory Authority to enable and NDA submission, then, such trial shall be deemed to constitute a Phase III Clinical Trial on the date of such determination by the applicable Regulatory Authority.

4. Section 2.2(c) of the License Agreement is hereby replaced in its entirety by the following:

   (c) include any Solid Cancer Indication as part of the Field of Use, on an indication-by-indication basis, subject to the payment of (i) the Option Fee (as defined below) and (ii) the milestones payments for each Solid Cancer Indication as set forth in Section 4.6 of this Agreement. In the event that Genenta exercises the option set forth under this Section 2.2(c) with respect to any Solid Cancer Indication (other than the GBM, as defined below), the Option Period for any other Solid Cancer Indication shall be extended only once for a period of twenty-four (24) months from the exercise of such option. By means of signature of the Amendment No. 2 to License Agreement, Genenta exercises the option set forth under this Section 2.2(c) with respect to Glioblastoma Indication (**"GBM"**) that shall be deemed effective as of the Amendment Effective Date of such Amendment No. 2 to License Agreement.

5. Section 2.3 of the License Agreement is hereby replaced in its entirety by the following:

   2.3 Option Fee and Additional Milestones. Further to the exercise of the Option set forth by Section 2.2(c) above, the Field of Use of this License shall be (and shall be considered) extended so as to include the relevant Solid Cancer Indication, only upon effective receipt by OSR of the following amounts: (a) Euro [redacted] for the first Solid Cancer Indication; (b)

Euro [redacted] for the second Solid Cancer Indication; and Euro [redacted] for the third Solid Cancer Indication. The foregoing amounts shall become due and payable upon receipt of the Notice. No Option Fee shall be due for the 4th (fourth) and following Solid Cancer Indications. For clarity, should Genenta exercise the option granted under Section 2.2(c), the Milestones Payment B shall become effective and due upon occurrence of the relevant Milestone Event with respect to such Solid Cancer Indication, as set forth in Section 4.6 of this License Agreement and the other financial terms and conditions set forth by this License Agreement shall apply, *mutatis mutandis*, to the sale of any Licensed Products for such Solid Cancer Indication. Notwithstanding the foregoing, in relation to the option exercised by Genenta with respect to GBM under Section 2.2(c), the Parties hereby agree that Genenta shall pay to OSR the amount of Euro [redacted] only in the event of the tenth patient has been dosed for the relevant clinical trial of GBM.

6. The table at the end of Section 4.6 of the License Agreement is hereby replaced in its entirety by the following:

Milestone Event	**Milestone Payment A**	**Milestone Payment B**
First patient dosed with a Licensed Product in Phase I/II Clinical Trial	[redacted]	[redacted]
First patient dosed with such Licensed Product in a Phase III Clinical Trial	[redacted]	[redacted]
MAA Approval for such Licensed Product in the first Major EU Country	[redacted]	[redacted]
NDA acceptance for such Licensed Product (United States of America)	[redacted]	[redacted]
First Commercial Sale of such Licensed Product in the United States of America	[redacted]	[redacted]
First Commercial Sale of such Licensed Product in three (3) out of 5 Major EU Countries	[redacted]	[redacted]
Aggregated Net Sales in the Territory during a single Calendar Year firstly exceeding Euro [redacted]	[redacted]	[redacted]

7. Notwithstanding the foregoing, in relation to the option exercised by Genenta with respect to GBM under Section 2.2(c), the Parties hereby agreed that the amount of Euro [redacted] provided under Milestone Payment B for the Milestone Event "First patient dosed with a Licensed Product in Phase I/II Clinical Trial" shall be paid by Genenta to OSR only upon the occurrence of the Milestone Event "First patient dosed with such Licensed Product in a Phase III Clinical Trial", together with the additional Euro [redacted] already provided for such Milestone Event in the table above. Section 7.8 of the License Agreement is hereby replaced in its entirety by the following:

7.8 Clinical trial primary site. For the Term of this License Agreement, Genenta hereby elects OSR as primary site in any pre-clinical study or clinical trial (including all phases thereof) relating to any Licensed Products in the Field of Use (as eventually extended in accordance with Section 2.2. above), subject to OSR (b) maintaining at all times any required quality standards and otherwise complying with the OSR-Genenta Scientific Collaboration Agreement and (b) providing its services on customary and reasonable terms and consistent with then-applicable market standards. Genenta can identify other site(s) to carry out clinical studies under the License Agreement with OSR's prior written consent on a case-by-case basis. Such consent will not unreasonable withheld.

8. Section 10.4(c) of the License Agreement is hereby replaced in its entirety by the following:

(c) no patient has been dosed with a Licensed Product in a Phase III Clinical Trial for a Lympho-Hematopoietic Indication by the fifth (5th) anniversary of the initiation (first patient dosed) of the first human clinical trial for a Licensed Product in any Lympho Hematopoietic Indication or Solid Cancer Indication and, in any case, if earlier, by September 1, 2025, it being understood that in such case: (a) the termination rights shall be limited to all Lympho-Hematopoietic Indications (but not to any Solid Cancer Indication, to the extent it shall be included under this License Agreement, for which the provisions of this License Agreement shall survive); (b) any further activity on all Lympho-Hematopoietic Indications shall be immediately discontinued by Genenta; and (c) the provisions of Section 10.9 below shall apply to all Lympho-Hematopoietic Indications.

9. Section 3.2 of Amendment No.1 is hereby replaced in its entirety by the following:

3.2 Genenta may exercise the Competing Product Option by written notice to OSR ("**Competing Product Notice**") within September 30, 2021 but in any event prior to commencing any clinical development activities involving the applicable Alternative Payload and/or Competing Product ("**Competing Product Option Period**"), provided, however, that in the event Genenta exercises the Competing Product Option at any time during such period, the Competing Product Option Period shall be deemed extended only once for a period of eighteen (18) months from the end of such period [i.e., eighteen (18) months from September 30, 2021] . Each Competing Product Notice shall identify the Alternative Payload and/or Competing Product(s) for which Genenta intends to exercise the Competing Product Option. With regard to each Competing Product identified in each Competing Product Notice, OSR will confirm in writing the possibility to carry out the relevant research and development activities and the ability to expand the rights granted under the License Agreement in

accordance with Section 3.1 of this Amendment ("**OSR Confirmation**"), provided, however, that (for clarity, without limiting OSR's covenants under Section 3.1 of the License Agreement), OSR may withhold the OSR Confirmation only in the event that, prior to the receipt of the Competing Product Notice, OSR granted to one or more Third Parties any rights with respect to the applicable Competing Product that are inconsistent with an expansion of Genenta's license grant in accordance with Section 3.1 of this Amendment. Upon OSR Confirmation, Genenta shall pay to OSR the following amounts: (a) Euro [redacted] for the first product for which Genenta exercises its option under this Section 3.2, (b) Euro [redacted] for the second product and (c) Euro [redacted] for the third and following products Notwithstanding the above, in the event Genenta exercises the Competing Product Option for the use of the Alternative Payload in alternative to the Current Payload no payment under the above mentioned letter (a) shall be due to OSR. In addition, in the event the Competing Product Option is first exercised for a Solid Cancer Indication, Genenta shall pay to OSR (in lieu of the amount set forth under Section 2.3(a) of the License Agreement): (i) Euro [redacted] upon exercise by Genenta of such Competing Product Option, and (ii) the remaining [redacted] upon the earlier of (1) the first anniversary of Genenta's exercise of the Competing Product Option and (2) dosing of the first patient with such Competing Product in such Solid Cancer Indication in a Phase I/II Clinical Trial. Upon OSR Confirmation of each Competing Product Notice:

(a) in the event such OSR Confirmation is related to the Alternative Payload to be used in addition to the Current Payload and/or other Competing Product(s), the definitions of "Licensed Product" and "Field of Use" shall be deemed amended to include the applicable Alternative Payload and/or Competing Product(s), and the definition of "Competing Product" shall be deemed amended to exclude such Alternative Payload and/or Competing Product(s)

(b) In the event such OSR Confirmation is related to the Alternative Payload to be used in alternative to the Current Payload, the definitions of "Licensed Product" and "Field of Use" shall be deemed amended to include such Alternative Payload and exclude the Current Payload and the definition of "Competing Product" shall be deemed amended to exclude such Alternative Payload. It is understood that in such case: (i) any further activity on the Current Payload shall be immediately discontinued by Genenta; (ii) any right granted by OSR to Genenta in relation to the Current Payload shall revert to OSR; (iii) Genenta shall assign and transfer to OSR, without any monetary consideration by OSR, any right, title and interest to Genenta Product Improvements and all tangible materials related to the Current Payload.

(c) Without limiting Genenta's obligations under the License Agreement, Genenta shall commit to spend at least Euro [redacted] in the twenty-four (24) month-period following such OSR Confirmation to conduct research and development activities regarding each Competing Product (including the Alternative Payload) for which Genenta exercises its option under this Section 3.2.

10. The Parties acknowledge and agree that (a) the patent family known as "Type 1 Interferon Gene Therapy" UK N.1706410.6 filed on 21.04.2017, UK N.1801511.5 filed on 30.01.2018, PCT/EP2018/060238.20.04.2018 covers certain OSR Product Improvements as well as certain Competing Product(s) (including the applicable Alternative Payload(s)), and (b)

notwithstanding Section 2.2(b) of the License Agreement, the Option Period (to include the OSR Product Improvements only under such patent family in the license granted to Genenta under Section 2.1 of the Agreement) shall be forty eight (48) months from the Amendment Effective Date, provided that (i) OSR shall prosecute and maintain such patent family in accordance with Section 9.1 of the Agreement, (ii) Genenta shall reimburse OSR for the costs incurred by OSR in connection with such prosecution and maintenance activities, including the costs incurred prior to the Amendment Effective Date. The Parties acknowledge and agree that, prior to Genenta's exercise of such option, OSR may (but is under no obligation to) conduct research and/or development activities with respect to the OSR Product Improvements described above, whether in its own or in collaboration with any Third Parties, provided that OSR may not conduct such activities in collaboration with any for-profit Third Party without Genenta's prior written consent on a case-by-case basis. For the sake of clarity, in relation to any other OSR Product Improvements (different from the OSR Product Improvements under the said patent family) shall apply the Option Period as defined under Section 1.36 of the Licensed Agreement (ad amended by this Amendment).

11. Section 5.4 of the Collaboration Agreement is hereby replaced in its entirety by the following:

Scientific publications. In the event that OSR be willing to issue a publication related to the results of the Research Activities, it shall provide Genenta with a copy of the proposed written or oral publication or presentation at least thirty (30) Business Days prior to submission for publication or presentation in order to allow Genenta an opportunity to protect its Confidential Information that may be disclosed by the proposed public disclosure. If Genenta determines that its Confidential Information would likely be disclosed by the proposed public disclosure, it shall so advise OSR within such thirty (30) Business Days period, whereupon OSR: (a) shall delete all references to such Confidential Information of Genenta and (b) shall postpone the proposed publication or presentation for up to, and for no more than, an additional thirty (30) Business Days to afford the opportunity to prepare and file one or more patent applications with respect thereto. Without prejudice to the foregoing, for the avoidance of doubts, OSR shall be free to discuss the results of the Research Activities among its research staff and during internal research development and clinical meetings, as well as for its own non-commercial research, teaching, education, clinical and publication purposes, provided, however, that OSR shall not disclose any Confidential Information without the prior written consent of Genenta, which shall not be unreasonably denied.

IN WITNESS WHEREOF, the Parties have executed this agreement effective as of the Amendment Effective Date

Ospedale San Raffaele S.r.l.

By:

Name: Elena Angela Maria Bottinelli
Title: Chief Executive Officer

Genenta Science S.r.l.

By:

Name: Mr. Pierluigi Paracchi

Title: Chief Executive Officer

AMENDMENT NO. 3 TO LICENSE AGREEMENT

This **AMENDMENT NO. 3 TO LICENSE AGREEMENT** ("**Amendment**") is entered into as of December 23, 2020 ("**Amendment 3 Effective Date**")

Between

Ospedale San Raffaele S.r.l., an Italian company having registered office at via Olgettina No 60, 20132, Milan, Italy, Fiscal Code 07636600962, duly represented for the purposes hereof by its Chief Executive Officer, Mrs. Elena Angela Maria Bottinelli ("**OSR**")

- on the one side -

And

Genenta Science S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 08738490963, duly represented for the purposes hereof by its Chief Executive Officer, Mr. Pierluigi Paracchi ("**Genenta**")

- on the other side -

(OSR and Genenta shall be, collectively but not jointly, defined as the "**Parties**" and, severally, a "**Party**")

WHEREAS:

(A) OSR and Genenta entered into that certain license agreement dated December 15, 2014, as amended by Amendment No 1 dated March 16, 2017 ("**Amendment No.1**") and by Amendment No 2 dated February 1, 2019 ("**Amendment No.2**"; such agreement, as amended, is hereinafter referred to as "**License Agreement**"), as well as into the Scientific Collaboration Agreement dated December 15, 2014 (such agreement, as amended, the "**Collaboration Agreement**");

(B) With the execution of Amendment No 2

- Genenta exercised the Option in accordance with Section 2.2(c) of the License Agreement with respect to the Glioblastoma Indication ("**GBM**", which, for the avoidance of doubt, is the first Solid Cancer Indication in relation to which the Option was exercised by Genenta),

- the Parties agreed to derogate to Section 2.3 in relation to the payment of the Option Fee due in relation to the exercise of such Option, stating that the Option Fee amounting to Euro [redacted] ("**GBM Option Fee**") shall be paid by Genenta to OSR upon the dosing of the tenth patient in the relevant clinical trial of GBM,

(C) Genenta is willing to exercise the Option with respect to an additional Solid Cancer Indication, i.e solid liver cancer ("**LC**"), concurrently with the execution of this Amendment No.3;

(D) The Parties are now willing to amend the License Agreement to include their mutual arrangements (including, but not limited to) in relation to the payment of the GBM Option Fee and to the Option Fee due for the exercise of the LC Option,

NOW, THEREFORE, also in consideration of the foregoing premises, which form an integral and substantial part of this Amendment, and the mutual covenants herein contained, the **PARTIES HEREBY AGREE AS FOLLOWS**

1. **Definitions**. Capitalized terms not defined herein have the meaning set forth in the License Agreement

2. **LC Option Exercise.** By means of the signature of this Amendment No 3 Genenta exercises the option set forth under this Section 2 2(c) with respect to LC, that shall be deemed effective as of the Amendment 3 Effective Date.

   As a consequence of the above, Section 2 2(c) of the License Agreement is hereby replaced in its entirety by the following and, for the avoidance of doubt, the Option Period to exercise the Option for any other Solid Cancer Indication shall be deemed to extend until the second anniversary of the Amendment No. 3 Effective Date and shall not be subject to further extensions

   "(c) include any Solid Cancer Indication as part of the Field of Use, on an indication-by-indication basis, subject to the payment of (i) the Option Fee (as defined below) and (ii) the milestones payments for each Solid Cancer Indication as set forth in Section 4 6 of this Agreement. In the event that Genenta exercises the option set forth under this Section 2 2(c) with respect to any Solid Cancer Indication (other than GBM and LC, each as defined below), the Option Period for any other Solid Cancer Indication shall be extended only once for a period of twenty-four (24) months from the exercise of such option By means of the signature of the Amendment No 2 to License Agreement, Genenta has exercised the option set forth under this Section 2 2(c) with respect to Glioblastoma Indication ("**GBM**") as the first Solid Cancer Indication, that became effective as of the Amendment Effective Date of such Amendment No 2 to License Agreement By means of the signature of the Amendment No 3 to License Agreement, Genenta exercises the option set forth under this Section 2 2(c) with respect to solid liver cancer ("**LC**") as the second Solid Cancer Indication, that shall be deemed effective as of the Amendment No 3 Effective Date. Without limiting the foregoing, if Genenta is not able to obtain approval of the Regulatory Authorities to initiate a human clinical trial in any country with respect to solid liver cancer on or before the expiry of nine (9) months from the Amendment No 3 Effective Date , then Genenta shall have the right, at no additional cost, to convert the option exercise for the second Solid Cancer Indication to an indication (the "**Alternate Indication**") other than solid liver cancer, upon written notice to OSR specifying the Alternate Indication that is to replace solid liver cancer ("**Alternate Indication Notice**") Thereafter the term "LC," as used in this Agreement, shall no longer mean "solid liver cancer" and instead will be defined as the Alternate Indication."

3. **Option Fee.** The Parties agree that:

   (a) The amount of the GBM Option Fee shall be equal to Euro [redacted] and shall be paid by Genenta to OSR upon the earlier to occur of December 31, 2020 and the closing of the

tenth patient within the GBM clinical trial mentioned under recital (B) of Amendment No 2. The reduction of the GBM Option Fee to Euro [redacted] (in lieu of the amount of Euro [redacted]) shall be subject to the execution of the Sponsored Research Agreement (as defined under Section 6 below) within forty-five (45) days from the Amendment No 3 Effective Date ("**SRA Long Stop Date**"); provided that, in the event that the Sponsored Research Agreement is not executed by such date, OSR shall be entitled to receive the remaining portion of the GBM Option Fee (i.e Euro [redacted]) upon the earlier to occur of

- thirty (30) days from the SRA Long Stop Date; and

- the dosing of the tenth patient within the GBM clinical trial mentioned under recital (B) of Amendment No 2 (or upon the SRA Long Stop Date in the event that the dosing of the tenth patients has occurred prior to the SRA Long Stop Date);

(b) In accordance with Section 2.3 of the License Agreement the amount of the Option Fee for the exercise of the Option in relation to LC shall be equal to Euro [redacted] ("**LC Option Fee**"). In derogation to the payment terms set forth in Section 2.3, Genenta shall pay the LC Option Fee upon the earlier to occur of June 30, 2021 and the occurred enrollment of the first patient within the phase I clinical study for a Licensed Product in relation to LC

In consideration of the above Section 2.3 of the License Agreement is hereby replaced in its entirety by the following

"**2.3 Option Fee and Additional Milestones** Further to the exercise of the Option set forth by Section 2 2(c) above, the Field of Use of this License shall be (and shall be considered) extended so as to include the relevant Solid Cancer Indication, only upon effective receipt by OSR of the following amounts: (a) Euro [redacted] for the first Solid Cancer Indication; (b) Euro [redacted] for the second Solid Cancer Indication, and Euro [redacted] for the third Solid Cancer Indication. The foregoing amounts shall become due and payable upon receipt of the Notice (subject however to (i) and (ii) below). No Option Fee shall be due for the 4th (fourth) and following Solid Cancer Indications For clarity, should Genenta exercise the option granted under Section 2.2(c), the Milestones Payment B shall become effective and due upon occurrence of the relevant Milestone Event with respect to such Solid Cancer Indication, as set forth in Section 4.6 of this License Agreement and the other financial terms and conditions set forth by this License Agreement shall apply, *mutatis mutandis*, to the sale of any Licensed Products for such Solid Cancer Indication. Notwithstanding the foregoing,

(i) in relation to the option exercised by Genenta with respect to GBM under Section 2 2(c), the Parties hereby agree that Genenta shall pay to OSR the amount of Euro [redacted] (in lieu of the amount of Euro [redacted] specified above in clause (a) of Section 2 3, subject however to the proviso set forth in this Section 2 3(i)) upon the earlier to occur of December 31, 2020 and the dosing of the tenth patient within the relevant clinical trial of GBM; provided that, in the event that the Parties fail to execute the Sponsored Research Agreement (as defined below) within forty-five (45) days from the Amendment No 3 Effective Date ("**SRA Long Stop Date**"), Genenta shall pay to OSR an additional amount equal to Euro [redacted] upon the earlier to occur of thirty (30) days from the SRA Long Stop Date and the dosing of the tenth patient within the relevant clinical trial of GBM (or upon the SRA Long Stop Date in the event that the dosing of the tenth patients has occurred prior to the SRA Long Stop Date)

"**Sponsored Research Agreement**" shall mean that certain sponsored research agreement that the Parties are willing to execute to carry out research activities as set forth in Section 6 of Amendment No. 3 (which shall include those terms and conditions set forth in Amendment No 3),

(ii) the Option Fee due in relation to the option exercised by Genenta with respect to LC, which amounts to Euro [redacted] shall be paid upon the earlier to occur of June 30, 2021 and the occurred enrollment of the first patient within the phase I clinical study for a Licensed Product in relation to LC For clarity, and notwithstanding anything to the contrary contained herein, if Genenta converts the option exercise for the second Solid Cancer Indication (i e LC) to the Alternate Indication pursuant to Section 2 2(c), the License shall be (and shall be considered) to include the Alternate Indication (in lieu of LC) starting from the Alternate Indication Notice subject to Genenta's payment of such Euro [redacted] and Genenta shall not be required to pay any additional option exercise fees in connection with such conversion

Genenta shall provide immediate notice in relation to the occurrence of the dosing of the tenth patient within the relevant clinical trial of GBM and in relation to the enrollment of the first patient within the phase I clinical study for a Licensed Product in relation to LC".

The Parties further agree that (a) all payments made in accordance with this Agreement shall be non-refundable and (b) Section 10.3 of the License Agreement shall be intended as including OSR's right to terminate the License Agreement in the event that Genenta fails to pay the Option Fee within thirty (30) days following the expiration of the applicable deadline indicated in Section 2.3

4. **Milestone Payments.** In relation to the option exercised by Genenta with respect to LC (or the Alternate Indication in lieu of LC, as applicable) under Section 2.2(c), the Parties hereby agree that the Milestone Payment due in relation to the "First patient dosed with a Licensed Product in Phase I/II Clinical Trial" with respect to LC (such Milestone Event the "**LC First Milestone Event**" and such Milestone Payment the "**LC First Milestone Payment**") shall be equal to Euro [redacted] (in lieu of the amount of Euro [redacted] set forth under the column Milestone Payment B of the table under Section 4 6 of the License Agreement), provided that (i) such reduction shall apply to the LC First Milestone Payment only; and (ii) in the event that clinical proof of concept is not achieved in relation to GBM on or before the date on which the LC First Milestone Event occurs, the reduction mechanism set forth in Section 4.6(b) shall not apply to such LC First Milestone Payment It is understood that all the additional Milestone Payments set forth under the column Milestone Payment B of the table under Section 4.6 of the License Agreement (other than the last Milestone Payment of such column) shall be due and payable to OSR on a Licensed Product-by-Licensed Product basis and/or on an indication-by-indication basis (i e with respect to each primary and secondary LC indication, including -but not limited to- hepatocarcinoma, colagiocarcinoma and tumor metastasis to the liver irrespectively of such indications being treated using the same License Product).

5. **Competing Product Option Period.** The Parties agree that the first sentence of Section 3.2 of the License Agreement shall be entirely replaced by the following

"**3.2** Genenta may exercise the Competing Product Option by written notice to OSR ("**Competing Product Notice**") on or before September 30, 2022 but in any event prior to commencing any clinical development activities involving the applicable Alternative Payload and/or Competing Product ("**Competing Product Option Period**"), provided, however, that in the event Genenta exercises the Competing Product Option at any time during such period, the Competing Product Option Period shall be deemed extended only once for a period of twelve (12) months from the end of such period (i.e., twelve (12) months from September 30, 2022) "

For the sake of clarity, the remaining part of Section 3.2 shall remain unchanged.

6. **Sponsored Research.** The Parties agree that, forthwith upon the execution of this Amendment No. 3, they will start good faith negotiations with the intent to execute within forty-five (45) days from the Amendment No. 3 Effective Date a sponsored research agreement ("**Sponsored Research Agreement**" or "**SRA**") in relation to the research programs aimed at (a) exploratory studies towards acquiring additional evidence for biological activity of Temferon and (b) detecting Temferon-expressing TEMs/myeloid cells in GBM and exploring combination between Temferon and GBM-targeting CAR T cells in relation to which

- [redacted] and [redacted] will be identified as the PIs,
- the above-mentioned research programs ("**SRA Research Programs**") may continue beyond year 2021 from the date of execution of the SRA, provided that in year 2021 Genenta shall pay to OSR Euro[redacted] in relation to the conduct of the activities that will be identified under the SRA for that year,
- solely for the avoidance of doubt, the activities to be carried out under such SRA shall not be regarded as comprised within the definition of Research Activities as set forth in the Collaboration Agreement (which shall not apply to regulate the SRA Research Programs);
- the intellectual property rights related to the results generated in the performance of the SRA shall be owned by OSR, Fondazione Telethon;
- under the SRA, OSR shall grant to Genenta an exclusive option (which may be exercised by Genenta at any time during the Competing Product Option Period, or such other period as mutually agreed by the Parties in the SRA) to negotiate an exclusive or non-exclusive license under such intellectual property rights, without prejudice to the rights granted to Genenta under the License Agreement in relation to the OSR Product Improvements.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this agreement effective as of the Amendment Effective Date.

Ospedale San Raffaele S.r.l.

By:

Name: Elena Angela Maria Bottinelli
Title: Chief Executive Officer

Genenta Science S.r.l.

By Pierluigi Paracchi Firmato digitalmente da Pierluigi Paracchi Data 2020 12 23

Name: Mr. Pierluigi Paracchi

Title: Chief Executive Officer

SPONSORED RESEARCH AGREEMENT

This Sponsored Research Agreement ("**Agreement**"), effective as of the date of the last signature hereto ("**Effective Date**"), is made

Between

Ospedale San Raffaele S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 07636600962, duly represented for the purposes hereof by its Chief Executive Officer, Mrs. Elena Angela Maria Bottinelli ("**Institution**")

- on the one side -

and

Genenta Science S.r.l., an Italian company having registered office at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 08738490963, duly represented for the purposes hereof by its Chief Executive Officer, Mr. Pierluigi Paracchi ("**Sponsor**")

- on the other side -

(OSR and Genenta shall be, collectively but not jointly, defined as the "**Parties**" and, severally, a "**Party**").

WHEREAS:

a) OSR and Genenta are parties to that certain license agreement executed by and between the parties on December 15, 2014, as amended by Amendment No.1 dated March 16, 2017 ("**Amendment No.1**"), by Amendment No.2 dated February 1, 2019 ("**Amendment No.2**") and by Amendment No.3 dated December 23, 2020 ("**Amendment No.3**"; such agreement, as amended, is hereinafter referred to as "**License Agreement**"), as well as to the Scientific Collaboration Agreement dated December 15, 2014 (such agreement, as amended, the "**Collaboration Agreement**");

b) In accordance with Amendment No.3, Sponsor desires to fund the research activities related to certain research projects conducted at Institution, namely:

- exploratory studies towards acquiring additional evidence for biological activity of Temferon ("**Research Project 1**" or "**RP1**") and
- studies aimed at detecting Temferon-expressing TEMs/myeloid cells in GBM and exploring combination between Temferon and GBM-targeting CAR T cells ("**Research Project 2**" or "**RP2**")

in accordance with the terms and conditions of this Agreement; and

c) The research projects mentioned above are of mutual interest to Sponsor and Institution, also in relation to the scope of the rights and licenses granted to Genenta under the License Agreement.

NOW, THEREFORE, in consideration of the promises and mutual covenants contained herein, and intending to be legally bound hereby, the Parties hereto agree as follows:

AGREEMENT

1 DEFINITIONS

1.1 **"Affiliate"** means, with respect to any person or entity, any other person or entity which directly or indirectly controls, is controlled by or is under common control with such person or entity, during the term of such control. A person or entity will be deemed to be "controlled" by any other person or entity if such other person or entity (a) possesses, directly or indirectly, power to direct or cause the direction of the management and policies of such person or entity whether by contract or otherwise, (b) has direct or indirect ownership of fifty percent (50%) or more (in the aggregate) of the voting power of all outstanding shares entitled to vote at a general election of directors of the person or entity or (c) has direct or indirect ownership of fifty percent (50%) or more of the equity interests in a partnership or a limited liability company.

1.2 **"Agreement"** has the meaning set forth in the preamble.

1.3 **"Competing Product"** has the meaning set forth in the License Agreement.

1.4 **"Competing Product Option Period"** has the meaning set forth in the License Agreement.

1.5 **"Confidential Information"** has the meaning set forth in Section 6.1.

1.6 **"Disclosing Party"** has the meaning set forth in Section 6.1.

1.7 **"Effective Date"** has the meaning set forth in the preamble.

1.8 **"Field of Use"** has the meaning set forth in the License Agreement, subject to possible restrictions pursuant to Section 10.4 of the License Agreement.

1.9 **"Institution"** has the meaning set forth in the preamble.

1.10 **"Institution Background IP"** means such intellectual property rights (i) owned by Institution as at the Effective Date and/or (ii) related to results generated by or on behalf of the Institution following to the Effective Date other than in the performance of the Sponsored Research.

1.11 **"Institution Inventions"** means all Inventions conceived, made, created, developed during the Term, in the performance of the Sponsored Research.

1.12 "**Invention**" means any discovery, invention, creation, improvement or modification, whether or not patentable, including, but not limited to, processes, methods, formulas, technical information, materials, compositions, formulas, biological materials, assays, compounds, techniques, computer software and documentation, data and know-how, together with any patent, copyright or other intellectual property rights therein.

1.13 "**Licensed Competing Product**" shall mean those Competing Product in relation to which, prior to the exercise of the Option granted to Sponsor under Section 5 of this Agreement, Sponsor has exercised the Competing Product Option pursuant to the License Agreement.

1.14 "**Licensed Product**" has the meaning set forth in the License Agreement.

1.15 "**Negotiation Period**" has the meaning set forth in Section 5.4.

1.16 "**Option**" has the meaning set forth in Section 5.4.

1.17 "**Option Notice**" has the meaning set forth in Section 5.4.

1.18 "**Option Period**" shall mean the term starting on the Effective Date of this Agreement and ending upon the earlier to occur of (i) the expiry of the Competing Product Option Period according to the License Agreement and (ii) the earlier termination of the License Agreement.

1.19 "**OSR Product Improvements**" has the meaning set forth in the License Agreement.

1.20 "**Party**" and "**Parties**" have the meaning set forth in the preamble.

1.21 "**Principal Investigator**" has the meaning set forth in Section 2.3.

1.22 "**Publication**" has the meaning set forth in Section 6.5.

1.23 "**Receiving Party**" has the meaning set forth in Section 6.1.

1.24 "**Research Plan**" means each research plan set forth in Exhibit A in relation to RP1 and to RP2.

1.25 "**Research Project 1**" and "**Research Project 1**" shall have the meaning set forth in the preamble.

1.26 "**Research Results**" means all data and information generated in the performance of the Sponsored Research and any research reports furnished to Sponsor under this Agreement, including Institution Inventions, descriptions of experiments conducted under the Research Plans and corresponding analyses and conclusions.

1.27 "**Rules**" has the meaning set forth in Section 9.2.

1.28 "**Sponsor**" has the meaning set forth in the preamble.

1.29 "**Sponsored Research**" means the set of activities described in the Research Plan related to RP1 ("**Sponsored Research 1**") and the set of activities described in the Research Plan related to RP2 ("**Sponsored Research 2**").

1.30 "**Term**" has the meaning set forth in Section 8.1.

2 SPONSORED RESEARCH

2.1 Institution shall perform the Sponsored Research 1 and the Sponsored Research 2 in accordance with the applicable Research Plan and the terms and conditions of this Agreement. The Parties agree that Institution after consultation with Sponsor shall be entitled to subcontract the performance of the activities under the Research Plans to third parties.

2.2 Each Research Plan may be modified only upon mutual written agreement of Sponsor and Institution.

2.3 Institution principal investigators shall be

- [redacted], in relation to the RP1;
- [redacted], in relation to the RP2,

(jointly the "**Principal Investigators**" and severally "**Principal Investigator**"), who shall supervise, respectively, the Sponsored Research 1 and the Sponsored Research 2. In the event that a Principal Investigator becomes unavailable to Institution for any reason, Institution shall be entitled to designate another member of its faculty who is reasonably acceptable to Sponsor to serve as Principal Investigator of the applicable Sponsored Research. If a substitute Principal Investigator has not been designated within sixty (60) days after the Principal Investigator has ceased its services under this Agreement, Sponsor may terminate this Agreement solely as related to the applicable Sponsored Research upon written notice thereof to Institution, subject to the provisions of Section 8 (and provided that Institution shall in no event be held liable to Sponsor for such termination).

3 FUNDING AND PAYMENT

3.1 In relation to the conduct of the Sponsored Research, Sponsor shall pay to Institution an amount equal to Euro [redacted], as set forth in the payment schedule attached hereto as Exhibit B. Exhibit B further identifies the portion of such amount which is allocated to Sponsored Research 1 and to Sponsored Research 2. Amounts paid by Sponsor to Institution pursuant to Exhibit B shall be paid in Euros. The amounts mentioned under Exhibit B are exclusive of VAT, which shall be added to all payments as applicable.

3.2 If at any time Institution determines that it will require additional funds for the Sponsored Research, it shall notify Sponsor and provide an estimate of the additional costs for completing the Sponsored Research and the Parties shall in

good faith negotiate an amendment to the Research Plan in the event that such increase of the budget is agreed upon by the Parties in accordance with Section 2.2.

3.3 Without prejudice to Section 8.2 below, any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest at a rate equal to the thirty (30) day Euribor rate, divisor 365, effective for the date that the payment was due, we reported by "Il Sole 24 Ore" plus [redacted].

3.4 All payments set forth by this Agreement shall be made through bank transfer to the bank account indicated by Institution in writing.

4 RECORDS, RESEARCH RESULTS AND REPORTS

4.1 During the 30 days from the expiry of each four (4) month period after the Effective Date, Institution shall deliver to Sponsor a written summary (including in the form of a power point presentation) of the activities conducted under each Research Project (i.e., for the avoidance of doubt, a written summary related to the RP1 and a written summary related to the RP 2) and all Research Results obtained during the applicable reporting period in relation to the applicable Research Plan. Sponsor shall be entitled to have visibility of the raw data on which the summary reports will be based. Within sixty (60) days after completion of the applicable Research Project or earlier termination of this Agreement, Institution shall submit to Sponsor comprehensive final reports containing all Research Results related to the applicable Research Plan and detailing all activities conducted in connection with the Sponsored Research.

4.2 Institution and Principal Investigators shall be entitled to publicly disclose the Research Results and/or any information contained in the reports provided pursuant to Section 4.1, subject however to Section 6.

5 INTELLECTUAL PROPERTY

5.1 Institution shall be the owner of and shall retain all right, title and interest to the Institution Background IP. Institution shall furthermore be the owner, jointly with Fondazione Telethon, in their quality as joint venturers in SR-Tiget, of the Research Results (including all intellectual property rights related thereto), subject however to Section 5.4.

5.2 Institution shall promptly notify Sponsor of any Institution Invention, which notice shall include a detailed written description (including copies of written invention disclosures received by Institution) of all such Inventions.

5.3 As between the Parties, Institution shall have the right to file, prosecute and maintain patent applications on such Institution Inventions. Institution will consult with, and reasonably consider in good faith comments provided by, Sponsor on patent applications for Institution Inventions. Sponsor shall reimburse Institution within forty-five (45) days after receipt of invoice for all documented, reasonable, out-of-pocket costs and expenses incurred by Institution in connection with the filing, prosecution and defence of the patent applications and maintenance of the patents on Institution Inventions. Notwithstanding the foregoing, if no Option is exercised during the Option Period (or no license agreement is executed within the applicable Negotiation Period in relation to the

applicable Institution Invention following to the exercise of the Option in relation to the applicable Institution Invention following to the exercise of the Option in relation to the applicable Institution Invention following to the exercise of the Option in relation to the applicable Institution Invention), Sponsor shall have no further obligation to reimburse Institution's costs and expenses under this Section 5.3 (or shall have no further obligation to reimburse such costs and expenses limited to the applicable Institution Invention in the event that no license agreement is executed within the applicable Negotiation Period following to the exercise of the Option in relation to the applicable Institution Invention), to the extent that such costs and expenses are incurred after the expiry of the Option Period (or after the expiry of the Negotiation Period in the event that no license agreement is executed within the applicable Negotiation Period following to the exercise of the Option in relation to the applicable Institution Invention).

5.4 Without prejudice to the rights granted to Genenta under the License Agreement in relation to the OSR Product Improvements, Institution hereby grants to Sponsor an option (**"Option"**) to negotiate either an exclusive or non-exclusive, royalty-bearing, non-transferrable, world-wide license, on commercially reasonable terms, under the Institution Inventions to research, develop, make, have made, use, offer for sale, sell and import any Licensed Product and/or Licensed Competing Product limited to the Field of Use. Sponsor may exercise such option with respect to any Institution Inventions by providing to Institution written notice thereof (**"Option Notice"**) at any time during the Option Period; provided that such Option Notice shall mention (i) whether Sponsor is interested in an exclusive or a non-exclusive license, as well as (ii) the indications within the Field of Use and the applicable Licensed Product(s) and/or Licensed Competing Product(s) in relation to which Sponsor is interested to start negotiations in accordance with Section 5.5.

5.5 For up to three (3) months after Institution receives such Option Notice (the **"Negotiation Period"**), Institution and Sponsor will negotiate in good faith the terms of a license agreement to the Institution Inventions under which Institution would grant to Sponsor an exclusive or non-exclusive license (as set forth in the Option Notice) in relation to such Licensed Products(s) and/or Licensed Competing Products(s) and such indication(s) within the Field of Use as set forth in the Option Notice.

5.6 Institution shall have no further obligation to Sponsor in accordance with Sections 5.4 and 5.5 in relation to the applicable Institution Invention in the event that Sponsor and Institute fail to execute a License Agreement during the Negotiation Period.

5.7 For the sake of clarity, nothing in this Agreement shall be intended as a grant by Institution to Sponsor of any rights or licenses in Institution Background IP. All rights not expressly granted by a Party under this Agreement are reserved by such Party and may be used by such Party for any purpose.

6 CONFIDENTIALITY, PUBLICATION, USE OF NAMES

6.1 As used herein, the term **"Confidential Information"** includes, without limitation, the terms of this Agreement and any technical, scientific, business or other information that may be disclosed by one Party (the **"Disclosing Party"**) to the other Party (the **"Receiving Party"**) in connection with this Agreement,

regardless of whether such information is specifically designated as confidential and regardless of whether such information is in oral, written, electronic or other form. The Receiving Party shall (a) hold in confidence the Confidential Information of the Disclosing Party and refrain from disclosing the Confidential Information of the Disclosing Party to any third party without the express written consent of the Disclosing Party and (b) not use the Confidential Information of the Disclosing Party for any purpose other than as expressly permitted under this Agreement. Without limiting the foregoing, either Party shall not use the other Party's Confidential Information for any purpose other than performing the Sponsored Research and shall permit only those employees who have a need to know such Confidential Information to access such Confidential Information. The Receiving Party's obligations under this Section 6.1 shall continue throughout the Term and for ten (10) years following termination or expiration of this Agreement.

6.2 The confidentiality and non-use obligations set forth in Section 6.1 shall not apply to Confidential Information that the Receiving Party can demonstrate by competent written proof:

(i) was known by the Receiving Party without restriction prior to disclosure under this Agreement;

(ii) was lawfully disclosed to the Receiving Party by a third party without an obligation of confidentiality;

(iii) entered the public domain through means other than an unauthorized disclosure or other breach of this Agreement by the Receiving Party;

(iv) was independently developed by the Receiving Party without knowledge or use of or access to Confidential Information disclosed by the Disclosing Party under this Agreement; or

(v) was published or publicly disclosed in accordance with the terms of this Agreement.

6.3 Notwithstanding Section 6.1, limited disclosure of Confidential Information shall not be prohibited to the extent such Confidential Information is required to be produced under applicable law; provided that, to the extent permitted under applicable law, in such case the Receiving Party shall (a) promptly notify the Disclosing Party in writing of the existence, terms and circumstances of such required disclosure; (b) allow the Disclosing Party to offer its objections to the production of the applicable Confidential Information; (c) cooperate with the Disclosing Party to take legally available steps to limit such disclosure; (d) disclose only those portions of Confidential Information that the Receiving Party is, in the opinion of its counsel, legally obligated to disclose; and (e) seek confidential treatment for all Confidential Information so disclosed.

6.4 Promptly after expiration or termination of this Agreement, Institution shall return to Sponsor all Sponsor's Confidential Information in the possession or control of Institution (unless Sponsor requires Institution during the fifteen (15) days prior to the expiry or termination of the Agreement).

6.5 Institution shall be entitled to publish, present or otherwise disclose Research Results or other information and material resulting from the Sponsored Research for any purpose, subject to the terms and conditions of this Section 6.5. Notwithstanding the foregoing, Institution shall furnish the Sponsor with a final draft of any proposed publication, presentation or other public disclosure at least sixty (60) days in advance of the submission of such proposed publication, presentation or other public disclosure ("**Publication**") in order for the Sponsor to review and comment thereon, including to review for the possible inclusion in such Publication of Sponsor's Confidential Information disclosed to Institution. Institution shall consider Sponsor's suggestions for modifications as long as the neutrality and scientific character of the publication is not impaired and shall delete from its proposed Publication all Sponsor's Confidential Information that the other Party identifies and requests Institution to delete. Sponsor shall not be entitled to publish the Research Results (subject to the provisions of the license agreement possibly executed during the Negotiation Period in the event that Sponsor exercises the Option).

6.6 Institution shall not use Sponsor's name without Sponsor's prior written consent except that Institution may acknowledge Sponsor's funding of the Sponsored Research and any scientific contributions in scientific publications, in listings of sponsored research projects and for other academic purposes. Sponsor shall not use Institution's name, mark or symbol, or the name of any trustee, officer, faculty member, student or employee thereof, without Institution's prior written consent, except as required by applicable laws or as expressly consented under the License Agreement and/or under the Collaboration Agreement.

7 REPRESENTATIONS, WARRANTIES AND COVENANTS

7.1 Institution shall comply with all laws, regulations and other legal requirements applicable in connection with the performance of the Sponsored Research, including but not limited to any legal requirements related to the use of animals in the Sponsored Research and use of cell lines, tissue, human clinical isolates or similar human-derived materials.

7.2 Institution makes no warranties, express or implied, as to (i) the completion, success or particular results of the Sponsored Research, or (ii) the condition, merchantability, or fitness for a particular purpose of the Research Results, or (iii) the fact that Institution Inventions will be generated in the performance of the Sponsored Research.

8 TERM AND TERMINATION

8.1 Unless earlier terminated in accordance with its terms, the Sponsored Research shall begin on the Effective Date and shall end upon the earlier of (a) the date of completion of all activities relating to the Sponsored Research 1 and Sponsored Research 2, as set forth in the Research Plans related to RP 1 and RP2 and (b) 31 December 2022 (unless the Parties mutually agree upon an extension of the Sponsored Research term). This Agreement shall be effective upon the Effective Date and shall expire upon the date of expiry of the Negotiation Period (or upon the expiry of the Option Period in the event that no option is exercised during such Option Period); the term of this Agreement is referred to as the "**Term**".

8.2 Either Party may terminate this Agreement effective upon written notice to the other Party, if the other Party breaches any of the terms or conditions of this Agreement and fails to cure such breach within thirty (30) days after receiving written notice thereof.

8.3 Sponsor may terminate this Agreement for any reason or for no reason upon thirty (30) days' prior written notice to Institution; provided that Sponsor shall not be entitled to send such notice to Institution during the 12 months period from the Effective Date.

8.4 If this Agreement terminates prior to its expiration, Institution shall be entitled to retain the payments made by Sponsor prior to termination; provided that, in the event that such payments are lower than [redacted], Sponsor shall pay to Institution within 30 days from the date of termination the difference between [redacted] and the amounts paid by Sponsor to Institution prior to the date of termination.

8.5 Termination or expiration of this Agreement shall not affect the rights and obligations of the Parties accrued prior to termination or expiration hereof. The provisions of Sections 4.1, 4.2, 5.1, 5.7, 6, 7, 8.4, 9, 10.1 and 10.6 shall survive such termination.

9 GOVERNING LAW AND ARBITRATION

9.1 This Agreement shall be governed by and construed in accordance with the laws of Italy, without regard to the conflicts of law principles thereof.

9.2 Any dispute, controversy or claim initiated by either Party arising out of or relating to this Agreement, its negotiations, execution or interpretation, or the performance by either Party of its obligations under this Agreement (other than (a) any dispute, controversy or claim regarding the validity, enforceability, claim construction or infringement of any patent rights, or defenses to any of the foregoing), shall be finally resolved through arbitration by a panel of three (3) arbitrators appointed under the Rules of the International Court of Arbitration of the International Chamber of Commerce of Paris (the "**Rules**"), which both Parties declare to know and accept. Each Party shall appoint one arbitrator and the two thus-appointed arbitrators shall appoint the third arbitrator, who shall act as chairman of the panel. In case of disagreement, the third arbitrator shall be appointed by the Chairman of the International Chamber of Commerce, in accordance with the provisions of the Rules. Where necessary the Chairman of the International Chamber of Commerce shall also appoint an arbitrator on behalf of the Party that has failed to appoint its arbitrator within the deadline set forth by the Rules. The seat of the arbitration shall be Milan, Italy. Any such arbitration shall be conducted in the Italian language, without prejudice to the Parties right to file documents in the English or other foreign language, along with the relevant certified translation into Italian English or to hear witness in languages other than Italian provided that a simultaneous translation is offered to the panel. Any award issued by the arbitration panel shall binding upon the Parties and the arbitration shall be "rituale" in its nature. The arbitration shall be conducted in accordance with the Rules and the Parties hereby declare that the Emergency Arbitrators Provisions shall not apply between them. The award rendered by the arbitrators may be challenged on the grounds of breach of rules of law (impugnazione per violazione

delle regole di diritto) pursuant to Article 829 (Casi di nullità), third paragraph, of the Italian Code of Civil Procedure.

9.3 Any other dispute which may not be submitted to the arbitration proceeding pursuant to Section 9.2 above, including those relating to injunctive reliefs and provisional and/or urgent measures and payment injunctions (decreto ingiuntivo) shall be devoted to the exclusive jurisdiction of the Court of Milan.

10 MISCELLANEA

10.1 No rights hereunder may be assigned by either Party, directly or by merger or other operation of law, without the express written consent of the other Party; provided that Sponsor may assign this Agreement to an Affiliate and to the sole and limited extent that such Affiliate is assigned also the License Agreement and the Collaboration Agreement. Any prohibited assignment of this Agreement or the rights hereunder shall be null and void. No assignment shall relieve either Party of responsibility for the performance of any obligations which accrued prior to such assignment.

10.2 No change, modification, or addition or amendment to this Agreement (including to the Research Plans attached herewith), or waiver of any term or condition of this Agreement, is valid or enforceable unless in writing and signed and dated by the authorized officers of the Parties to this Agreement.

10.3 A waiver by either Party of a breach or violation of any provision of this Agreement will not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision of this Agreement.

10.4 Nothing herein shall be deemed to establish a relationship of principal and agent between Institution and Sponsor, nor any of their agents or employees, nor shall this Agreement be construed as creating any form of legal association or arrangement which would impose liability upon one Party for the act or failure to act of the other Party. Nothing in this Agreement, express or implied, is intended to confer on any person other than the Parties or their permitted assigns any benefits, rights or remedies.

10.5 All communications hereunder shall be in writing, electronic mail or by confirmed fax, and shall be deemed to have been duly given (a) upon personal delivery, (b) upon deposit with a recognized courier with next-day delivery instructions, (c) one (1) business day after sending, if sent by electronic mail and no delivery failure notification has been received or (d) upon confirmation of transmission, if sent by confirmed fax, to the address or fax number set forth below or such other address or fax number as either Party may specify by notice sent in accordance with this Section 9.5:

If to Institution:

[redacted]

[redacted]

If to Principal Investigators:

[redacted]

If to Sponsor:

[redacted]

10.6 This Agreement shall be construed and governed in accordance with the laws of Italy, without giving effect to conflict of law provisions.

10.7 This Agreement, including the exhibits hereto embody the entire understanding between the Parties relating to the subject matter hereof and supersedes all prior understandings and agreements, whether written or oral. This Agreement may not be varied except by a written document signed by duly authorized representatives of both Parties. Solely for the avoidance of doubt, the activities to be carried out under this Agreement (in accordance with the Research Plan) shall not be regarded as comprised within the definition of Research Activities as set forth in the Collaboration Agreement (which shall not apply to regulate the Research Program 1 and the Research Program 2).

10.8 This Agreement may be executed in more than one counterpart, each of which shall be deemed an original but all such counterparts taken together shall constitute one and the same agreement.

11 ADDITIONAL COVENANT

[redacted]

[redacted]

[Signature Page Follows]

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Agreement as of the Effective Date.

Genenta Science S.r.l.

By: Pierluigi Paracchi Firmato digitalmente da Pierluigi Paracchi Data: 2021.02.11 17:41:12 +01'00'

Name:

Title: CEO

Date:

Ospedale San Raffaele S.r.l.

By:

Name: Elena Bottinelli

Title: CEO

Date: February 12th 2021

Exhibit A

SPONSORED RESEARCH 1

RESEARCH PLAN (years 21-22) - [redacted]

1. **Detecting Temferon-expressing TEMs/myeloid cells in GBM**
   We will investigate the use of RNAscope to detect Temferon-expressing TEMs/myeloid cells in our GBM mouse models. These studies will be first performed on cryo or paraffin-fixed GBM sections using probes specific for mouse Tie2 and the vector DHFR transgene to assess detectability of LVTie2-expressing TEMs in the GBM context (the universal WPRE lentiviral vector probe cannot be used in our main GBM model) (Part A). If satisfactory, further studies will be performed on tumors (including GBM) models grown in immunodeficient mice reconstituted with Temferon-transduced human CD34+ cells and probed with a universal WPRE lentiviral vector probe to assess detection of Temferon-expressing human TEMs in the tumor context (Part B). *Timeline: 6 months for Part a + 12 months for Part B*

2 **Exploring combination between Temferon and GBM-targeting CAR T cells**
   We will explore the synergistic effect of CAR T cells and TEM-mediated IFN-gene therapy in our GBM model taking advantage of 2 GBM-directed CARs, i.e. anti-GD2 and anti-B7H3, rationally selected because: 1) they are undergoing early clinical testing in GBM patients; 2) they cross react with the mouse orthologue target; 3) their target is expressed in our GBM model. Different routes of administration of CAR T cells, e.g. intravenous and intratumor, will be investigated to evaluate recruitment and activity improvements provided by TEM gene therapy in different settings of invasiveness towards the clinical translation.
   In view of an extension of Temferon indications, we can also exploit the broad expression of the 2 identified targets in different tumor types and models to test the combination in other disease settings at the preclinical level. *Timeline: 24 months*

Budget requested
[redacted]

RESEARCH PLAN (years 21-22) [redacted]

Title: Exploratory Endpoints of the Temferon studies towards acquiring additional evidence for biological activity

1. Dosing of IFNa

IFNa dosing in body fluids (including blood, bone marrow and CSF) by ELISA is emerging as an informative test to establish dose-effect relationships, in combination with vector copy number and IFN responsive gene expression assessments (the latter two already being included in the study budget). This budget considers a total of 100 samples per year from the TEM-GBM trial, with an average of 6 samples per patient, including the tests already run during 2019 and 2020.

2. Single cell RNA sequencing and TCR sequencing

Single cell RNA sequencing is rapidly becoming the state-of-the-art for unbiased and comprehensive characterization of complex cell populations, such as those found in tumor microenvironments. Its successful implementation requires advanced technical, bioinformatics and computational skills, all of which have been established at SR-TIGET and in the Gentner laboratory during the past years bringing this revolutionary technology within the reach of Genenta. Cost per sample is [redacted] and comprises sample preparation (purification of subpopulation, death cell removal), 10x library preparation for transcriptome and targeted cell receptor sequencing, next generation sequencing to adequate depth and a basic bioinformatic analysis.

For the TEM-GBM study, we have already sequenced a total of 18 samples, with a request for reimbursal of [redacted] (total cost of [redacted] of materials directly ordered by Genenta)

- GBM01002 second surgery: 7 samples (2x PB baseline, 2x PB post Temferon, 3x tumor infiltrate)
- GBM01006 second surgery: 8 samples (1xPB baseline, 1xPB post Temferon, 3x progressed tumor infiltrate, 3x stable tumor infiltrate, 1x CD45-neg progressed)
- GBM01008 second surgery: 3 samples (2x CD45+ tumor infiltrate, 1x CD45-neg tumor infiltrate)

For the year 2021, we project an additional 20 samples to be subjected to scRNAseq within the TEM-GBM study, as follows. 10 tumor controls (from 3-4 patients that have not received Temferon) and 10 tumors from Temferon patients (from 3 additional second surgeries from patients enrolled in the TEM-GBM study).

For the year 2022, we project an additional 15 samples to be subjected to scRNAseq Samples will be primarily derived from the TEM-GBM trial, with the possibility to assign some analysis slots for a potential third indication.

3. Additional Studies

These include accessory studies in support of single cell RNA sequencing, including but not limited to flow cytometry, exploratory immunohistochemistry/immunfluorescence analysis using new markers detected in single cell analysis, development of Cite-Seq (e.g. with the Tie2 antibody), RNA sequencing analysis of

additional material, e.g. CSF or locally sampled blood from tumor-draining samples, genetic profiling of GBM tumors and cloning of tumor-specific TCRs.

[redacted] Budget summary 2021

Dosing of IFNa in blood, bone marrow and CSF	[redacted]
Already performed scRNAseq/TCR analysis on second surgery samples	[redacted]
New scRNAseq/TCR analysis on TEM-GBM (2021)	[redacted]
Additional studies	[redacted]
Subtotal [redacted] 2021	[redacted]

[redacted] Budget summary 2022

Dosing of IFNa in blood, bone marrow and CSF	[redacted]
scRNAseq/TCR analysis	[redacted]
Additional studies	[redacted]
Subtotal [redacted] 2022	[redacted]
Total budget request 2021	[redacted]
Of which	[redacted]
	[redacted]
Total budget request 2022	[redacted]
Of which	[redacted]
	[redacted]

Exhibit B

Payment Schedule

The overall consideration for the Sponsored Research is equal to [redacted]

Such amount shall be paid by Sponsor to Institution as follows:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

KNOW-HOW LICENSE AGREEMENT

This Know-how License Agreement (the "**Agreement**") is made as of February 02, 2016 (the "**Effective Date**"), between Fondazione Telethon, a non-profit organization headquartered at Via Varese No. 18b, Rome, Italy (the "**Licensor**") and Genenta Science S.r.l., an Italian corporation headquartered at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 08738490963 (the "**Licensee**"). Licensor and Licensee shall be collectively referred to as the "**Parties**" and each severally as a "**Party**".

RECITALS

1. Licensee previously entered into a License Agreement with Ospedale San Raffaele S.r.l., an Italian corporation headquartered at via Olgettina No. 60, 20132, Milan, Italy, Fiscal Code 07636600962, ("**OSR**") in order to license certain intellectual property rights jointly owned by OSR and Licensor (the "**Existing License**").

2. Licensor possesses valuable additional know-how that is necessary or useful for the manufacture of Product (as defined below), and Licensee wishes to obtain a license to such know-how.

3. In consideration of the mutual promises contained in this Agreement, and intending to be legally bound, the Parties agree to the terms and conditions of this Agreement.

ARTICLE 1: DEFINITIONS

1.1. "**Affiliate**" shall mean any corporation in which a Party owns more than 50% of the stock entitled to vote for the election of directors. At such time as a corporation which was an Affiliate ceases being so owned, its status as an Affiliate and its entitlements under this Agreement shall thereupon prospectively cease.

1.2. "**Business Day**" shall mean any day, excluding Saturday, Sunday and any day which shall be in Milan, Italy a day on which banking institutions are not open for their business activity.

1.3. "**CMO**" shall refer to any third party designated to manufacture Product.

1.4. "**Control**" or "**Controlled**" shall mean the Licensor's possession of the ability to grant a license (in its quality as the owner) or sublicense (in its quality as licensee of third party's rights entitled to grant sublicenses consistent with this Agreement) of the rights related to the information reasonably necessary or useful to manufacture the Product without violating the terms of any agreement or arrangement with any third party.

1.5. "**Governmental Authority**" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court, tribunal or other entity), including a regulatory authority.

1.6. "**Product**" shall mean any lentiviral vector regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of any anticancer protein under the control of a Tie2 promoter or interferon under the control of any promoter other than Tie2 for any cancer indication.

1.7. "**Licensed Know-how**" shall mean any information Controlled by Licensor as of the Effective Date that is reasonably necessary or useful to manufacture Product, including the information described Exhibit A to this Agreement.

1.8. "**Territory**" shall mean worldwide.

ARTICLE 2: KNOW-HOW LICENSE

2.1 License Grant. Licensor hereby grants to Licensee a non-exclusive, perpetual, sublicensable (through multiple tiers), royalty-bearing, non-transferrable (except in connection with a permitted assignment of the Agreement in accordance with Section 8.9) license to use the Licensed Know-how to conduct research and to develop, make, have made, use, offer for sale, sell, import and/or export Product in the Territory.

2.2 Sublicense. Licensee shall inform Licensor in writing prior to executing any sublicense agreement, providing indication of the third party sublicensee and of the scope of the sublicense, it being understood that in no case the scope of the sublicense may exceed the scope of this license. This Section 2.2 shall not apply to sublicenses granted to providers engaged by Licensee for the purpose of providing services related to the research, development and/or commercialization of Product.

2.3 Know-How Delivery. Licensor shall use reasonable efforts to deliver to Licensee the Licensed Know-How as soon as reasonably practicable following the Effective Date or upon Licensee's reasonable request.

ARTICLE 3: CONFIDENTIALITY

3.1. Confidential Information. During the term of this Agreement, and for five (5) years following the expiration or termination of this Agreement each Party shall maintain in strict confidence all information of the other Party that is disclosed by the other Party and/or is identified as, or acknowledged to be, confidential at the time of disclosure (the "**Confidential Information**"), and shall not use, disclose or grant the use of the Confidential Information, except on a need-to-know basis to those directors, officers, Affiliates, employees, permitted licensees, permitted assignees and agents, consultants, clinical investigators or contractors, to the extent that such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, each disclosee must be bound by obligations of confidentiality and non-use consistent and at least comparable to those set forth in this Article 3. Each Party shall notify the other Party promptly upon discovery of any unauthorized use or disclosure of the other Party's Confidential Information. Licensee recognizes that the value of the Licensed

Know-How depends on the secrecy of the same. It is therefore understood that the five year term provided under this Section 3.1 does not apply to the Licensed Know-How, which shall be protected in accordance with Articles 98 and 99 of the Legislative Decree 30/2005; Licensee shall maintain secrecy in relation to the Licensed Know-How until it becomes public knowledge.

3.2. Permitted disclosures.

3.2.1 The confidentiality obligations contained in Section 3.1 shall not apply to the extent that:

(a) any receiving Party (the "**Recipient**") is required: (i) to disclose information by law, regulation or order of a Governmental Authority, or (ii) to disclose information to any Governmental Authority for purposes of obtaining approval to test or market Product, provided in either case that the Recipient shall provide prior written notice thereof to the other Party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof; or

(b) the Recipient can demonstrate that: (i) the disclosed information was public knowledge at the time of such disclosure to the Recipient, or thereafter became public knowledge, other than as a result of actions of the Recipient in violation hereof; (ii) the disclosed information was rightfully known by the Recipient (as shown by its written records) prior to the date of disclosure to the Recipient by the other Party hereunder; (iii) the disclosed information was disclosed to the Recipient on an unrestricted basis from a source not under a duty of confidentiality to the other Party; or (iv) the disclosed information was independently developed by the Recipient without use of the Confidential Information disclosed by the other Party.

3.3. Terms of this Agreement. Each Party agrees not to disclose any terms of this Agreement to any third party without the consent of the other Party, except as set forth in Section 3.2.

ARTICLE 4: REPRESENTATIONS AND WARRANTIES

4.1. Mutual Warranties. Each Party is duly authorized to enter into and fully perform this Agreement.

4.2. Additional Licensor's Warranties.

4.2.1 Licensor hereby represents and warrants that as of the Effective Date, Licensor has not received any claim from any third party contesting that the use of the Licensed Know How constitutes a breach of such third party's rights.

4.2.2 Licensor shall in no case be held liable towards Licensee in relation to any claim by any third party which may contest or claim the violation of any intellectual property rights deriving from the use by Licensee or any sublicensee of the Licensed Know How under this Agreement.

4.3. Disclaimer. Except as set expressly set forth in this Agreement, the Licensed Know-How is provided "As-Is", without any warranties of any kind.

ARTICLE 5: PAYMENTS

5.1. Royalty

5.1.1 Royalty Rate. As consideration of the right to use the Licensed Know-how granted in Section 2.1, Licensee shall pay to the Licensor a royalty equal to one percent (1%) of any actual payments (excluding for clarity any sales or value added taxes) to any CMO, executed either by Licensee or any sub-licensee, in consideration for the manufacturing of Product using the Licensed Know-How ("**Royalty**"). The Royalty shall be due in relation to actual payment to CMOs executed by Licensee during the eight (8) years from the Effective Date.

5.1.2 Royalty Payments. The Royalty shall be paid to Licensor within sixty (60) days after the end of each calendar quarter during the term of this Agreement (each a "**Royalty Quarter**"), following receipt of invoice from Licensor. Each such payment shall be accompanied by a written royalty report setting forth the amount of Product manufactured by CMOs on behalf of Licensee or any sublicensee, and the basis of calculation of the Royalty during the Royalty Quarter.

5.1.3 Royalty Audit. Upon the written request of Licensor (but not more than once every twelve (12) months), Licensee shall permit (and undertakes that any sublicensee shall permit) an independent certified public accountant designated by Licensor and reasonably acceptable to Licensee to have access during ordinary business hours to the relevant records of Licensee and of any sublicensee solely as necessary to determine the accuracy of the payment of the Royalty due to Licensor under Section 5.1.1. Such accountant shall not disclose to Licensor any information other than the amount of Royalty due to Licensor under Section 5.1.1. Findings on the accuracy or supposed inaccuracy of such payment shall be disclosed to Licensor by such accountant who shall, at the time of reporting his conclusions to Licensor, supply Licensee with a copy of such findings. If the audit shall determine a discrepancy of more than ten percent (10%) between the royalty reported and that actually due, then the reasonable expense of the audit shall be borne by the Licensee; otherwise, by Licensor.

ARTICLE 6: TERM AND TERMINATION

6.1. Term. This Agreement and the rights and licenses hereunder shall be effective beginning on the Effective Date and shall continue in effect until terminated as set forth in Section 6.2.

6.2. Termination. Either Party may terminate this Agreement upon written notice in the event that the other Party shall have materially breached this Agreement, and such breach is not cured within sixty (60) Business Days after receiving written notice of and providing reasonable details regarding such breach.

6.3. Effect of Termination. Upon termination of the Agreement under Section 6.2, Licensee shall return to Licensor all tangible embodiments of the Licensed Know-How in Licensee's possession and stop making any use of the Licensed Know-How other

than as provided in the following sentence under this Section 6.3. Notwithstanding the above, Licensee shall be permitted to use and/or commercialize any Product made utilizing the Licensed Know-How that was in inventory or in production on the date of such termination.

6.4. Survival. The following provisions shall survive the expiration or termination of this Agreement: Articles 3 and 4, Sections 6.3, 6.4 and Articles 7 and 8.

ARTICLE 7: DISPUTE RESOLUTION

7.1. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of Italy, without regard to the conflicts of law principles thereof.

7.2. Arbitration. Any dispute, controversy or claim initiated by either Party arising out of or relating to this Agreement, its negotiations, execution or interpretation, or the performance by either Party of its obligations under this Agreement (other than (a) any dispute, controversy or claim regarding the validity, enforceability, claim construction or infringement of any patent rights, or defenses to any of the foregoing), shall be finally resolved through arbitration by a panel of 3 (three) arbitrators appointed under the Rules of the International Court of Arbitration of the International Chamber of Commerce (the "**Rules**"), which both Parties declare to know and accept. Each Party shall appoint one arbitrator and the two thus-appointed arbitrators shall appoint the third arbitrator, who shall act as chairman of the panel. In case of disagreement, the third arbitrator shall be appointed by the Chairman of the International Chamber of Commerce, in accordance with the provisions of the Rules. Where necessary the Chairman of the International Chamber of Commerce shall also appoint an arbitrator on behalf of the Party that has failed to appoint its arbitrator within the deadline set forth by the Rules. The seat of the arbitration shall be Milan, Italy. Any such arbitration shall be conducted in the Italian language, without prejudice to the Parties right to file documents in the English or other foreign language, along with the relevant certified translation into Italian English or to hear witness in languages other than Italian provided that a simultaneous translation is offered to the panel. Any award issued by the arbitration panel shall binding upon the Parties and the arbitration shall be "*rituale*" in its nature. The arbitration shall be conducted in accordance with the Rules and the Parties hereby declare that the Emergency Arbitrators Provisions shall not apply between them. The award rendered by the arbitrators may be challenged on the grounds of breach of rules of law (*impugnazione per violazione delle regole di diritto)* pursuant to Article 829 (*Casi di nullità*), third paragraph, of the Italian Code of Civil Procedure.

7.3. Residual Jurisdiction. Any other dispute which may not be submitted to the arbitration proceeding pursuant to Section 7.2 above, including those relating to injunctive reliefs and provisional and/or urgent measures and payment injunctions (*decreto ingiuntivo*) shall be devoted to the exclusive jurisdiction and venue of Tribunal of Milan.

ARTICLE 8: MISCELANEOUS

8.1. Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other Party shall be in writing, delivered by any lawful means to such other Party at its address indicated below (where the Party hereby elect domicile for the purposes of servicing legal pleadings or arbitration requests), or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

(a) If to Licensor, to:

Lucia Faccio

LFaccio@Telethon.it

(b) If to Licensee, to:

Pierluigi Paracchi

pierluigi.paracchi@genenta.com

If personally delivered, such communication shall be deemed delivered upon actual receipt by the "attention" addressee or a person authorized to accept for such addressee; if transmitted by facsimile pursuant to this Section, such communication shall be deemed delivered the next business day after transmission (and sender shall bear the burden of proof of delivery); if sent by overnight courier pursuant to this Section, such communication shall be deemed delivered upon receipt by the "attention" addressee or a person authorized to accept for such addressee; and if sent by mail pursuant to this Section, such communication shall be deemed delivered as of the date of delivery indicated on the receipt issued by the relevant postal service, or, if the addressee fails or refuses to accept delivery, as of the date of such failure or refusal. Either Party may change its address for the purposes of this Agreement by giving notice thereof in accordance with this Section 8.1

8.2. Severability. Each provision contained in this Agreement is declared to constitute a separate and distinct covenant and provision and to be severable from all other separate, distinct covenants and provisions. It is agreed that should any clause, condition or term, or any part thereof, contained in this Agreement be unenforceable or prohibited by law or by any present or future legislation then such clause, condition, term or part thereof, shall be amended, and is hereby amended, so as to be in compliance with the said legislation or law but, if such clause, condition or term, or part thereof, cannot be amended so as to be in compliance with the said legislation or law, then such clause, condition, term or part thereof is severed from this Agreement and all the rest of the clauses, terms and conditions or parts thereof contained in this Agreement shall remain unimpaired.

8.3. No Amendment. This Agreement may not be amended or modified otherwise than by a written agreement executed by the Parties hereto or their respective successors and legal representatives.

8.4. Waiver. No waiver of a breach of any provision of this Agreement shall be deemed to be, or shall constitute, a waiver of a breach of any other provision of this Agreement, whether or not similar, nor shall such waiver constitute a continuing waiver of such breach unless otherwise expressly provided in such waiver.

8.5. Headings. The headings in this Agreement are inserted for convenience only and shall not constitute a part hereof.

8.6. Counterparts/Facsimiles. This Agreement may be executed in one or more counterparts, all of which taken together shall be deemed one original. Facsimile signatures shall be deemed original.

8.7. Recitals. The recitals to this Agreement are true and correct and are made a part of this Agreement.

8.8. Entire Agreement. This Agreement sets forth the complete agreement of the Parties concerning the subject matter hereof. No claimed oral agreement in respect thereto shall be considered as any part hereof. No waiver of or change in any of the terms hereof subsequent to the execution hereof claimed to have been made by any representative of either Party shall have any force or effect unless in writing, signed by duly authorized representatives of the Parties.

8.9. Assignment. This Agreement is not assignable by either Party without the prior written consent of the other Party (not to be unreasonably withheld or delayed), except that either Party may assign this Agreement without the consent of the other to any Affiliate, or to any successor (whether by merger, reorganization or sale of equity securities) of, or purchaser of a substantial part of, the assets of its business to which this Agreement pertains. This Agreement shall be binding upon and inure to the benefit of any successor or assignee of either Party.

8.10. NO CONSEQUENTIAL DAMAGES. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

In witness whereof, the Parties have executed this Agreement effective as of the Effective Date.

Fondazione Telethon

By: _____

Name: Francesca Pasinelli

Title: General Director

Genenta Science S.r.l.

By: _____

Name: Pierluigi Paracchi

Title: Chairman & CEO

Exhibit A

Licensed Know-How

A set of methods and processes for lentiviral based gene therapy, as described in more detail in separate documentation that will be provided by Telethon to Genenta by March 18, 2016. Such documentation is hereby incorporated by reference into the Know-How License Agreement.

MASTER SERVICE AGREEMENT

THIS MASTER SERVICE AGREEMENT ("**Agreement**") is made on the 6th day of March 2019

BETWEEN

MOLECULAR MEDICINE (MOLMED) S.p.A., a Company incorporated and existing under Italian law, with registered offices at via Olgettina 58, Milano, VAT registration number 11887610159, represented by Riccardo Palmisano, acting in his capacity as Chief Executive Officer (hereinafter referred to as "**MOLMED**");

AND

Genenta Science s.r.l., a Company incorporated and existing under Italian law, with registered offices at via Olgettina 58, Milano, recorded at the Companies' Register of Milan at No. 07636600962, such number also constituting its Italian Taxpayer Identification Number ("Codice Fiscale") and VAT registration number ("partita IVA"), represented by Pierluigi Paracchi, acting in his capacity as Chief Executive Officer (hereinafter referred to as "**CLIENT**");

(each hereinafter referred to individually as a "**Party**" and collectively as "the **Parties**").

RECITALS

(A) MOLMED is a pharmaceutical and biotechnology Company publicly listed at the Milan Stock Exchange, active inter alia in the development and manufacturing of viral vectors, cell products and materials for advanced therapy, and operated in compliance with applicable Good Manufacturing Practice (GMP) requirements;

(B) MOLMED, holds, inter alia, (i) know-how for the research, development and production of GMPs of cellular banks, retroviral and lentiviral vectors; (ii) know-how for control strategies (analytical methods) in cell and cell therapy and in the development and validation of analytical methods for characterization, release and stability of products to be used in cell and cell therapy, iii) know-how for the engineering of human cells, including mononuclear cells and stem cells, using retroviral and lentiviral vectors;

(C) CLIENT is a biotech company engaged in research and development projects for the treatment of hematologic malignancies and solid tumors;

(D) on the 12th of November 2018 AIFA approved the clinical trial application submitted by the CLIENT under EUDRA-CT no. 2018-001741-14; on the 26th of September 2018 AIFA approved the clinical trial application submitted by the CLIENT under EUDRA-CT no. 2018-001404-11;

(E) the CLIENT obtained a non-exclusive license for the use of certain specific know-how on manufacturing processes from Fondazione Telethon ("*a set of methods and processes for lentiviral-based gene therapy*") for the production of certain lentiviral vectors (herein after "**Telethon License**");

(F) on 22 March 2018, the Parties entered into a service agreement (contratto quadro di servizi) pursuant to which the CLIENT engaged MOLMED to perform the following activities: i) development and validation of production methods and analytical methods; ii) preparation and updating of the regulatory documentation needed to obtain authorization from regulatory authorities to initiate clinical trials; iii) manufacturing of GMP viral vectors (hereinafter the "**Development Agreement**");

(G) in accordance with Clause 10 of the Development Agreement CLIENT is willing to entrust MOLMED with, and MOLMED agrees to, perform the manufacturing of Advanced Therapy Medicinal Products (ATMP) for CLIENT, from time to time upon execution of a Production Agreement, for treatment of the applicable CLIENT Indication (as defined below).

NOW, THEREFORE, IT IS HEREBY AGREED as follows:

1. DEFINITIONS

In this Agreement, unless otherwise expressly provided, the following terms shall have meanings ascribed to them below:

"**Affiliates**" means: (i) an organisation, which directly or indirectly controls either Party; or (ii) an organisation which is directly or indirectly controlled by either Party; or (iii) an organisation, which is controlled, directly or indirectly, by the ultimate parent company of either Party. The term "control" as used herein means the possession of the power to direct or cause the direction of the management and the policies of an entity, whether through the ownership of a majority of the outstanding voting security or by contract or otherwise;

"**Availability Notice**" shall mean the notice provided by MOLMED in writing to CLIENT, stating that the Product has been Released in accordance with the Agreement and is ready for delivery and collection;

"**CLIENT Indication**" means the indication (whether haematological malignancy or solid tumor) set forth in the applicable Production Agreement;

"**CLIENT IP**" means any Intellectual Property owned or controlled by CLIENT, which is disclosed or otherwise supplied by CLIENT to MOLMED for the Activities.

"**CLIENT Know How**" means any Know How owned or controlled by CLIENT, including the Know How licensed under the Telethon License, which is disclosed or otherwise supplied by CLIENT (or Telethon, as applicable, including prior to the Effective Date) to MOLMED for the Activities;

"**CLIENT Materials**" means all reagents, human biological samples or other biotechnological components provided by CLIENT to MOLMED, as defined in each Production Agreement;

"**Confidential Information**" means the terms of this Agreement and any and all non-public IP, Know How, MOLMED IP, MOLMED Know how, CLIENT IP, CLIENT Know how, information, data, designs, memoranda, models, prototypes, and/or other material whether of scientific, technical, commercial, financial or other nature, furnished to or obtained by a Party from another Party under this Agreement in written, oral or other tangible form clearly marked or designated as "Confidential" or by words of similar meaning, or that a reasonable person under the circumstances would understand to be confidential;

"**Critical Material**" means the materials identified in the Production Agreement and used in the manufacture of any Product;

"**Deliverables**" means the final Product and related documents to be produced and delivered by MOLMED as specified in the Production Agreement;

"**Effective Date**" means the date first written above;

"**Intellectual Property**" **or** "**IP**" means all intellectual property rights, including without limitation patents, copyrights and registered designs in all countries of the world arising under statutory or common law, and whether or not perfected, and any pending applications of the foregoing, it being understood that IP excludes Know How;

"**Know How**" means any non-patented, unregistered confidential method, technique, process, or technology, howsoever denominated;

"**Manufacturing Facilities**" shall mean the qualified and authorized (licensed) GMP facility of MOLMED, where the Product is to be manufactured as set forth in the applicable Production Agreement;

"**Manufacturing Process**" shall mean the process by which the Product is manufactured, as set out in the Investigational Medicinal Product Dossier;

"**MOLMED IP**" means any Intellectual Property owned or controlled by MOLMED, which is disclosed or otherwise supplied by MOLMED for the Activities, or otherwise used by MOLMED in connection with the manufacturing of Product(s) under this Agreement;

"**MOLMED Know How**" means any Know How owned or controlled by MOLMED, which is introduced to or disclosed or otherwise supplied by MOLMED for the Activities, or otherwise used by MOLMED in connection with the manufacturing of Product(s) under this Agreement;

"**Net Sales**" means the gross invoice amount (not including value added taxes, sales taxes, or similar taxes) of Product sold by CLIENT or its sublicensees to the first unrelated third party in a bona fide arms-length transaction after deducting, if not previously deducted, from the amount invoiced or received: (i) trade and quantity discounts off the invoice price, to the extent actually incurred or allowed; (ii) amounts actually credited or allowed for rejections or returns of Product; (iii) all rebates, chargebacks, retroactive price reductions and other sales allowances that are actually allowed or granted, including rebates, reductions and allowances mandated by government; (iv) early payment cash discounts, (v) insurance, customs charges, freight, postage, shipping, handling, and other transportation costs incurred by the applicable selling party in shipping Product to a third party. In the case of any sale which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time all revenue recognition criteria are met. Any nominal consideration received in exchange for the transfer of Products for use in clinical trials, sampling or promotional use, in each case at or below cost, shall not be included in Net Sales;

"**Non- Conforming Batch**" shall mean a batch of Product which is not compliant, or which has not been manufactured in compliance, with the Safety Specifications and/or (if applicable) GMP requirements;

"**Partner**" shall mean a company or other party which has entered into an agreement with CLIENT to develop, market and/or sell the Product;

"**Personnel**" means the representatives, agents, independent contractors, sub-contractors and employees appointed by each Party for the performance of its obligations under this Agreement and/or the applicable Production Agreement;

"**Primary Release**" means with respect to a Product batch, that such batch meets the specifications required under the first panel of testing as defined in the relevant Production Agreement;

"**Product**" shall mean Frozen autologous CD34+ Haematopoietic Stem and Progenitor Cells (HSPC) genetically modified with the lentiviral vector TEMFERON, carrying transgene encoding for the human interferon-α2, Tie2 enhancer/promoter and miRNA-126 target sequences;

"**Production Agreement**" shall mean a document setting forth the terms and conditions for the manufacturing and supply of the Product by MOLMED for each Client Indication. Production Agreement No. 1 is attached as **Annex A** hereto; Each Production Agreement will contain, without limitation, any relevant information such as definition of Product, Client Indication/s, Deliverables, and Manufacturing Facility;

"**Quality Agreement**" means the agreement that sets forth each Party's obligations with respect to the conduct of quality assurance procedures in relation to GMP production and testing and in compliance with the defined quality standards, as specified in Article 8 below;

"**Safety Specifications**" means the specifications marked as "Safety" in the Product Specification File (PSF), (for clarity the Safety Specifications include sterility, microbiological control, and mycoplasma specifications);

"**Secondary Release**" means, with respect to a Product batch, that such batch meets the Specifications;

"**Specifications**" shall mean the specifications for the Product as set out in the PSF;

"**Technical Agreement**" shall mean the agreement, to be signed between the Parties within 2 months from the Effective Date, to regulate the chain of custody of the CLIENT Material and derivates;

"**Term**" means the period referred to in Clause 4 below.

2. APPOINTMENT

2.1 This Agreement sets forth the terms and conditions under which:

i) The CLIENT will engage MOLMED to perform i) the preparatory activities for the GMP manufacturing campaign and ii) the manufacturing services, as set forth in the relevant Production Agreement (the "**Services**");

ii) MOLMED will perform the Services and timely perform the Primary Release and Secondary Release of the Product, provided that the CLIENT has timely supplied MOLMED with the CLIENT Material;

iii) CLIENT will purchase from MOLMED all of its requirements of Product for CLIENT's Phase I/II clinical trial in any CLIENT Indication.

2.2 Prior to the commencement of any Services, the Parties shall mutually agree on a Production Agreement.

2.3 Each and every time the CLIENT is willing to entrust MOLMED with the performance of the Services, the CLIENT shall submit to MOLMED a purchase order based on the format attached as **Annex B** and MOLMED shall promptly accept such purchase order.

2.4 CLIENT shall, within ten (10) business days after the Effective Date and thereafter no later than the fifth (5th) business day of each month, provide MOLMED with (or with access to) a rolling manufacturing forecast of Product batches for the following twelve (12) months, or such shorter period as may then remain under the Term (the "**Forecast**"). The Forecast shall show estimates and required delivery timings of required Products for each month during the twelve (12) month period covered by the Forecast based on CLIENT 's assumptions as to likely demand for the Product.

2.5 As soon as reasonably practicable following receipt of each Forecast (and in any case within ten (10) business days from the receipt of the Forecast), MOLMED shall accept the Forecast or suggest alternative manufacturing slots, Redacted

2.6 No later than Redacted before the manufacturing date set forth in the Forecast, the CLIENT shall be obliged to submit a purchase order to MOLMED for the relevant forecasted quantities of Product and, if the CLIENT fails to do so, the relevant slot reservations shall be deemed to be deleted. Notwithstanding the foregoing, for the first Redacted

2.7 MOLMED will periodically keep CLIENT informed and promptly answer all questions reasonably raised by CLIENT regarding the progress of the Services.

2.8 MOLMED shall perform the Services in accordance with:

(a) all applicable laws;
(b) the approval granted by relevant competent Authorities as applicable; and
(c) the provisions of the Production Agreement and Quality Agreement.

MOLMED shall promptly notify CLIENT in the event any of the approvals mentioned in the preceding sub-Clause (b) have been modified, suspended or revoked, and in case of any other breach of this Clause 2.8.

2.9 The Parties shall each appoint a dedicated representative to supervise the conduct of the Services.

3. ADDITIONAL INDICATIONS

3.1 If, at any time during the Term, CLIENT requires MOLMED to conduct the Activities in relation to any indication not already covered under any Production Agreement, CLIENT shall notify MOLMED in writing. The Parties shall discuss and agree in good faith whether or not to enter into a Production Agreement with respect to that indication. For the avoidance of doubt, upon execution of such Production Agreement, the relevant indication shall be deemed to be a CLIENT Indication for the purposes of this Agreement.

4. PERIOD OF PERFORMANCE

This Agreement shall come into force on the Effective Date and shall remain in force for a period of five (5) years unless earlier terminated in accordance with the terms of this Agreement.

5. ACCESS TO MANUFACTURING FACILITIES FOR ACTIVITIES

5.1 Once per year (except for "for cause" audits, which shall not be subject to the foregoing limitation), MOLMED shall grant CLIENT and its Personnel access to the Manufacturing Facilities exclusively for the purpose of (i) making quality audits of the Manufacturing Facilities and of the procedures and processes used by MOLMED in the manufacture of the Product; provided that (ii) a representative of MOLMED is permitted to be present during such visit and (iii) the audit is conducted during normal business hours at a time on which the Parties have mutually agreed and upon prior reasonable written notice in any case not less than sixty (60) days specifying the subject matter of the audit, in accordance with the terms and conditions of this Agreement and the Quality Agreement.

5.2 Notwithstanding the foregoing, MOMED shall allow CLIENT to access, in accordance with the process set forth in Section 5.1, the Manufacturing Facilities in the event that:

(i) a deviations from the Safety Specifications, generating batch rejection,might arise;
(ii) CLIENT has reasonable grounds to suspect that MOLMED is in material breach of any obligations under this Agreement; in such event, CLIENT shall be allowed to conduct an additional audit solely in respect to the suspected breach. It remains understood that CLIENT shall provide to MOLMED written notice thereof, which shall contain a reasonably documented explanation of such grounds seven (7) days before the date of inspection.

5.3 CLIENT shall inform MOLMED of a list of its personnel who will be involved in the audit and therefore require access to the facility.

6. CLIENT MATERIALS; DELIVERY

6.1 In order to enable MOLMED to properly discharge its duties as manufacturer of the Deliverables, CLIENT shall timely provide MOLMED with (i) any CLIENT Materials that the relevant Production Agreement requires CLIENT to supply to MOLMED, and (ii) adequate documentation, as well as specifications and any useful information regarding any CLIENT Materials as described in the Quality Agreement.

6.2 CLIENT shall deliver for free the CLIENT Materials, if any, to MOLMED Manufacturing Facility, in accordance with the terms of each Production Agreement and Quality Agreement. MOLMED shall take all reasonable measures and precautions to ensure the security of the CLIENT Materials.

6.3 Upon completion of the manufacturing process of each batch, the CLIENT shall notify MOLMED if the CLIENT is interested in any unused CLIENT Material and/or derivatives in accordance with the condition set forth in the Technical Agreement. It is understood that the CLIENT shall be responsible for arranging for the shipment of such CLIENT Material and/or derivatives at its cost. In the event of failure by CLIENT to provide such notice, MOLMED shall destroy such CLIENT Material and/or derivatives at CLIENT cost.

7. DELIVERABLES

7.1 Title and risk in Deliverables shall pass to CLIENT upon Primary Release in accordance with this Agreement and delivery to CLIENT in accordance with Clause 7.3.
Except as set forth below, the Deliverables shall be deemed to be accepted by CLIENT, unless CLIENT provides a reasonably detailed notice in writing of any alleged defect to MOLMED within fifteen (15) days from the Secondary Release. Acceptance covers all defects which CLIENT could reasonably be expected to discover in the within fifteen (15) days following the Secondary Release when carrying out a reasonable review of the documentation included in the Deliverables. The Parties acknowledge and agree that that the nature of the Product means that the transfer of the Product to the relevant patient may take place at the time of Primary Release, when a full analysis of the Product has not been completed and only those parts of the testing specified in the Production Agreement will have been conducted. It is clearly understood by the Parties that MolMed is not involved in any clinical decision relating to the use of Product or in the selection of patients for treatment by means of Product.

7.2 MOLMED shall, unless CLIENT instructs otherwise in writing, store the Products free of charge for thirty (30) days after Secondary Release. Storage of any Products not collected by that date shall be governed by a storage agreement to be signed between the Parties within 60 days from the Effective Date.

7.3 In the absence of any written agreement to the contrary, delivery of the relevant Deliverables to CLIENT will be made Ex Works MOLMED Manufacturing Facilities (Incoterms 2010). The Product shall be collected by CLIENT at the MOLMED Manufacturing Facilities during normal business hours (Monday to Friday, excluding statutory holidays). Any different delivery term agreed upon between the Parties may regulate the passing of title but shall not prejudice the passing of risk from MOLMED to CLIENT, which will at all times remain Ex Works MOLMED Manufacturing Facilities.

8. QUALITY MATTERS

As soon as possible following execution of this Agreement, and in any case prior to commencement of any GMP activity, the Parties shall execute the Quality Agreement. Upon execution, the Quality Agreement shall be deemed incorporated into this Agreement.

9. REJECTION, REPAIR AND REPLACEMENT OF PRODUCT

9.1 If it is ascertained that a batch of Product is a Non-Conforming Batch, MOLMED shall promptly notify that it is unable to perform the Primary Release or the Secondary Release of the batch. In such case:

- if the non-conformance arose other than as a result of MOLMED negligence or willful misconduct: (i) MOLMED shall provide CLIENT with written evidence (which will include i) the out of specification description, ii) the investigation performed by MOLMED and iii) MOLMED conclusion) that the Non-Conforming Batch is not attributable to MOLMED negligence or willful misconduct and (ii) following receipt of such evidence, the CLIENT shall be obliged to make the

payment in full, and (iii) If CLIENT wishes MOLMED to carry out additional work, including the rework or reprocessing of the Non-Conforming Batch or further manufacture MOLMED shall, as soon as reasonably possible, carry out such work at a commercially reasonable, mutually agreeable price.

- if the non-conformance arose as a result of MOLMED negligence or willful misconduct, as soon as reasonably practice MOLMED shall at CLIENT's option, either: (i) rework or reprocess the Non-Conforming Batch in accordance with GMP; or (ii)manufacture a further Batch, in each case at MOLMED's cost and expense.

9.2 In the event of any disagreement between the Parties as to whether a batch is a conforming batch or a Non-Conforming Batch and/or whether a Non-Conforming Batch is a result of a MOLMED negligence or willful misconduct, the Parties shall use reasonable efforts to resolve the matter promptly. In the event that a resolution cannot be reached, any relevant documentation shall be submitted for review to an independent expert mutually agreed upon by the Parties or, failing agreement on a common identification, by an expert chosen by the Milan Chamber of Arbitration. The costs associated with such review and the other costs and fees of the independent expert shall be borne by the Party which was incorrect about whether the GMP batch is a conforming batch or Non-Conforming Batch or whether a Non-Conforming Batch is a result of a MOLMED negligence or willful misconduct.

10. FINANCIAL CONSIDERATIONS

10.1 In consideration of due performance of the services set forth in this Agreement and the applicable Production Agreement, CLIENT agrees to pay MOLMED the amounts set forth in **Annex C**. Payments are exclusive of Value Added Tax, which shall be paid at the applicable rate. All the prices are in EURO.

10.2 With effect from each anniversary date of the Effective Date, MOLMED shall be entitled to revise each price the price according to the Consumer Price Index inflation rate published by ISTAT (Italian National Institute of Statistics). In addition to, the Parties shall meet at least once per year to evaluate if there are any significant changes to the processor analytics or regulatory requirements that should result in any change to each price set out in paragraph 10.1.

10.3 Redacted

10.4

10.5

10.6 Invoices shall be sent to:

Company: Genenta Science
Address: Via Olgettina 58
Name: Pierluigi Paracchi
Title: CEO
Email: Pierluigi.paracchi@genenta.com
Tel.: 02 / 2643 5125
Unique Code for Electronic Invoice: BA6ET11

Payment shall be made by wire transfer to the following bank account:
Bank Name: Redacted
Bank Address:
Account Number:

IBAN: Redacted

10.7 Without prejudice to other remedies, if CLIENT does not pay any undisputed sum of money when it falls due, MOLMED shall, following prior written notice to CLIENT, be entitled to interest upon that sum. The level of interest for late payment shall be at the rate of two percent (2%) per year.

10.8 If any invoice is not paid within thirty (30) days of the sum becoming due, MOLMED shall be entitled to immediately suspend its services, upon notice to CLIENT by registered letter.

10.9 The CLIENT may change or cancel any purchase order (including changing the required delivery date) at any time in writing to MOLMED provided that the CLIENT shall pay to MOLMED a fee equal to *** of the total amount payable pursuant to each purchase order in the following cases: (i) if the CLIENT changes or cancels the purchase order/s submitted for the manufacture of the first three batches of Product less than *** the manufacture (as stated in the Forecast) or (ii) if CLIENT changes or cancels any following purchase orders less than *** prior to the date of the manufacture (as stated in the Forecast). In addition, in the foregoing cases, CLIENT shall reimburse MOLMED the costs incurred in the purchase of Critical Materials that MOLMED can evidence in writing that it has incurred with respect to that purchase order (MOLMED having used reasonable endeavors to mitigate those expenses including where possible allocating any Critical Materials to other purchase orders including any third party purchase orders), it being understood that in no event shall CLIENT be liable for any amount in excess of one hundred percent (100%) of the total amount payable pursuant to CLIENT purchase order

Redacted

10.10 Milestone and royalty payment. Conditioned upon MOLMED having supplied conforming Product in accordance with this Agreement in sufficient quantities for CLIENT (or a Partner, if applicable) to successfully complete CLIENT's Phase I/II clinical trial, CLIENT shall pay to MOLMED the following amounts:

Redacted

Twice per year, by the end of June and the end of December,the CLIENT shall submit to MOLMED a report providing an accounting of the Net Sales of Product during such six months period, and the calculation of royalties due under this Clause 10.10 (the "**Report**").

The CLIENT shall pay to MOLMED the royalties payable by it under this Clause 10.10, as indicated in the Report delivered by the end of December, within thirty (30) days of the issuance of the relevant invoice.

Redacted

Audits. During the term of this Agreement and for a period of three (3) years thereafter, the CLIENT shall keep, and shall cause its Partner to keep, complete accurate and up-to-date books and records (the "**Records**") relating to the sales of the Product as to enable the Net Sales thresholds hereunder to be determined. Upon the written request of MOLMED with at least 30 (thirty) days prior written notice and not more than once in each calendar year, the CLIENT shall permit, and shall require its Partner to permit MolMed to have access during normal business hours to the Records. MOLMED shall bear any costs incurred for the purposes of exercising its audits and/or inspections rights (the "**Audit Costs**"). Should, however, any audit or inspection reveal a non-compliance to this Agreement by the CLIENT, without prejudice to any further remedy under this Agreement or at law, the CLIENT shall bear the Audit Costs and refund them to MolMed, together with the amount of any underpayment of royalties due to MolMed for the applicable accounting period, within thirty (30) days from written request by the latter.

10.11 Technology transfer fee. Once MOLMED has supplied the Product in any CLIENT Indication for Phase I/II clinical trial as set forth in the first Production Agreement (or in case of MOLMED's failure to supply such Product as set forth in the first Production Agreement), CLIENT may elect to have MOLMED proceed with a technology transfer of the Manufacturing Process (including any MOLMED's IP and MOLMED Know How necessary or useful to practice such Manufacturing Process) from MOLMED to CLIENT, a Partner or another manufacturer, in which case:

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The Parties acknowledge and agree that Clauses 10.10 and 10.11 of this Agreement supersede in its entirety Clause 10 of the Development Agreement.

11. CONFIDENTIALITY

11.1 Each Party agrees, for the Term of the Agreement and for a period of ten (10) years from the end of the Term, to treat the Confidential Information of the other Party as strictly confidential and not to disclose it to any third party for any purpose whatsoever and not make use of the Confidential Information or any part thereof other than for the performance of the Activities and to treat it with at least the same care and in the same manner as its own secret and valuable information. The receiving Party agrees to allow access to the Confidential Information exclusively to those of its directors, officers, advisors, counsels, auditors, representatives and employees (collectively the "**Representatives**"), who have a reasonable need to know about the Confidential Information, for performance of the Activities, who are informed of the confidential nature of the information and who have agreed to abide by the terms of this Agreement. The receiving Party shall ensure that its employees to whom Confidential Information is disclosed keep such information confidential to the extent and as long as the receiving Party is bound by this Agreement.

11.2 The provisions of Clause 11.1 above shall not apply to any:

- information which is or was already known to the receiving Party at time of disclosure to it, or
- information which after disclosure to the receiving Party under this Agreement is published or otherwise generally available to the public otherwise than through any act, default or omission by the receiving Party of its obligations hereunder, or
- information which can be established was independently developed by the receiving Party without the use of or reference to the disclosing Party's Confidential Information; or
- information which is required to be disclosed to governmental or regulatory bodies or to a court of competent jurisdiction pursuant to any written law, provided, however, that such disclosure is limited to that required to be disclosed; or
- information which is disclosed to the receiving Party by a third party without restriction and without breach of the confidentiality obligations under this Agreement by the receiving Party.

11.3 CLIENT acknowledges that MOLMED is a listed company on the Italian stock exchange and is therefore subject, among others, to the provisions of the EU Market Abuse Regulation no. 596/2014, the Italian Legislative Decree no. 58 dated February 24th, 1998 (the "Financial Act") and Consob Regulations and official guidance implementing the Financial Act as such provisions related to "inside information" ("informazioni privilegiate") (the "Market Abuse Provisions"). CLIENT undertakes to comply with the provisions set forth in the Market Abuse Provisions to the extent applicable to CLIENT in connection with this Agreement.

11.4 Furthermore, CLIENT agrees that it will, to the extent such dealing is prohibited by applicable law, not use the content of Confidential Information, to deal in any securities of MOLMED or in any derivative products related thereto or to encourage another person or entity so to deal.

11.5 In the case of communication of inside information to third parties who are not bound by a confidentiality agreement, CLIENT undertakes to immediately inform MOLMED.

11.6 CLIENT acknowledges that in the event of dissemination or unauthorized use of inside information, criminal and administrative penalties will apply (included those provided for under Articles 184 of the Financial Act).

11.7 The receiving Party acknowledges that unauthorised disclosure or use of Confidential Information could cause great or irreparable injury to disclosing Party and that pecuniary compensation would not afford adequate relief or it would be extremely difficult to ascertain the amount of compensation which would afford adequate relief. Therefore, the receiving Party agrees that, in the event of such unauthorised disclosure or use of Confidential Information, the disclosing Party will have the right to seek and obtain injunctive relief in addition to any other rights and remedies it may have.

11.8 Except for the disclosure of the existence of this Agreement, which information shall not be deemed confidential, no Party shall disclose the specific terms and conditions of this Agreement without the prior written consent of the other Party, except that each Party may disclose such terms and conditions to its current and prospective investors, lenders, underwriters and acquires (or, in the case of CLIENT, Partners) in connection with due diligence activities subject to a commercially reasonable obligation of confidentiality, further provided that MOLMED may not disclose technical or financial terms of any Production Agreement without CLIENT's prior written consent in each case.

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12. IP AND KNOW HOW

12.1 Nothing in this Agreement shall affect either Party's ownership in its IP and Know How existing as of the Effective Date or developed outside of the scope of this Agreement.

12.2 Subject to this Agreement and the relevant Production Agreement, the CLIENT hereby grants MOLMED a non-exclusive, Royalty-free, non-transferable right and licence, sub-licenseable solely to MOLMED subcontractors, to use the CLIENT IP, CLIENT know how, CLIENT Materials and related Intellectual Property during the term of the relevant Production Agreement and solely for the purposes of the Activities detailed in the relevant Production Agreement.

12.3 If CLIENT elects to transfer the Manufacturing Process under Clause 10.11 MOLMED will grant, and does hereby grant, to CLIENT a worldwide, fully paid-up, perpetual, non-revocable, non-terminable, non-exclusive, sublicensable (through multiple tiers) license to exploit (notwithstanding anything to the contrary in Clause 11) any IP or Know-how (including MOLMED IP, MOLMED Know How) so transferred by MOLMED for the purpose of freely manufacturing and/or having manufactured the Product and any gene therapy based on the combination of transcriptional and microRNA-mediated control to regulate the expression of interferon-α2.

13. NON-EXCLUSIVE COLLABORATION

For the avoidance of doubt, it is agreed that, notwithstanding the terms and conditions of this Agreement and any Production Agreement, but subject in each case to Clause 11 (Confidentiality), MOLMED shall remain free to:

a) conduct any research or development work in any field and indications, whether by itself or in collaboration with any other party, provided however, that for as long as MOLMED is manufacturing or supply Product(s) in any indication(s) under this Agreement, MOLMED may not manufacture or supply any Product for any third party, except for Partners.
b) subject to the preceding sub-clause (a), use or otherwise exploit (including by sub-licensing) MOLMED IP and MOLMED Know-How.

14. REPRESENTATIONS AND WARRANTIES

14.1 Each Party represents and warrants that:

a) it has full capacity to enter into this Agreement and carry out its respective obligations set out in this Agreement; and
b) this Agreement represents valid, legal and binding obligations on it and is fully enforceable in accordance with its terms.
c) it has authority to grant the rights and licences granted to the other Party under this Agreement;
d) it is not a party to any agreement or understanding with any third party which in any way prevents it from fulfilling any of its obligations set out in this Agreement.

14.2 CLIENT represents and warrants that:

a) it is the owner of CLIENT IP and CLIENT Know How or has the right to license CLIENT IP and CLIENT Know How to the other Party for the purposes of this Agreement;
b) any and all CLIENT Materials supplied to MOLMED are fit for their intended use under this Agreement and any Production Agreement, and may be used by MOLMED in accordance with this Agreement without infringing the IP rights of third parties;
c) the CLIENT IP and CLIENT Know How, may, if applicable, be transferred in accordance with Clause 10.11 without infringing the IP rights of third parties.

14.3 MOLMED represents and warrants that:

a) it is the owner of MOLMED IP and MOLMED Know How or has the right to license its MOLMED IP and MOLMED Know How to the other Party for the purposes of this Agreement;
b) the MOLMED IP and MOLMED Know How, may be used and transferred to third parties in accordance with Clause 10.11 and 12.3 without infringing the IP rights of third parties;
c) the Product will be manufactured in accordance with this Agreement and any Production Agreement, and will meet the Safety Specifications.

For the avoidance of doubt, CLIENT, as the regulatory sponsor of the Product, will be solely responsible for verifying that the Specifications for the Product conform with the relevant regulatory documents currently in force.

14.4 Save as expressly set out in this Agreement or in a Production Agreement, MOLMED makes no representation or warranty, express or implied, as to the merchantability or fitness for any purpose or that the use of the Deliverables will not infringe or violate Intellectual Property or any other rights of any third party. Neither Party makes any representation or warranty, express or implied, with respect to its IP or Know How, including without limitation, any warranty of non-infringement of third party rights, accuracy, completeness, quality or fitness for a particular purpose.

14.5 MOLMED shall not be liable for any non-compliance of any Product with the warranties expressly provided in this Agreement to the extent such non-compliance arises directly out of any act or omission of CLIENT or its Personnel including without limitation in the event of any inaccurate instruction, notice, document, or communication originating from the CLIENT.

14.6 Notwithstanding any provision to the contrary in this Agreement, MOLMED shall indemnify and hold harmless CLIENT from and against any third party-claims, liabilities, losses, demands, damages, causes of action of any kind, obligations, costs, judgments, interest and awards (including recoverable legal counsel fees and costs of litigation of the third party), arising out of any breach by MOLMED of any its obligations, representations and warranties; except to the extent that the liability or loss in question resulted from the negligence or willful misconduct of CLIENT or its Personnel, or from any breach by CLIENT of any its obligations, representations or warranties under this Agreement.

14.7 The CLIENT agrees to indemnify and keep indemnified MOLMED from and against any and all any third-party claims, liabilities, losses, demands, damages, causes of action of any kind, obligations, costs, judgments, interest and awards (including recoverable legal counsel fees and costs of litigation of the third party), arising out of: (i) any breach of the representation or warranty made by the CLIENT under this Agreement; (ii) any third party personal injury, illness or death, or loss or damage to third party property arising from the use or sale of the Product manufactured according to and in compliance with the terms of this Agreement; except to the extent that the liability or loss in question resulted from the negligence or willful misconduct of MOLMED, or its Personnel, or from any breach by MOLMED of any its obligations, representations or warranties under this Agreement.

14.8 Except for breach of Clause 11 (Confidentiality), and for the indemnity obligations set forth in Clause 14.6 and/or 14.7, in no event shall any Party be liable to the other Party for any loss of profits, loss of goodwill, loss of use, loss of production or business interruption costs, or any type of indirect, special, consequential or incidental damages arising from any breach of this Agreement, the Quality Agreement or any Production Agreement whether or not the other Party has been advised of the possibility of such damage.

15. COMPLIANCE WITH LAWS

Each Party shall comply with all laws and regulations as well as of any government department or local authority applicable to it, including but not limited to those competent for workplace safety and/or data privacy. Each Party shall indemnify and hold the other Party harmless from and against any loss, damage, cost or expense arising from the Party's failure to comply with the foregoing.

16. HUMAN BIOLOGICAL SAMPLE

16.1 CLIENT shall verify that the consent form used to collect any human biological samples as part of the Client Materials (the "Human Biological Samples") includes appropriate statements informing the donor (and in the case of post mortem Human Biological Samples, supplied with consent provided by or on behalf of the original donor).

16.2 The Human Biological Samples and related data are provided to MOLMED with all the necessary authorizations, licenses and approvals (for example, ethical approval from a research ethics committee or an institutional review board, or as may be otherwise prescribed by) to obtain, collect, store, transfer, use, disclose, import, export and dispose of Human Biological Samples and related data in the Service.

17. USE OF NAMES

After the Effective Date, the Parties are permitted to make an announcement concerning this Agreement in a form to be agreed between them. Upon CLIENT's prior written approval in each case, MOLMED shall be entitled to use the CLIENT's name (in any format) for promotion, publicity, marketing or advertising purpose.

18. TERMINATION

18.1 This Agreement and/or one or more Production Agreement(s) may be terminated by i) CLIENT for convenience on ***** written notice to the other Party ii) MOLMED may terminate this Agreement upon t*** months prior written notice of termination to CLIENT. For clarity MOLMED will continue to provide manufacturing services to CLIENT during this period, and accept new purchase orders from CLIENT as long as the projected date of finalization of MOLMED's tasks under such purchase orders does not exceed such **** period. However, the Parties shall not be entitled to execute any new Production Agreement during any such survival period.

18.2 For the avoidance of doubt, termination of one or more Production Agreement(s) shall not affect the validity of, or result in any termination of, this Agreement.

18.3 Either Party ("**Terminating Party**") may terminate this Agreement immediately upon written notice to the other Party ("**Defaulting Party**") upon the occurrence of any of the following events:

a) the Defaulting Party being in breach of any material term of this Agreement which is either incapable of rectification or if capable of rectification, which is not rectified within sixty (60) days of receipt of notice therefor;

b) if the Defaulting Party:

(i) is unable to pay its debts when due;

(ii) has a receiver, manager, judicial manager or an administrator appointed on behalf of a creditor over all or a substantial part of its assets;

(iii) enters into an arrangement or compromise or convenes a meeting with its creditors;

(iv) being a company, shall pass a resolution to enter into liquidation or the courts shall make an order that the company be compulsorily wound up (other than for the purposes of amalgamation or reconstruction);

(v) suffers any distress or execution levied or enforced in relation to any of its assets; or

(vi) ceases to carry on its business.

Provided that, in the cases set forth in the proceedings under (ii), (iii) (iv), and/or (v) the relevant proceedings have not been dismissed within sixty (60) days.

19. CONSEQUENCE OF TERMINATION

19.1 Upon the expiry of termination of this Agreement for any reason:

a) MOLMED shall:

(i) upon receipt of CLIENT's written notice, cease any and all activities under this Agreement to the extent feasible;

(ii) at CLIENT's request, within thirty (30) days after the effective date of such termination, return all the CLIENT's Confidential Information to CLIENT, provided that the foregoing shall not require MOLMED to access and remove any of CLIENT's Confidential

Information located in any archived back up electronic mail tapes so long as such archived backup electronic mail tapes are not accessible in the ordinary course of business of MOLMED and provided that such archived back-up electronic tapes shall continue to be the Confidential Information of CLIENT and shall remain subject to the terms of Article 11 herein; and

(iii) at CLIENT's request make available all Deliverables and Products (already paid by CLIENT) to CLIENT.

b) CLIENT shall, at MOLMED's written request, within thirty (30) days after the effective date of such termination return or otherwise destroy (at the election of MOLMED) the Confidential Information (including all such documents containing such Confidential Information) of MOLMED, in the CLIENT's possession or control.

The foregoing shall not require CLIENT to access and remove any of MOLMED's Confidential Information located in any archived back up electronic mail tapes so long as such archived backup electronic mail tapes are not accessible in the ordinary course of business of CLIENT and provided that such archived back-up electronic tapes shall continue to be the Confidential Information of MOLMED, and shall remain subject to the terms of Article11 herein.

19.2 In the event of termination by MOLMED for CLIENT's breach or termination by CLIENT under Clause 18.1 of this Agreement or one or more Production Agreement(s), CLIENT shall pay to MOLMED:

a) All amounts due under this Agreement for all activities already duly performed and/or Products for which Secondary Release have been performed by MOLMED, less the amounts already paid;

b) cancellation fees, where applicable, as defined in Clause 10.9; and

c) reasonable costs of MOLMED for archiving the quality management documentation and for returning and/or destruction of Confidential Information and/or CLIENT Materials, and any costs for which, as at the date of termination, MOLMED has already committed and which cannot reasonably be cancelled or mitigated by MOLMED (having used all reasonable endeavors to do so), less any and all upfront amounts already paid by CLIENT under the relevant purchase order.

19.3 In the event of termination of this Agreement by CLIENT for MOLMED's breach, or termination for convenience by MOLMED:

a) CLIENT shall pay to MOLMED all amounts due for Products ordered by CLIENT prior to the effective date of such termination and Products for which Secondary Release have been performed in accordance with this Agreement.

Redacted

19.4 Redacted

19.5 Save as expressly provided herein, termination of this Agreement or any Production Agreement by a Party for any reason shall not affect the rights and obligations of

the Parties which have accrued prior to the effective date of termination of this Agreement or the Production Agreement. Termination of this Agreement or any Production Agreement, however effected, shall not release the Parties from their rights and obligations under Clauses 9 (Rejection, repair and replacement of product); 10 (Financial considerations); 11 (Confidentiality), 14 (Representations and warranties); 19 (Consequences of termination); 22 (Notice); 23 (Governing law); 24 (Dispute resolution) of this Agreement, which have accrued prior to termination.

20. ASSIGNMENT; SUBCONTRACTING

20.1 Save as expressly provided in this Agreement, no Party shall assign this Agreement or otherwise transfer its rights or obligations, or any part thereof, under this Agreement without the prior written consent of the other Parties, provided, however, that each Party may assign this Agreement without consent in case of any merger, acquisition or sale by the assigning Party of substantially all of its assets. In addition, CLIENT may assign this Agreement without consent on an indication-by-indication basis to the applicable Partner. Any assignee shall agree in writing to comply with the terms of this Agreement.

20.2 MOLMED may not subcontract the performance of the Activities to any third party without CLIENT's prior written consent in each case, not to be unreasonably withheld. For the purpose of this Agreement, the following entity shall be considered pre-approved by the CLIENT: Bioreliance Limited.

21. FORCE MAJEURE

21.1 No Party shall be liable for delays in delivery or performance when caused by any of the following which are beyond the actual control of the delayed Party: (i) acts of God, (ii) acts of the public enemy, (iii) acts or failure to act by the other Party, (iv) acts of civil or military authority, (v) governmental priorities, (vi) hurricanes, (vii) earthquakes, (viii) fires, (ix) floods, (x) epidemics or pandemics or disease outbreak, (xi) embargoes, (xii) war, and (xiii) riots (hereinafter referred to as the "Force Majeure Event").

21.2 The respective obligations of a Party hereunder shall be suspended during the time and to the extent that such Party is prevented from complying therewith by a Force Majeure Event provided that such Party shall have given written notice thereof, specifying the nature and details of such event and the probable extent of the delay to the other Parties.

21.3 In case of a Force Majeure Event, the time for performance required by a Party under this Agreement shall be extended for any period during which the performance is prevented by the event. However, the other Parties may terminate this Agreement by notice if such an event prevents performance continuously for more than sixty (60)] days.

22. NOTICES

All requests, notices, approvals consents (collectively and individually referred to as "Notice") to be given under this Agreement shall be in writing and shall be served personally, by facsimile or by pre-paid registered post or courier with return receipt requested to the electronic mail, facsimile number or address of the intended addressee as set out hereunder or to such other address as may be notified to the other Party in writing:

If to CLIENT:

Attn: Pierluigi Paracchi
email: pierluigi.paracchi@genenta.com
Tel: 02 / 2643 5125
Fax: NA
If to MOLMED:

Attn: Luca Alberici

email: luca.alberici@molmed.com
Tel: 02 21277 1
Fax: 02 21277 404

23. GOVERNING LAW

The validity and interpretation of this Agreement shall be governed by the laws of Italy.

24. DISPUTE RESOLUTION

24.1 The Parties agree to attempt to settle any claim or controversy arising out of this Agreement through consultation and negotiation in good faith and spirit of mutual cooperation.

24.2 Any dispute which cannot be resolved by amicable settlement through the process described in Clause 24.1 above shall be submitted to the exclusive jurisdiction of the Courts in Milan, Italy.

24.3 Nothing in Clause 24.2 shall prevent the Parties from seeking equitable relief (including injunctions or requests for specific performance ("esecuzione in forma specifica") from any Court of competent jurisdiction and any purpose where such relief would be warranted under this Agreement.

25. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof. No purported variation of this Agreement shall be effective unless made in writing and signed by both Parties.

26. WAIVER

The failure by either Party at any time to enforce any provision of this Agreement shall not be construed as a waiver of such provision or any other provision hereof. A waiver shall not be effective unless it is in writing.

27. SEVERABILITY

If at any time any provision of this Agreement shall be or shall become illegal, invalid or unenforceable in any respect, the legality, validity and enforceability of the remaining provisions of this Agreement shall not be affected or impaired thereby, and shall continue in force as if such illegal, invalid or unenforceable provision was severed from this Agreement

28. NO PARTNERSHIP OR AGENCY

The Parties are independent contractors and nothing in this Agreement shall be deemed to constitute a partnership or a principal-agent relationship between the Parties nor otherwise entitle a Party to have authority to bind the other Party for any purpose.

29. COUNTERPARTS

This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed to be an original and all of which together shall constitute the same Agreement.

30. VARIATIONS

No variation, amendment or rescission of this Agreement shall bind a Party unless made in writing in the English language and signed by both Parties.

31. RIGHTS OF THIRD PARTIES

Save for indemnitees under and for the purpose of Clauses 14.7 and 14.8, a person or entity not being a party to this Agreement shall have no right to enforce any term of this Agreement, regardless of whether such person or entity has been identified by name, as a member of a class or as answering a particular description. For the avoidance of doubt, nothing in this Clause shall affect the rights of any permitted assignee or transferee of this Agreement.

32. CODE OF ETHICS

32.1 CLIENT acknowledges that MOLMED has adopted a Code of Ethics pursuant to Legislative Decree no. 231/2001. The Code of Ethics is available on MOLMED's website (http://www.MOLMED.com/investors-documents/corporate-governance) in the following section: corporate governance/documents

32.2 By signing the Agreement, the CLIENT declares that it has read the Code of Ethics and Legislative Decree no. 231/2001, has understood the principles contained therein; and agrees to comply with the obligations and principles contained therein.

32.3 The CLIENT hereby agrees to promptly notify MOLMED if, during the Term, it becomes aware of any act or omission conflicting with, or any breach of the principles expressed in the Code of Ethics and/or in the Legislative Decree no. 231/2001.

32.4 Finally, the CLIENT is aware that violation by the CLIENT of the provisions contained in the Code of Ethics and/or the Legislative Decree no. 231/2001 will constitute a breach of the Agreement and will entitle MOLMED to terminate the Agreement with immediate effect, pursuant to article 1454 of Italian Civil Code, without prejudice to compensation for any damages caused to MOLMED.

In witness whereof this Agreement has been entered into on the date stated at the beginning.

Genenta Science S.r.l.

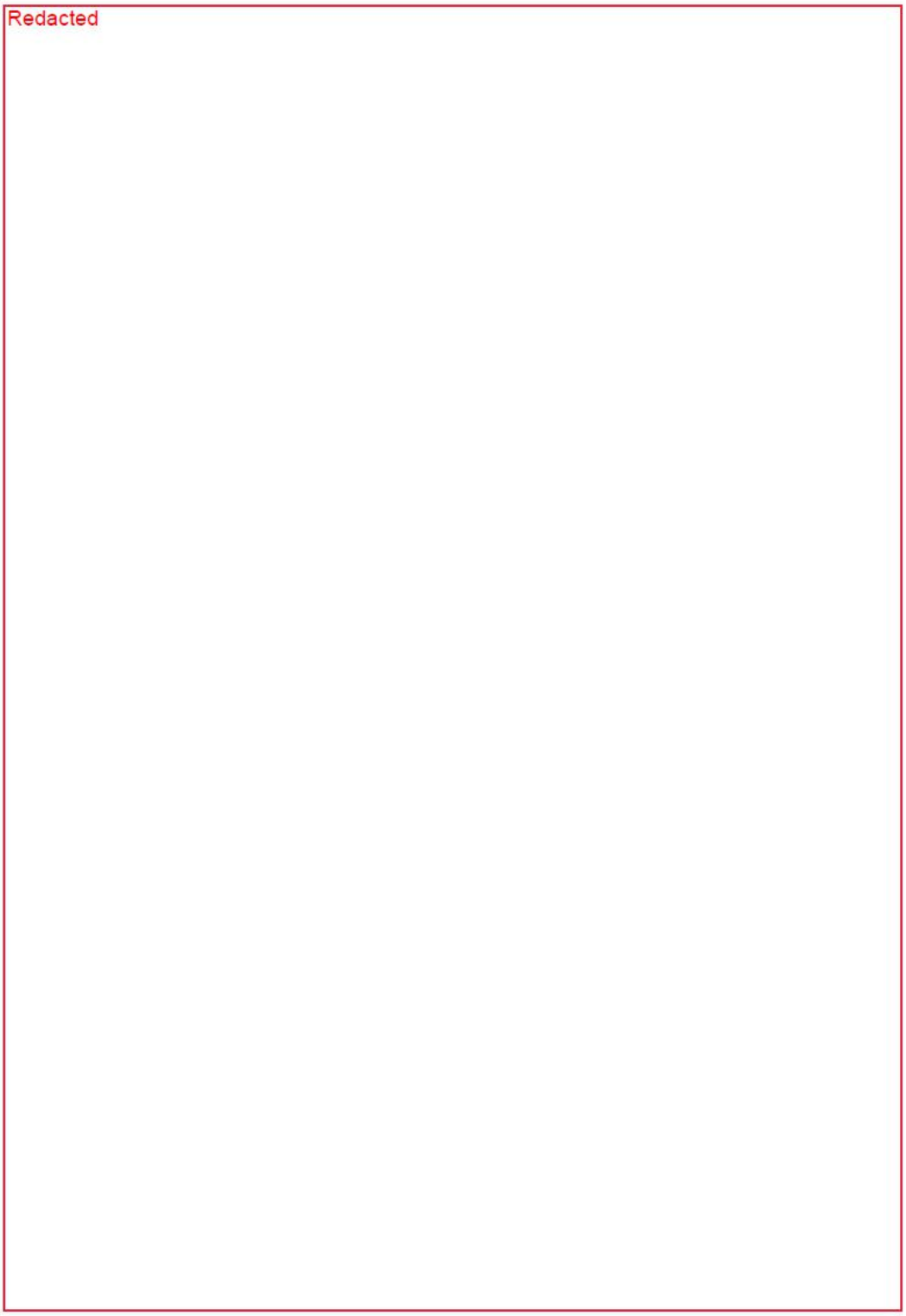
Pierluigi Paracchi
Chief Executive Officer
Date_____

MOLECULAR MEDICINE (MOLMED) S.p.A.

Riccardo Palmisano
Chief Executive Officer
Date 06/03/2019

PRODUCTION AGREEMENT

Redacted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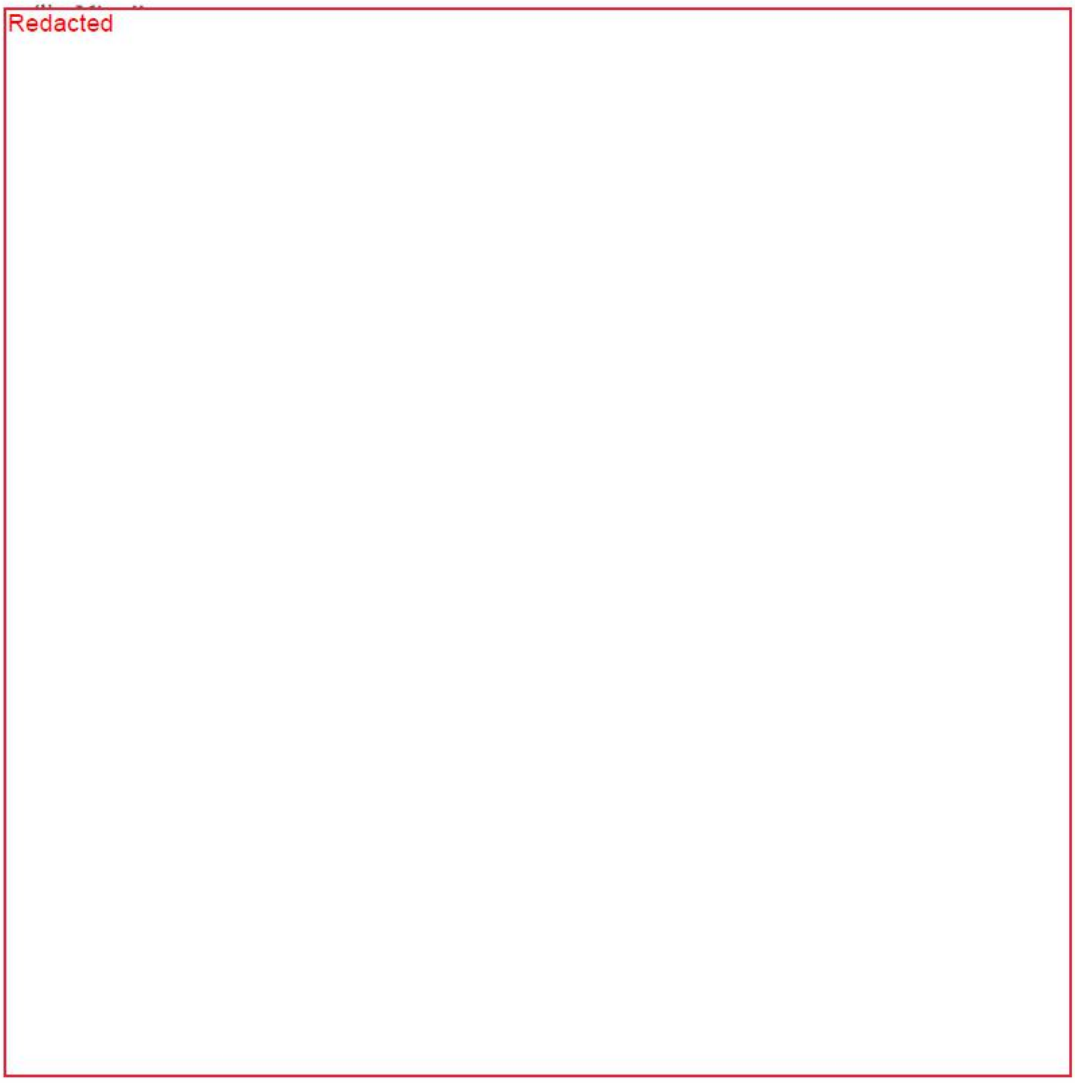
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APPENDIX 1: QC testing panel for Primary release and Secondary release

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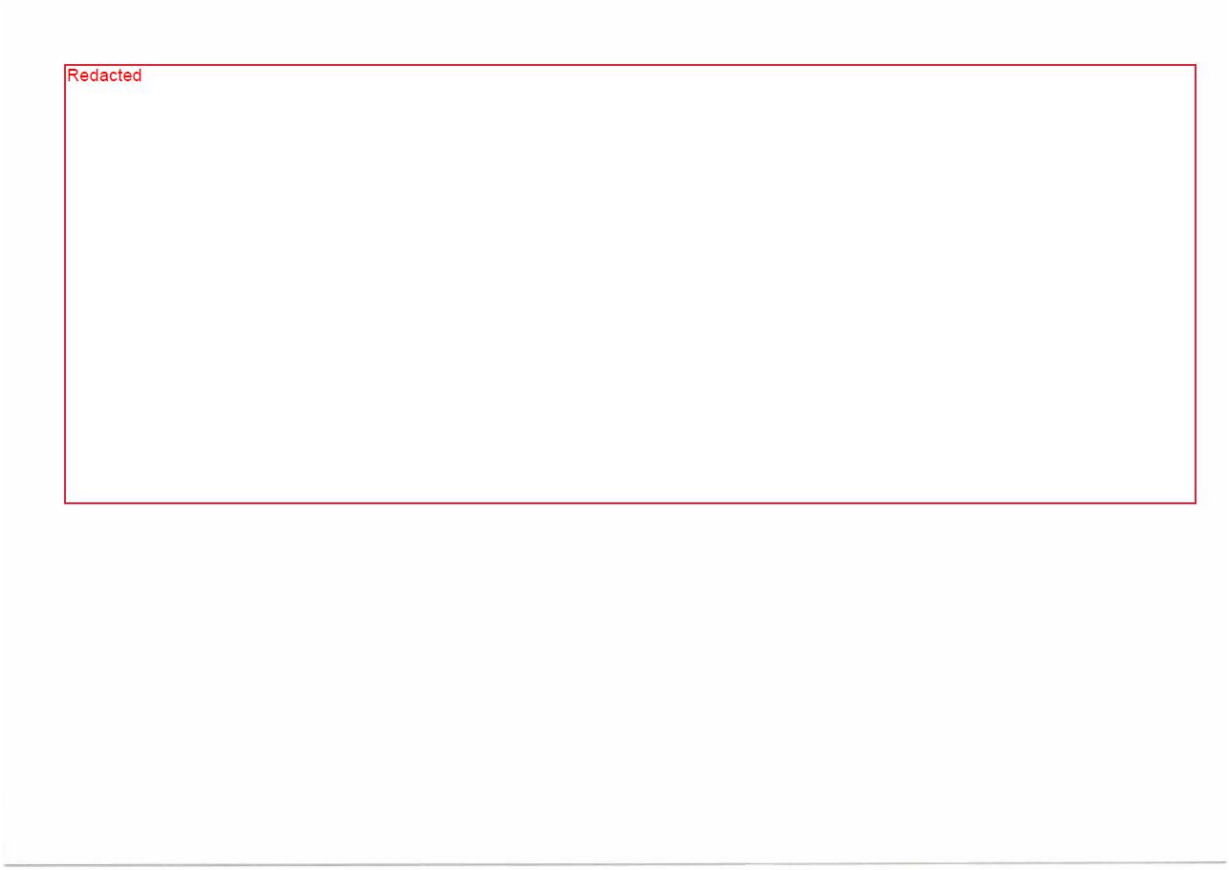
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Annex B- Purchase order form

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Annex C- Financial considerations

Redacted

Exhibit 10.9

Open-ended
employment contract

between

Genenta Science S.r.l., Tax Code and VAT No. 08738490963, with registered offices in Milano, Via Olgettina 58 (the "**Company**"), represented by __ in his capacity as director

and

Mr. Pierluigi Paracchi, Tax Code PRCPLG73E22F 205F, born in Milan on 22 May 1973, resident in Milan, Piazza Maria Adelaide di Savoia 1 ("**Executive**" and, jointly with the Company, the "**Parties**")

The Parties - superseding any previous agreement and/or undertaking even already executed between the Parties, thus including the directorship agreement entered on 18 December 2019, which is terminated by the parties for mutual consent and, however, entirely replaced by this agreement (the "**Agreement**") - agree as follows:

1. TITLE, DUTIES AND OFFICE

1.1 The Executive is employed by the Company from __ 2021 under an open-ended employment contract and he is an executive pursuant to the collective bargaining agreement for the executives of the industrial sector (the "**NCLA**").

1.2 The Executive will perform the duties of "*General Manager*" and shall report exclusively and directly to the Board of Directors of the Company. Notwithstanding the provisions set forth by Article 2103 of the Italian Civil Code, the Company will not have the right to assign to the Executive different and/or less important duties.

1.3 From __ 2021, the Executive will be also appointed as "director" of the Company and he will perform the functions/powers granted by the Board of Directors of the Company.

2. PLACE OF WORK

2.1 The Executive is based at the offices of the Company in Milan, Via Olgettina, 58.

2.2 The Executive will be required to travel extensively both within Italy and abroad in the proper performance of his duties.

3. WORKING TIME

3.1 Given the qualification as "*Dirigente"* and to the provisions set out in the Article 17 of the Legislative Decree 8 April 2003, no. 66, the Executive shall not be subject to working-time limitations and therefore he will not be entitled to any additional compensation for any work carried out outside the normal working-hours.

4. SALARY

4.1 The Executive's gross annual salary will be EUR 420,000.00 (less any statutory tax and social security deductions) payable in accordance with the applicable NCLA and the Company's customary payroll practices. From time to time, the Board of Directors of the Company, at its sole discretion, may review by increasing the above-mentioned salary of the Executive.

4.2 The parties expressly agree that the portion of the salary exceeding the minimum wage provided by the NCLA, is paid to the Executive as "*superminimo assorbibile*" and it is a better treatment granted as unilateral advance on future pay increases which could be established at any title from any source of regulation of the employment relationship. In addition, such "*superminimo assorbibile*" represents the consideration for all the additional undertakings hereunder, including the office indicated under point 1.3 above and all the potential appointments and/or directorship positions which should be assigned to the Executive, as well as the unique terms of performance of the employment relationship.

5. BONUS

5.1 The Company can award the Executive with a variable and discretionary bonus of up to an aggregate gross annual maximum amount up to 20% of the annual gross base salary of the Executive, conditional upon the achievement of pre-determined and reasonable targets, whose amount, terms and conditions will be determined, on the basis of those already indicated in the last years, by the Board of Directors of the Company with a specific notice on an annual basis.

5.2 The bonus will be payable (less any statutory deductions) on a date and in a manner to be determined by the Company.

5.3 Subject to the approval of the Board of Directors of the Company, the Executive will be granted an equity award (the "**Equity Award**") under an equity incentive plan to be adopted by Parent after the IPO (the "**Equity Plan**"). The Equity Award will be subject to the terms and conditions of the Equity Plan.

6. INSURANCE POLICIES AND OTHER BENEFIT

6.1 The Company will enter into, in favour of the Executive:

a) a standard health insurance policy that the Company purchases for its executives;

b) a standard accident insurance policy that ensures the case of permanent disability (total or partial) or death, and the case of occupational disease of the Executive that the Company purchases for its executives;

c) a standard D&O insurance covering also the legal expenses related to civil/criminal proceedings in which the Executive is involved for acts committed under the reasonable exercise of his functions that the Company purchases for its executives.

6.2. The Executive will be provided with the following benefit: (i) a mobile phone, (ii) a personal computer, (iii) corporate credit card, (iv) iPad, (v) printer and (vi) monitor; all of which are Company property.

6.3. Furthermore, the Executive will be entitled to receive, upon presentation of invoices, the reimbursement of reasonable expenses incurred in the performance of his duties.

7. Exclusivity

7.1 With the exception of the provisions set forth by the following point 7.2. and of the additional cases that will be expressly authorized by the Board of Directros of the Company, during the employment relationship the Executive, shall refrain from performing any form of work (employment, independent contractor, consultancy, *etc*.) in competition with the Company.

7.2 During the employment relationship, the Executive is authorized to hold (i) the office of non-executive member of the board of directors of Lipogems International S.r.l. and Aurora-TT S.r.l. and its subsidiaries Altheia Science S.r.l. and Aurora Science S.r.l., and (ii) his quota in Aurora-TT S.r.l.

8. Confidentiality

8.1 During the employment relationship and after its termination, the Executive shall keep secret and retain in strictest confidence, and may not, either during or after termination of the employment relationship, without the prior written consent of the Company, furnish, make available or disclose to any third party or use for the benefit of himself or any third party, any Confidential Information. As used in this section, "**Confidential Information**" shall mean any information relating to the business or affairs of the Company or the other Group companies, including, without limitation, to information relating to financial statements, clients or customer identities, potential clients or customers, employees, suppliers, programs, strategies and information, analyses, profit margins or other proprietary information, as referred to compounds of biotechnological, biological and chemical origin, related to the pharmaceutical, biotechnological, molecular/ cellular medicine, genetic and diagnostic sectors; provided, however, that the Executive shall not be in breach of this undertaking by virtue of any disclosure required by applicable law, made pursuant to an order issued by a competent administrative or judicial authority, required to be made to enforce performance of this Agreement or made in relation to Confidential Information which is in the public domain or has become generally known in the public domain through no wrongful act on the part of the Executive.

9. Termination Indemnity

9.1 By way of more favourable treatment, in the event the employment relationship is terminated - even if in the period comprised between 6 months before and 2 years later a "*change of control*" event pursuant to Article 2359 of the Italian Civil Code - (i) by the Company without "*cause*" pursuant to Article 2119 of the Italian Civil Code or (ii) by the Executive with resignation for "*cause*" pursuant to Article 2119 of the Italian Civil Code the Company undertakes to pay the Executive a pre-determined indemnity that entirely replaces the additional indemnity provided by applicable law and the NCLA for unlawful termination. Such indemnity will be equal to 36 months of the overall salary, as provided by Article 2121 of the Italian Civil Code.

9.2 Such termination indemnity will be paid by the Company to the Executive by way of "*incentive to leave*", pursuant to Article 17 of the Presidential Decree No. 917/86 (so-called "TUIS"), upon the execution of a settlement and release agreement pursuant to article 2113, 4th paragraph of the Italian Civil Code, which shall contain a provision whereby the Executive waives any against the Company any possible claim or legal action related to the Agreement and to the employment relationship, within the terms provided by the same settlement agreement (and, in any event, no later than 30 days from its execution).

9.3 The TFR accrued, pro-rata 13th and 14th instalments accrued, indemnity in lieu of unused holidays and leaves will be paid in any event on top of the termination indemnity.

10. Non-solicitation of employees consultants and clients

10.1. For all the duration of the employment relationship and for a period of one year after the termination of the same, for whatever reason, the Executive agrees that he will not directly or indirectly, even by way of a third party (i.e. by way of a trust agent or by way of a company controlled by him) endeavour or attempt to induce any employee, executive, or consultant of the Company and/or Group to terminate the existing working relationship engaged with them in order to establish a working relationship of employment or self-employment with any person carrying out activities even if not in competition with the Company's business or which is not in conflict of its interest.

10.2. The Executive undertakes, moreover, for the same period mentioned under point 10.1 above, not to contact, directly or indirectly, and not to entice any client, employee, executive or consultant of the Company or in any way interfere in the relationship between the Company and/or the Group and the clients, employees, executives, consultants of the same.

10.3 The consideration for the obligations under point 10.1. and 10.2 will be equivalent to 12 months of the salary set forth by clause 4.1. paid to the Executive at the time of termination of the employment and it will be paid to the Executive within 30 days after the termination.

10.4. In case of non-compliance, even partial, of the obligations under this clause "*Non-Solicitation of Employees, Consultants And Clients*" the Executive shall return to the Company the entire sum received by the latter as consideration for the present covenant pursuant to point 10.3, without prejudice to the right of the Company to claim for any damages.

12. Non-competition covenant

11.1. Pursuant to article 2125 of the Italian Civil Code, during the course of the employment and for a period of 12 months from the termination of the Agreement, regardless the reason of said termination and the party which has withdrawn from the employment, the Executive shall not (i) perform any work, in any form (employment, independent contractor, consultancy, agency, corporate offices, etc.), also through third parties, in favor of businesses or organizations which operate in the sector of the Company or that perform activities in competition with those of the Company and the Group, nor shall not (ii) set up, directly or through a third party (thus including the family members of the Executive), companies, associations, or other entities that operate in the sector of the Company or that in any case are in competition with the Company; and acquiring and holding Qualified Holdings as defined under Section 11.2 below in any other entity that operates in the sector of the Company or that in any case is a competitor of the Company.

11.2. For the purposes of this Agreement, the term "**Qualified Holdings**" means any holding of shares or quotas which represent more than 2% of the voting rights with reference to listed companies and 10% of the voting rights with reference to not-listed companies that can be exercised in the ordinary shareholders meeting of such companies.

11.3. The covenant under section 11.1 above is restricted to the territory of following countries: Europe, UK, Canada, United States of America, China and Japan. Considering the current technological applications available (*e.g.*, e-mail, videoconferences, *etc*.) that allow a disassociation between the place of work, and the place where the work may be used, and produce its effects, the obligation under the present clause is binding, not only with reference to the location where the Executive performs his duties, in whichever form but also to any other location where the performance may produce its effects habitually and permanently, regardless of the Executive's physical presence in that location.

11.4. For purposes of enabling the Company to monitor full compliance with the obligations under section 11.1 above, the Executive undertakes to inform the Company, by way of registered letter with return receipt or by fax or by letter hand delivered o by courier with return receipt, of every work or professional assignment that he performs during the term of the non-competition covenant and every modification and variation thereof, no later than the 30th day following the date of commencement or changes of said activities.

11.5 In case the Executive omits to fulfil the obligations under 11.4 above, and/or delays the fulfilments of the obligations to inform the Company, the Executive shall pay to the Company a non-reducible penalty pursuant to Article 1382 of the Italian Civil Code equal to Euro 200.00 for each day of delay.

11.6 The consideration for the obligations under point 11.1 will be equivalent to 12 months of the salary set forth by clause 4.1. paid to the Executive at the time of termination of the employment and it will be paid to the Executive within 30 days after the termination.

11.7. In case of non-compliance, even partial, of the obligations under this clause "*Non-Competition Covenant*" the Executive shall return to the Company the entire sum received by the latter as consideration for the present covenant pursuant to point 11.5, without prejudice to the right of the Company to claim for any damages.

12. MISCELLANEOUS

12.1 This Agreement is governed by Italian law and regulations. Any disputes arising between the Parties concerning the interpretation, validity, performance or termination of the Agreement will be submitted to the exclusive jurisdiction of the Court of Milan.

12.2. The Agreement constitutes the entire agreement between the Parties regarding the subject matter hereof and replaces and supersedes any prior understandings (oral or written) concerning the same subject.

12.3 This Agreement is executed in both Italian and English. The Parties represent that there is no material different between the Italian and English versions. The Parties agree that in the event of conflict of interpretation of this Agreement, the Italian text shall prevail over the English text.

Executed in Milan (Italy), on __ 2021
Two originals signed, each Party receiving one original.

Mr. Pierluigi Paracchi

_____

Genenta Science S.r.l.

_____

As a sign of specific approval of the replacement of the previous employment contract and of the following articles: 3. Working time; 4. Salary; 5. Bonus; 7. Exclusivity; 8. Confidentiality; 9. Termination Indemnity; 10. Non-solicitation of employees, consultants and clients; 11. Non-competition clause; 12. Miscellaneous.

Mr. Pierluigi Paracchi

_____

Exhibit 10.10

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT (this "Agreement"), dated as of [●], between **[Insert name of Genenta's US subsidiary]** (the "Company") and Carlo Russo ("Executive," together with the Company, the "Parties" and, each, a "Party").

WHEREAS, Genenta Science S.p.A. ("Parent") is the parent company of the Company;

WHEREAS, Parent is in the process of an initial public offering (the "IPO");

WHEREAS, the effectiveness of this Agreement is conditioned on the successful completion of the IPO; and

WHEREAS, effective on the later of the date of the IPO or July 1, 2021 (the "Commencement Date"), the Company desires to employ Executive, and Executive desires to accept such employment, on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, on the basis of the foregoing premises and in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

1. Employment; Title; Duties and Location. Contingent on the successful completion of the IPO, the Company hereby agrees to employ Executive, and Executive hereby accepts employment with the Company, on the terms and subject to the conditions set forth herein. During the Employment Period (as defined in Section 2 below), Executive shall serve the Company as Chief Medical Officer ("CMO") and shall report exclusively and directly to the Chief Executive Officer of the Company (the "CEO"). Executive shall perform the duties consistent with Executive's title and position and such other duties commensurate with such position and title as shall be specified or designated by the CEO from time to time. Subject to Executive's appointment thereto, and without additional compensation, Executive shall hold such other or additional titles and serve, during the Employment Period, in such other or additional capacities to which Executive may be appointed from time to time in the Company and its affiliated companies, provided such titles and additional capacities are consistent with Executive's above-stated position and duties. The principal place of performance by Executive of Executive's duties hereunder shall be the Company's offices in New York City, although Executive may be required to reasonably travel outside of such area in connection with the performance of Executive's duties.

2. Term. Executive's employment hereunder shall commence on the Commencement Date and continue until terminated pursuant to the terms of Section 6 below (the "Employment Period").

3. Compensation. During the Employment Period only (unless otherwise expressly provided for herein), Executive shall be entitled to the following compensation and benefits.

3.1 Salary. Executive shall receive a base salary (the "Base Salary") payable in substantially equal installments in accordance with the Company's normal payroll practices and procedures in effect from time to time and subject to applicable withholdings and deductions. Executive's starting Base Salary shall be at the annual rate of $500,000. From time to time, the Company, at its sole discretion, may review and adjust Executive's Base Salary, except that Executive's Base Salary may only be decreased if the decrease is the same, on a percentage basis, for all similarly situated executives due to business conditions**.**

3.2 Discretionary Bonus. Executive shall be eligible to receive a discretionary bonus (a "Discretionary Bonus") with respect to each fiscal year of the Company (a "Fiscal Year") based on the terms and conditions hereof. The amount of any Discretionary Bonus for a Fiscal Year may be up to 20% of Executive's Base Salary as of the end of such Fiscal Year, based upon an individualized determination, by the CEO, of the achievement of objectives to be set from time to time by the CEO and approved by the Board of Directors of the Company (the "Board"). To be eligible for a Discretionary Bonus, Executive must be employed by the Company at the time such Bonus is paid. Any Discretionary Bonus for a given Fiscal Year shall be paid in the following Fiscal Year as soon as practicable after it is determined that such bonus has been awarded. The payment and amount of any Discretionary Bonus shall be determined in the sole discretion of the Company and is not guaranteed in any way.

3.3 Equity. Subject to the approval of the Board of Directors of Parent or its Compensation Committee, Executive will be granted an equity award (the "Equity Award") under an equity incentive plan to be adopted by Parent by no later than July 31, 2021 (the "Equity Plan"). The Equity Award will be subject to the terms and conditions of the Equity Plan and an applicable equity award agreement.

3.4 Benefits. Executive shall have the right to receive or participate in all employee benefit programs and perquisites generally established by the Company from time to time for employees similarly situated to Executive, subject to the general eligibility requirements and other terms of such programs and perquisites, and subject to the Company's right to amend, terminate or take other similar action with respect to any such programs and perquisites. Subject to the foregoing, the Company anticipates that such employment benefit programs will include, without limitation, medical insurance, dental insurance, vision insurance, and a 401K plan (with a minimal matching program).

3.5 Vacation and Other Paid Time Off. Executive shall be entitled to 20 days of paid vacation, as well as sick days and any other paid time off, each year in accordance with then current Company policy.

3.6 Required Taxes and Withholdings. The Company shall withhold from any payments made to Executive (including, without limitation, those made under this Agreement) all federal, state, local or other taxes and withholdings as shall be required pursuant to any law or governmental regulation or ruling.

4. Exclusivity and Best Efforts. During the Employment Period, Executive shall (i) in all respects conform to and comply with the lawful directions and instructions given to Executive by the Company; (ii) devote Executive's entire business time, energy and skill to Executive's services under this Agreement; (iii) use Executive's best efforts to promote and serve the interests of the Company and to perform Executive's duties and obligations hereunder in a diligent, trustworthy, businesslike, efficient and lawful manner; (iv) comply with all applicable laws and regulations, as well as the policies and practices established by the Company from time to time and made applicable to its employees generally or senior executives; (v) not engage in any other business, profession or occupation for compensation or otherwise; and (vi) not engage in any activity that, directly or indirectly, impairs or conflicts with the performance of Executive's obligations and duties to the Company, provided, however, that the foregoing shall not prevent the Executive from (i) serving, with the prior written consent of the Board, as a member of the boards of directors or advisory boards (or their equivalents in the case of a non-corporate entity) of non-competing businesses and charitable organizations, (ii) managing Executive's personal affairs and passive personal investments, and (iii) participating in charitable, civic, educational, professional or community affairs, so long as, in the aggregate, any such activities do not unreasonably interfere or conflict with the Executive's duties hereunder or create a potential business or fiduciary conflict with the Company, as reasonably determined by the Company.

5. Reimbursement for Expenses. Executive is authorized to incur reasonable expenses in the discharge of the services to be performed hereunder in accordance with the Company's expense reimbursement policies, as the same may be modified by the Company from time to time in its sole and complete discretion (the "Reimbursement Policies"). Subject to the provisions of Section 17.2 below (Section 409A Compliance), the Company shall reimburse Executive for all such proper expenses upon presentation by Executive of itemized accounts of such expenditures in accordance with the terms of the Reimbursement Policies.

6. Termination.

6.1 Death. Executive's employment shall immediately and automatically be terminated upon Executive's death.

6.2 Disability. The Company may, subject to applicable law, terminate Executive's employment due to a Disability by providing written notice of such termination and its effective date to Executive. For purposes of this Agreement, "Disability" means a "disability" that entitles Executive to benefits under the applicable Company long-term disability plan covering Executive and, in the absence of such a plan, that Executive shall have been unable, due to physical or mental incapacity, to substantially perform Executive's duties and responsibilities hereunder for 120 days out of any 365 day period, whether or not consecutive. In the event of any question as to the existence, extent or potentiality of Executive's Disability upon which the Company and Executive cannot agree, such question shall be resolved by a qualified, independent physician mutually agreed to by the Company and Executive, the cost of such examination to be paid by the Company. If the Company and Executive are unable to agree on the selection of such an independent physician, each shall appoint a physician and those two physicians shall select a third physician who shall make the determination of whether Executive has a Disability. The written medical opinion of such physician shall be conclusive and binding upon each of the Parties as to whether a Disability exists and the date when such Disability arose. This section shall be interpreted and applied so as to comply with the provisions of the Americans with Disabilities Act (to the extent applicable) and any applicable state or local laws.

6.3 For Cause by the Company. The Company may terminate Executive's employment for Cause, at any time, upon written notice reasonably describing the nature of such Cause. For purposes of this Agreement, the term "Cause" means Executive's (i) willful misconduct; (ii) willful or gross neglect of Executive's job duties; (iii) material failure to materially perform Executive's job duties; (iv) refusal to follow a lawful directive of the Company that is materially related to and consistent with the provisions of Section 1 above; (v) material failure to materially comply with the Company's policies and practices; (vi) act of moral turpitude, theft, fraud or dishonesty; (vii) commission of any felony or misdemeanor (other than minor traffic violations or offenses of a comparable magnitude not involving dishonesty, fraud or breach of trust); (viii) material breach of any material term of a contractual agreement between Executive and the Company, including, without limitation, this Agreement; or (ix) willful act that is (or reasonably would be expected to be) materially damaging or detrimental to the Company; provided, however, that, in the event of conduct described in clauses (iii), (iv), (v) or (viii) that is capable of being cured, Cause shall exist only if the Company provides written notice to Executive reasonably detailing such grounds giving rise to Cause and Executive fails to cure such grounds for Cause to the reasonable satisfaction of the Company within two (2) business days after delivery to Executive of such written notice, if reasonably curable within two (2) business days, or, if not, then within such time as is reasonable under the circumstances, which in no event shall exceed twenty (20) calendar days. Notwithstanding the foregoing, notice and an opportunity to cure an event giving rise to Cause shall not be required for any event that is the same or of similar to an event that was the subject of a prior notice to cure. Executive's date of termination in the event Executive's employment is terminated for Cause shall be the date on which Executive is given notice of termination under this Section 6.3, except, if a notice period is required, Executive's date of termination shall be upon the expiration of said notice period if Executive fails to previously cure the grounds giving rise to Cause. If, subsequent to termination of Executive's employment for a reason other than for Cause, the Company learns that, during the Employment Period, Cause existed to terminate Executive's employment on a ground that would not have required notice and an opportunity to cure, the Company may retroactively designate Executive's termination of employment to be for Cause under this Section 6.3.

6.4 Resignation by Executive for Good Reason. Executive may resign Executive's employment hereunder for Good Reason, at any time, provided that Executive provides the Company with ten (10) days' prior written notice of such resignation and such notice is given within thirty (30) days of when Good Reason first arises. For the purpose of this Agreement, "Good Reason" means (i) a material and substantial diminution in Executive's duties, authority, or responsibilities that would be inconsistent with Executive's position (other than while Executive is temporarily physically or mentally incapacitated, as permitted under Section 8 below or as required by applicable law), (ii) a material failure by the Company to pay Executive's compensation as provided for herein, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith; (iii) a change in the location of Executive's principal place of performance from other than that specified in Section 1 above; or (iv) other material breach by the Company of a material provision of this Agreement or any other agreement between the Company and Executive; provided (x) Executive has provided the Company with written notice reasonably detailing the grounds giving rise to Good Reason within thirty (30) days of the occurrence thereof or, if later, within thirty (30) days of the date upon which Executive first becomes aware of such grounds, and (y) the Company fails to cure such grounds within thirty (30) days after delivery to it of such written notice. Notwithstanding the foregoing, during the Employment Period, in the event that the Company reasonably believes that Executive may have engaged in conduct that could constitute Cause hereunder, the Company may, in its sole and absolute discretion, suspend Executive from performing Executive's duties hereunder for a period of up to sixty (60) days, and in such event such suspension shall not constitute an event pursuant to which Executive may terminate this Agreement with Good Reason; provided, however, that no such suspension shall alter the Company's obligations under this Agreement (including, without limitation, its obligations to provide Executive compensation and benefits) during such period of suspension. Executive's date of termination in the event Executive resigns Executive's employment for Good Reason shall be the effective date of Executive's notice of resignation for Good Reason, except that Company may waive all or any part of the above-referenced 10-day notice period or of the 30-day cure period, in which event Executive's date of termination shall be the last day of such notice or cure period that has not been waived or, if the entire notice or cure period has been waived, the date that Executive provided notice of the event giving rise to Good Reason or of Executive's resignation for Good Reason.

6.5 By the Company Without Cause or By Executive Without Good Reason. The Company may terminate Executive's employment without Cause, at any time, with or without prior notice, in its sole and complete discretion, by providing written notice of such termination and its effective date to Executive. Likewise, Executive may terminate Executive's employment without Good Reason upon at least sixty (60) days prior written notice to the Company without any liability. Termination of Executive's employment without Cause by the Company or without Good Reason by Executive shall not include termination of Executive's employment due to Executive's death or Disability.

6.6 Resignation from Other Positions. Upon termination of Executive's employment for any reason, Executive shall, upon request of the Company, immediately be deemed to have resigned from all boards, offices and appointments held by Executive in or on behalf of the Company. In furtherance hereof, upon Executive's termination of employment, Executive, at the direction of the Board, shall immediately submit to the Company letter(s) of resignation for any such boards, offices and appointments. If Executive fails to tender such letter(s) of resignation, then the governing body or person with respect to such boards, offices and appointments will be empowered to remove Executive from such boards, offices and appointments.

7. Effect of Termination of Employment.

7.1 Generally. In the event Executive's employment with the Company terminates, Executive shall have no right to receive any compensation, benefits or any other payments or remuneration of any kind from the Company, except as otherwise provided by this Section 7, in Section 12 below, in any separate written agreement between Executive and the Company or as may be required by law. In the event Executive's employment with the Company is terminated for any reason, Executive shall receive the following (collectively, the "Accrued Obligations"): (i) Executive's Base Salary through and including the effective date of Executive's termination of employment (the "Termination Date"), which shall be paid on the first regularly scheduled payroll date of the Company following the Termination Date or on or before any earlier date as required by applicable law; (ii) payment for accrued unused vacation time, subject to the Company's then current vacation policy, which shall also be paid on the first regularly scheduled payroll date of the Company following the Termination Date or on or before any earlier date as required by applicable law; (iii) payment of any vested benefit due and owing under any employee benefit plan, policy or program pursuant to the terms of such plan, policy or program; and (iv) payment for unreimbursed business expenses subject to, and in accordance with, the terms of Section 5 above, which payment shall be made within 30 days after Executive submits the applicable supporting documentation to the Company, and in any event no later than on or before the last day of Executive's taxable year following the year in which the expense was incurred.

7.2 Severance Benefits. In the event that Executive's employment is terminated by the Company pursuant to Section 6.5 above (without Cause) or by Executive pursuant to Section 6.4 hereof (Good Reason), in addition to the Accrued Obligations, Executive shall be entitled to receive severance benefits (the "Severance Benefits"), subject to and in accordance with the terms of this Section 7.2.

(a) Severance Benefits Not in Connection with a Change in Control. Except as provided in Section 7.2(b) below, the Severance Benefits shall consist of the payments and benefits provided by this Section 7.2(a).

(i) Executive shall receive payment of an amount (the "Severance Pay") equal to Executive's Base Salary immediately prior to the Termination Date (or, if Good Reason was attributable to the Company's failure to pay the minimum amount of Base Salary provided herein, such minimum amount) for the period of one year (the "Severance Period"). The Severance Pay shall be paid in the form of salary continuation pursuant to the terms and conditions of Section 3.1 above, commencing within ninety (90) days following the Termination Date on the first regularly scheduled payroll date of the Company that is practicable after the effective date of the Separation Agreement (defined in Section 7.2(c) below), *except* that, if the Separation Agreement may be executed and/or revoked in a calendar year following the calendar year in which the Termination Date occurs, the Severance Pay shall commence on the first regularly scheduled payroll date of the Company in the calendar year in which the consideration or, if applicable, release revocation period ends to the extent necessary to comply with Section 409A (as defined in Section 17.2 below). The first such payment shall include payment for any payroll dates between the Termination Date and the date of such payment.

(ii) Executive shall receive a Discretionary Bonus for the Fiscal Year in which the Termination Date occurs, pro-rated for the portion of such Fiscal Year Executive was employed hereunder. Any such Discretionary Bonus shall be determined and paid in accordance with the terms of Section 3.2 above.

(b) Severance Benefits in Connection with a Change in Control. In the event that Executive's employment is terminated by the Company pursuant to Section 6.5 above (without Cause) or by Executive pursuant to Section 6.4 hereof (Good Reason) within ninety (90) days prior to, or twelve (12) months after, a Change of Control (defined in Section 7.2(b)(iii) below), the Severance Benefits shall consist of the payments and benefits provided by this Section 7.2(b).

(i) Generally. Executive shall receive payment of an amount (the "Severance Pay") equal to Executive's Base Salary immediately prior to the Termination Date (or, if Good Reason was attributable to the Company's failure to pay the minimum amount of Base Salary provided herein, such minimum amount) for the period of five (5) years (the "Severance Period"). The Severance Pay shall be paid in the form of salary continuation pursuant to the terms and conditions of Section 3.1 above, commencing within ninety (90) days following the Termination Date on the first regularly scheduled payroll date of the Company that is practicable after the effective date of the Separation Agreement (defined in Section 7.2(c) below), *except* that, if the Separation Agreement may be executed and/or revoked in a calendar year following the calendar year in which the Termination Date occurs, the Severance Pay shall commence on the first regularly scheduled payroll date of the Company in the calendar year in which the consideration or, if applicable, release revocation period ends to the extent necessary to comply with Section 409A (as defined in Section 17.2 below). The first such payment shall include payment for any payroll dates between the Termination Date and the date of such payment.

(ii) Section 280G. If (a) Executive's termination of employment giving rise Severance Benefits under this Section 7.2(b) results in a "Separation from Service" (within the meaning of Section 409A (defined in Section 17.2 below)) by the Executive, and (b) the Change in Control constitutes a change in ownership or effective control of Company or a change in the ownership of a substantial portion of the assets of the Company (within the meaning of Section 280G(b)(2)(i) of the Internal Revenue Code of 1986, as amended (the "Code"), the Severance Benefits shall be subject to mitigation as provided in Treasury Regulations Section 1.280G-1 Q&A 42(c)(5), or, in lieu of the Severance Benefits provided under this Section 7.2(b), Executive, in Executive's complete and sole discretion, may elect to receive an alternative severance payment (the "Alternative Payment"), not subject to mitigation, payable at the same time the Severance Benefits would otherwise have been paid. Executive must give written notice to Company of such election: (i) within fifteen (15) days prior to the end of the Notice Period after resignation with Good Reason; or (ii) within fifteen (15) days prior to the end of the Notice Period after termination by Company without Cause (each, an "Alternative Payment Notice"). For purposes of this Agreement, the "Alternative Payment" shall be a payment made by Company in the form provided for in Section 7.2(b)(i) above to Executive in an amount equal to the product of 2.99 (or, if Code Section 280G(b)(2)(A)(ii) is amended providing for a safe harbor multiple other than 3, then the multiple as amended, less 0.01) *multiplied by* Executive's "base amount" (as defined in Code Section 280G(b)(3)); provided, however, that the amount of the Alternative Payment shall be reduced by the value of acceleration (as determined under Code Section 280G and the regulations thereunder) of any equity, stock options, incentive compensation or deferred compensation accelerated by reason of termination to the extent required to be included in the Executive's "base amount" pursuant to Code Section 280G. The value (as determined under Code Section 280G and the regulations thereunder) of acceleration of vesting of equity, stock options, incentive compensation or deferred compensation shall be taken into account to the minimum extent necessary so as not to violate Treasury Regulations Section 1.280G-1 Q&A 42(c).

(iii) Definition of Change in Control. As used herein, "Change in Control" means the occurrence of any of the following events during the Employment Period: (i) any direct or indirect sale, lease, license, exchange or other transfer (in one transaction or a series of related transactions) of all, or substantially all of the business and/or assets of the Company and/or Parent; (ii) a direct or indirect merger or consolidation of the Company and/or Parent, and the Company and/or Parent is not the surviving entity; (iii) a direct or indirect reorganization or liquidation of the Company and/or Parent; (iv) a direct or indirect merger, consolidation, tender offer or any other transaction involving the Company and/or Parent if the equity holders of the Company and/or Parent, as applicable, immediately before such merger, consolidation, tender offer or other transaction do not own, directly or indirectly, immediately following such merger, consolidation, tender offer or other transaction, more than fifty percent (50%) of the combined voting power of the outstanding voting securities of the entity resulting from such merger, consolidation, tender offer or other transaction; (v) a change in the composition of the Company's and/or Parent's Board as a result of which fewer than a majority of the directors are Incumbent Directors (defined below); or (vi) the consummation of any other transaction involving a significant issuance of the Company's and/or Parent's securities, or other material event, that the Company's and/or Parent's Board determines to be a Change in Control. As used herein, "Incumbent Directors" means directors of the Company or Parent who either: (A) are directors of the Company or Parent as of the Commencement Date hereof; or (B) are nominated for election to the Board of the Company or Parent with the affirmative votes of at least a majority of the directors of the Company or Parent who are Incumbent Directors ("Approved Successors") described in (A) above at the time of such nomination; or (C) are nominated for election to the Board of the Company or Parent with the affirmative votes of at least a majority of the directors of the Company or Parent who are Incumbent Directors or their Approved Successors. Notwithstanding the foregoing, "Incumbent Directors" shall not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company or Parent.

(c) Separation Agreement and Other Conditions for Severance Benefits. Provision of the Severance Benefits is conditioned on (i) Executive's continued compliance in all material respects with Executive's continuing obligations to the Company, including, without limitation, the terms of this Agreement that survive termination of Executive's employment with the Company, and (ii) Executive signing (without revoking if such right is provided under applicable law) a separation agreement and release in a form of that provided to Executive by the Company on or about the Termination Date (the "Separation Agreement"). Executive must so execute the Separation Agreement within 60 days following the Termination Date (or such shorter time as may be set forth in the Separation Agreement).

8. Notice of Termination. In the event Executive elects to terminate Executive's employment hereunder by resigning with or without Good Reason under Sections 6.4 or 6.5 above, Executive shall provide the Company with the applicable prior written notice of termination required by such Sections (the "Notice Period"). The Company may, in its discretion, waive all or any portion of such Notice Period. The Company may require that, during the Notice Period, or part or parts thereof, Executive does not do any of the following: (i) enter the Company's premises; (ii) perform any work for the Company; (iii) undertake any work for any third party whether paid or unpaid and whether as an employee or otherwise; (iv) have any contact or communication with any client, customer or supplier of the Company; or (v) have any contact or communication with any employee, officer, director, agent or consultant of the Company. Additionally, during the Notice Period, or any part or parts thereof, the Company may require Executive to do any of the following: (i) perform special projects or perform duties not within Executive's normal duties (provided such duties are commensurate with Executive's position and title) or perform some but not all of Executive's normal duties; and (ii) keep the Company informed of Executive's whereabouts so that Executive can be contacted if the need arises for Executive to perform any duties provided by clause (i) of this sentence. The Company retains the right to terminate Executive's employment under Section 6.3 above during the Notice Period.

9. Confidentiality, Non-Solicitation and Non-Competition.

9.1 Representations and Acknowledgements. For purposes of Sections 9-14 hereof, the term "Company" shall refer to not only the Company, but also, jointly and severally, any entity, directly or indirectly, through one or more intermediaries, controlled by, in control of, or under common control with, the Company (collectively, "Company Affiliates"). Executive acknowledges and agrees that: (i) among the most valuable and indispensable assets of the Company are its Confidential Information (defined below) and close relationships with its Customers (defined below) and Suppliers (defined below, which includes, without limitation, employees), which the Company has devoted and continues to devote a substantial amount of time, money and other resources to develop; (ii) in connection with Executive's employment with the Company, Executive will be exposed to and acquire the Company's Confidential Information and develop, at the Company's expense and support, special and close relationships with the Company's Customers and Suppliers; (iii) the Company's Confidential Information and close Customer and Supplier relationships must be protected; (iv) this Section 9 is a material provision of this Agreement and the Company would not engage Executive hereunder but for the promises and acknowledgements that Executive makes in this Section 9; (v) to the extent required by law, the covenants in this Agreement contain reasonable limitations as to time, geographical area and scope of activities to be restricted and that such covenants do not impose a greater restraint on Executive than is necessary to protect the Company's Confidential Information, close Customer and Supplier relationships and other legitimate business interests; (vi) Executive's compliance with such covenants will not inhibit Executive from earning a living or from working in Executive's chosen profession; and (vii) any breach of such covenants will result in the Company being placed at an unfair competitive disadvantage and cause the Company serious and irreparable harm to its business.

9.2 Confidential Information.

(a) Protection of Confidential Information. During the Employment Period and at all times thereafter, Executive will not, except to the extent necessary to perform Executive's duties hereunder or as required by law, directly or indirectly, use or disclose to any third person, without the prior written consent of the Company, any Confidential Information (defined 9.2(b) below) of the Company. If it is necessary for Executive to use or disclose Confidential Information so as to comply with any law, rule, regulations, court order, subpoena or other governmental mandate or investigation, Executive shall give prompt written notice to the Company of such requirement (to the extent legally permissible), disclose no more information than is so required, and cooperate with any attempts by the Company to obtain a protective order or similar treatment. In the event that the Company is bound by a confidentiality agreement or understanding with a customer, vendor, supplier or other party regarding the confidential information of such customer, vendor, supplier or other party, which is more restrictive than specified above in this Section 9.2, and of which Executive has notice or is aware, Executive shall adhere to the provisions of such other confidentiality agreement, in addition to those of this Section 9.2. Executive shall exercise reasonable care to protect all Confidential Information. Executive will immediately give notice to the Company of any unauthorized use or disclosure of Confidential Information. Executive hereby represents and warrants that it shall assist the Company in remedying any such unauthorized use or disclosure of Confidential Information.

(b) Confidential Information Defined. For purposes of this Agreement, "Confidential Information" means all information of a confidential or proprietary nature regarding the Company, its business or properties that the Company has furnished or furnishes to Executive, whether before or after the date of this Agreement, or is or becomes available to Executive by virtue of Executive's employment with the Company, whether tangible or intangible, and in whatever form or medium provided, as well as all such information generated by Executive that, in each case, has not been published or disclosed to, and is not otherwise known to, the public. Confidential Information includes, without limitation, customer lists, customer requirements and specifications, designs, financial data, sales figures, costs and pricing figures, marketing and other business plans, product development, marketing concepts, personnel matters (including employee skills and compensation), drawings, specifications, instructions, methods, processes, techniques, computer software or data of any sort developed or compiled by the Company, formulae or any other information relating to the Company's services, products, sales, technology, research data, software and all other know-how, trade secrets or proprietary information, or any copies, elaborations, modifications and adaptations thereof. For the avoidance of doubt, Executive acknowledges and agrees that Confidential Information protected under this Agreement includes information regarding pay, bonuses, benefits and perquisites offered to or received by employees of the Company, as well as non-public information regarding the unique and special skills of specific employees and how such skills are valuable and integral to the Company's operations. Notwithstanding the foregoing, Confidential Information shall not include any information (i) that is generally known to the industry or the public other than as a result of Executive's breach of this covenant; (ii) that is made available to Executive by a third party without that party's breach of any confidentiality obligation; or (iii) which was developed by Executive outside or independent of Executive's performance of Executive's obligation to render services on behalf of the Company.

(c) Immunity for Certain Limited Disclosures. Executive acknowledges that Executive has been notified in accordance with the federal Uniform Trade Secrets Act (18 U.S. Code § 1833(b)(1)) that an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; ***and*** (ii) solely for the purpose of reporting or investigating a suspected violation of law; ***or*** (b) is made in a complaint or other document filed in a lawsuit or other proceeding, ***if*** such filing is made under seal.

(d) Permitted Disclosures. Executive also acknowledges that nothing in this Agreement shall be construed to prohibit Executive from reporting possible violations of law or regulation to any governmental agency or regulatory body or making other disclosures that are protected under any law or regulation, or from filing a charge with or participating in any investigation or proceeding conducted by any governmental agency or regulatory body. In particular, notwithstanding the terms of this Section 9.2 or any other provision of this Agreement, Executive is not prohibited from disclosing factual information related to any claim of discrimination to law enforcement, the U.S. Equal Employment Opportunity Commission, the New York State Division of Human Rights, or any local commission on human rights (including the New York City Commission on Human Rights), or an attorney retained by Executive. Further, nothing herein shall prohibit Executive from inquiring about, discussing, or disclosing the wages of Executive or another employee of the Company with other employees of the Company.

9.3 Non-Interference, Non-Competition and Non-Diversion.

(a) No Interference with Customers. Executive agrees that, during the Restricted Period (defined in Section 9.3(e) below), regardless of whether, or on what basis, Executive's employment hereunder is terminated or any claim that Executive may have against the Company under this Agreement or otherwise, Executive shall not, directly or indirectly (defined below), actually or attempt to, (i) solicit, induce, or cause any Customer to terminate, reduce or refrain from renewing or extending its contractual or other business relationship with the Company; (ii) solicit, induce or cause any Customer to become a customer of or enter into any contractual or other relationship with Executive or any other person or entity for Competing Services (as defined in Section 9.3(e) below); and/or (iii) offer or provide to any Customer any Competing Services.

(b) No Interference with Employees and Other Suppliers. Executive agrees that, during the Restricted Period, regardless of whether, or on what basis, Executive's employment hereunder is terminated or any claim that Executive may have against the Company under this Agreement or otherwise, Executive shall not, directly or indirectly, actually or attempt to: (i) solicit, induce, or cause any Supplier of the Company to terminate, reduce or refrain from renewing or extending such person's or entity's business or employment relationship with the Company; (ii) solicit, induce or cause any employee of the Company to engage in Competing Services; or (iii) employ or otherwise engage as an employee, independent contractor or consultant (1) any employee of the Company or (2) any person who was employed by the Company within the then prior six-month period.

(c) Non-Competition. During the Restricted Period, regardless of whether, or on what basis, Executive's employment hereunder is terminated or any claim that Executive may have against the Company under this Agreement or otherwise, Executive shall not, directly or indirectly, actually or attempt to, engage in the business of providing Competing Services within the Territory (as defined in Section 9.3(e) below).

(d) Notice to Subsequent Employers. Upon commencing any engagement as a service provider (whether as an employee, independent contractor or otherwise) during the Restricted Period, Executive shall expressly advise each new employer and each other new recipient of Executive's services (each, a "Service Recipient") of Executive's continuing obligations to the Company under this Agreement and, in particular, this Section 9. Further, Executive hereby consents to the Company providing such notification to each such Service Recipient.

(e) Definitions. For the purposes of this Agreement, the following terms shall have the following meaning.

(i) "Competing Services" means products or services that are the same, similar or otherwise in competition with the products and services of the Company with which Executive was involved or about which Executive acquired Confidential Information.

(ii) "Customer" means any company or individual: (i) who purchased products or services from the Company whom Executive contacted or served during the Employment Period, for whom Executive supervised contact or service during the Employment Period or about whom Executive acquired Confidential Information; and/or (ii) who was a potential customer of the Company within the one year immediately preceding the Termination Date and (A) about whom Executive acquired Confidential Information or (B) who contacted Executive, whom Executive contacted, or for whom Executive supervised contact regarding the potential purchase of products or services of the Company.

(iii) "directly or indirectly" as it relates to an activity taken by Executive includes any activity taken directly by Executive or indirectly on Executive's behalf, including any activity taken in conjunction with any other person or entity, and including any activity taken by Executive as an employee, agent, consultant, independent contractor, officer, director, principal, shareholder, equity holder, partner, member, joint venturer, lender, investor or otherwise, except that nothing in this Agreement shall prohibit Executive from being a passive holder, for investment purposes only, of not more than two percent (2%) of the outstanding stock of any company listed on a national securities exchange, or actively traded in a national over-the-counter market.

(iv) "Restricted Period" means the Employment Period and for a period of one year thereafter, except that such period shall be extended for any period therein during which Executive was in violation of any provision of this Section 9.3.

(v) "Supplier" means any supplier of goods, services, funding, leads or prospects to the Company, including as an employee, independent contractor or in any other capacity.

(vi) "Territory" means anywhere in the world. Executive acknowledges that the Company does business throughout the world and, thus, it is necessary and appropriate to have the non-competition provision herein apply world-wide in order to protect the Company's legitimate interests in its Confidential Information and close customer relationships.

10. Intellectual Property.

10.1 The Company's Proprietary Rights. Executive acknowledges and agrees that all Intellectual Property (defined below) created, made or conceived by Executive (solely or jointly) during Executive's employment by the Company (regardless of whether such Intellectual Property was created, conceived or produced during Executive's regular work hours or at any other time) that relates to the actual or anticipated businesses of the Company or results from or is suggested by any work performed by employees or independent contractors for or on behalf of the Company ("Company Intellectual Property") shall be deemed "work for hire" and shall be and remain the sole and exclusive property of the Company for any and all purposes and uses whatsoever as soon as Executive conceives or develops such Company Intellectual Property, and Executive hereby agrees that its assigns, executors, heirs, administrators or personal representatives shall have no right, title or interest of any kind or nature therein or thereto, or in or to any results and proceeds therefrom. If for any reason such Company Intellectual Property is not deemed to be "work-for-hire," then Executive hereby irrevocably and unconditionally assigns all rights, title, and interest in such Company Intellectual Property to the Company and agrees that the Company is under no further obligation, monetary or otherwise, to Executive for such assignment. Executive also hereby waives all claims to any moral rights or other special rights ("Moral Rights"), including, without limitation, all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "moral rights," "artist's rights," "droit moral" or the like, that Executive may have or may accrue in any Company Intellectual Property. To the extent that any such Moral Rights cannot be assigned under applicable law, Executive hereby ratifies and consents to any action that may be taken with respect to such Moral Rights by or on behalf of the Company and waives and agrees not to enforce any and all such rights, including, without limitation, any limitation on subsequent modification, to the extent permitted under applicable law. Executive shall promptly disclose in writing to the Company the existence of any and all Company Intellectual Property. As used in this Agreement, "Intellectual Property" shall mean and include any ideas, inventions (whether or not patentable), designs, improvements, discoveries, innovations, patents, patent applications, trademarks, service marks, trade dress, trade names, trade secrets, works of authorship, copyrights, copyrightable works, films, audio and video tapes, other audio and visual works of any kind, scripts, sketches, models, formulas, tests, analyses, software, firmware, computer processes, computer and other applications, creations and properties, Confidential Information and any other patents, inventions or works of creative authorship.

10.2 Waiver. In the event that Executive owns or claims any rights to Company Intellectual Property that cannot be assigned to the Company, Executive irrevocably waives all claims and the enforcement of all such rights against the Company, and their respective officers directors, assigns and licensees, and agrees, at the Company's request and expense, to consent to and join in any action to enforce the Company's interests in such Company Intellectual Property. As to any rights to Company Intellectual Property that cannot be assigned to the Company or waived by Executive, Executive irrevocably grants to the Company an exclusive, irrevocable, perpetual, worldwide, fully paid and royalty-free license, with rights to license and sublicense, to reproduce, create derivative works, distribute, publicly perform and publicly display by all means now known or later developed, any and all such Company Intellectual Property.

10.3 Cooperation Regarding Intellectual Property. Executive agrees to assist the Company, and to take all reasonable steps, with securing patents, registering copyrights and trademarks, and obtaining any other forms of protection for the Company Intellectual Property in the United States and elsewhere. In particular, at the Company's expense (except as noted in clause (i) below), Executive shall forthwith upon request of the Company execute all such assignments and other documents (including applications for patents, copyrights, trademarks, and assignments thereof) and take all such other action as the Company may reasonably request in order (i) to vest in the Company all of Executive's right, title, and interest in and to such Company Intellectual Property, free and clear of liens, mortgages, security interests, pledges, charges, and encumbrances ("Liens") (and Executive agrees to take such action, at Executive's expense, as is necessary to remove all such Liens) and (ii), if patentable or copyrightable, to obtain patents or copyrights (including extensions and renewals) therefor in any and all countries in such name as the Company shall determine. In the event that Executive is unable or unavailable or shall refuse to sign any lawful or necessary documents required in order for the Company to apply for and obtain any copyright or patent with respect to any work performed by Executive in the course of his employment with the Company (including applications or renewals, extensions, divisions or continuations), Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agents and attorneys-in-fact to act for and in Executive's behalf, and in Executive's place and stead, to execute and file any such applications or documents and to do all other lawfully permitted acts to further the prosecution and issuance of copyrights and patents with respect to such Company Intellectual Property with the same legal force and effect as if executed or undertaken by Executive.

10.4 No infringement. Executive represents and warrants to the Company that all Intellectual Property Executive delivers to the Company shall be original and shall not infringe upon or violate any patent, copyright or proprietary right of any person or third party.

10.5 License to Prior Invention. If Executive in the course of Executive's employment for the Company incorporates into a Company product Intellectual Property that Executive has, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of Executive's employment with the Company in which Executive has a property right (each, a "Prior Invention"), Executive hereby grants to the Company a perpetual, nonexclusive, royalty-free, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use and sell such Prior Invention. Executive hereby represents and warrants that all Prior Inventions have been listed by Executive on Exhibit A hereto or, if no such list is attached, that there are no Prior Inventions. Executive will not incorporate any Intellectual Property owned by any third party into any Company Intellectual Property without the Company's prior written permission.

10.6 Severability. To the extent this Agreement is required to be construed in accordance with laws of any state which precludes as a requirement in an employee agreement the assignment of certain classes of inventions made by an employee, this Section 10 will be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes.

11. Non-Disparagement. During and after the Employment Period, Executive shall not make any disparaging statement (verbal, written or otherwise) about the Company or its financial status, business, personnel, directors, officers, consultants, services or business methods. This Section does not apply to (i) truthful statements made in connection with legal proceedings, governmental and regulatory investigations and actions; (ii) any other truthful statement or disclosure required by law; or (iii) business-related intra-Company communications.

12. Cooperation. During and after the Employment Period, Executive shall assist and cooperate with the Company in connection with the defense or prosecution of any claim that may be made against or by the Company, or in connection with any ongoing or future investigation or dispute or claim of any kind involving the Company, including any proceeding before any arbitral, administrative, judicial, legislative, or other body or agency, including testifying in any proceeding to the extent such claims, investigations or proceedings relate to services performed or required to be performed by Executive, pertinent knowledge possessed by Executive, or any act or omission by Executive. Executive will also perform all acts and execute and deliver any documents that may be reasonably necessary to carry out the provisions of this paragraph. The Company will reimburse Executive for reasonable expenses Executive incurs in fulfilling Executive's obligations under this Section 12. Notwithstanding the foregoing, this Section shall not be applicable to any claim by the Company against Executive or by Executive against the Company.

13. Company Property. Executive agrees that all Confidential Information, trade secrets, drawings, designs, reports, computer programs or data, books, handbooks, manuals, files (electronic or otherwise), computerized storage media, papers, memoranda, letters, notes, photographs, facsimile, software, computers, smart phones and other documents (electronic or otherwise), materials and equipment of any kind that Executive has acquired or will acquire during the course of Executive's employment with the Company are and remain the property of the Company. Upon termination of employment with the Company, or sooner if requested by the Company, Executive agrees to return all such documents, materials and records to the Company and not to make or take copies of the same without the prior written consent of the Company. With regard to such documents, materials and records in electronic form, Executive shall first provide a copy to Company, and then irretrievably delete such electronic information from her electronic devices and accounts, including but not limited to computers, phones, personal email accounts, cloud storage accounts, and removable storage media. Executive agrees to provide the Company access to Executive's system as reasonably requested to verify that the necessary copying and/or deletion is completed. Executive acknowledges and agrees that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets, and other work areas, is subject to inspection by personnel of the Company at any time with or without notice. Executive acknowledges and agrees that Executive has no expectation of privacy with respect to the Company's telecommunications, networking or information processing systems (including, without limitation, files, e-mail messages and voice messages) and that Executive's activity and any files or messages on or using any of those systems may be monitored at any time without notice. Notwithstanding anything in this Agreement to the contrary, Executive shall be entitled to retain, following Executive's termination of employment, information showing Executive's compensation or relating to reimbursement of business expenses incurred by Executive, and copies of this Agreement, any other agreement between Executive and the Company and any Company benefit programs in which Executive participated.

14. Injunctive Relief and Other Remedies. Executive acknowledges that a breach of Sections 9 through 13 of this Agreement will result in material irreparable injury to the Company for which there is no adequate remedy at law, that it will not be possible to measure damages for such injuries precisely and that, in the event of such a breach or threat thereof, the Company shall be entitled to obtain a temporary restraining order and/or a preliminary and/or permanent injunction, without the necessity of posting a bond or of proving irreparable harm or injury as a result of such breach or threatened breach of Sections 9 through 13, restraining Executive from engaging in activities prohibited by Sections 9 through 13 and such other relief as may be required specifically to enforce any of the provisions in Sections 9 through 13. Executive further agrees that, if Executive breaches any of the provisions in Sections 9 through 13 of this Agreement, to the extent permitted by law, Executive shall (i) forfeit Executive's right to receive the balance of any compensation and/or benefits due Executive under this Agreement; (ii) pay over to the Company all compensation, profits, monies, accruals, increments or other benefits derived or received by Executive as the result of any action or transaction constituting a breach of any provision thereof; and (iii) pay over to the Company all costs and expenses incurred by the Company resulting from Executive's breach (including, without limitation, reasonable attorneys' fees and expenses in dealing with Executive's breach or any suits or actions with regard thereto) and for all damages (compensatory, along with punitive) that may be awarded in connection therewith. The provisions of this section shall not limit any other remedies available to the Company as a result of a breach of the provisions of this Agreement or otherwise. Additionally, each of the covenants and restrictions to which Executive is subject under this Agreement, including, without limitation those in Section 9 above, shall each be construed as independent of any other provision in this Agreement, and the existence of any claim or cause of action by Executive against the Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement by the Company of such covenants and restrictions.

15. Representations Regarding Prior Work and Legal Obligations.

15.1 Executive represents and warrants that Executive has no agreement or other legal obligation with any prior employer, or any other person or entity, that restricts Executive's ability to accept employment with the Company. Executive further represents and warrants that Executive is not a party to any agreement (including, without limitation, a non-competition, non-solicitation, no hire or similar agreement) and has no other legal obligation that restricts in any way Executive's ability to perform Executive's duties and satisfy Executive's other obligations to the Company, including, without limitation, those under this Agreement.

15.2 Executive represents and acknowledges that Executive has been instructed by the Company that at no time should Executive divulge to or use for the benefit of the Company or any Company Affiliates any trade secret or confidential or proprietary information of any previous employer or entity with which Executive was affiliated or of any other third-party. Executive expressly represents and warrants that Executive has not divulged or used any such information for the benefit of the Company or Company Affiliates and will not do so.

15.3 Executive represents and agrees that the Executive has not and will not misappropriate any intellectual property belonging to any other person or entity.

15.4 Executive acknowledges that the Company is basing important business decisions on these representations, agreements and warranties, and Executive affirms that all of the statements included herein are true. Executive agrees that Executive shall defend, indemnify and hold the Company harmless from any liability, expense (including attorneys' fees) or claim by any person in any way arising out of, relating to, or in connection with a breach and/or the falsity of any of the representations, agreements and warranties made by Executive in this Section 15.

16. D&O Insurance. During the Employment Period and for a reasonable period thereafter, the Company or any successor to the Company (and it shall be a condition of any agreement by the Company with any such successor that such successor) shall purchase and maintain, at its own expense, directors' and officers' liability insurance providing coverage to Executive on terms that are no less favorable than the coverage provided to other managers, directors and senior officers of the Company.

17. Miscellaneous Provisions.

17.1 IRCA Compliance. This Agreement, and Executive's employment with the Company, is conditioned on Executive's establishing Executive's identity and authorization to work as required by the Immigration Reform and Control Act of 1986 (IRCA).

17.2 Section 409A Compliance. To the extent applicable, it is intended that this Agreement comply with the provisions of Section 409A of the Internal Revenue Code and the guidance promulgated thereunder ("Section 409A"). This Agreement shall be administered in a manner consistent with this intent, and any provision that would cause the Agreement to fail to satisfy Section 409A shall have no force and effect until amended by the parties to comply with Section 409A (which amendment may be retroactive to the extent permitted by Section 409A). Unless otherwise expressly provided, any payment of compensation by Company to Executive, whether pursuant to this Agreement or otherwise, shall be made no later than the 15th day of the third month (*i.e.*, 2½ months) after the later of the end of the calendar year or the Company's fiscal year in which Executive's right to such payment vests (*i.e.*, is not subject to a "substantial risk of forfeiture" for purposes of Code Section 409A). For purposes of this Agreement, "Separation from Service" shall have the meaning given to such term under Section 409A. Each payment and each installment of any severance payments provided for under this Agreement shall be treated as a separate payment for purposes of application of Section 409A. To the extent that any severance payments come within the definition of "short term deferrals" or "involuntary severance" under Section 409A, such amounts shall be excluded from "deferred compensation" as allowed under Section 409A, and shall not be subject to the following Section 409A compliance requirements. All payments of "nonqualified deferred compensation" (within the meaning of Section 409A) are intended to comply with the requirements of Section 409A, and shall be interpreted in accordance therewith. Neither party individually or in combination may accelerate, offset or assign any such deferred payment, except in compliance with Section 409A. No amount shall be paid prior to the earliest date on which it is permitted to be paid under Section 409A and Executive shall have no discretion with respect to the timing of payments except as permitted under Section 409A. Any payments to which Section 409A applies which are subject to execution of a waiver and release which may be executed and/or revoked in a calendar year following the calendar year in which the payment event (such as Separation from Service) occurs shall commence payment only in the calendar year in which the release revocation period ends as necessary to comply with Section 409A. In the event that Executive is determined to be a "key employee" (as defined and determined under Section 409A) of the Company at a time when its stock is deemed to be publicly traded on an established securities market, payments determined to be "nonqualified deferred compensation" payable upon separation from service shall be made no earlier than (i) the first day of the seventh (7th) complete calendar month following such termination of employment, or (ii) Executive's death, consistent with the provisions of Section 409A. Any payment delayed by reason of the prior sentence shall be paid out in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule. All expense reimbursement or in-kind benefits subject to Section 409A provided under this Agreement or, unless otherwise specified in writing, under any Company program or policy, shall be subject to the following rules: (i) the amount of expenses eligible for reimbursement or in-kind benefits provided during one calendar year may not affect the benefits provided during any other year; (ii) reimbursements shall be paid no later than the end of the calendar year following the year in which the Executive incurs such expenses, and the Executive shall take all actions necessary to claim all such reimbursements on a timely basis to permit the Company to make all such reimbursement payments prior to the end of said period, and (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit. Notwithstanding anything herein to the contrary, no amendment may be made to this Agreement if it would cause the Agreement or any payment hereunder not to be in compliance with Section 409A.

17.3 Assignability and Binding Effect. This Agreement shall inure to the benefit of and shall be binding upon the heirs, executors, administrators, successors and legal representatives of Executive, and shall inure to the benefit of and be binding upon the Company, the Company Affiliates and their successors and assigns, but the obligations of Executive are personal services and may not be delegated or assigned. Executive shall not be entitled to assign, transfer, pledge, encumber, hypothecate or otherwise dispose of this Agreement, or any of Executive's rights and obligations hereunder, and any such attempted delegation or disposition shall be null and void and without effect. This Agreement may be assigned by the Company to a person or entity that is an affiliate or a successor in interest to substantially all of the business operations of the Company. Upon such assignment, the rights and obligations of the Company hereunder shall become the rights and obligations of such affiliate or successor person or entity. Further, in the event Executive becomes employed by a parent, subsidiary or other affiliate of the Company, this Agreement shall thereupon automatically be assigned to such parent, subsidiary or other affiliate and Executive consents to be bound by the provisions of this Agreement for the benefit of the Company and/or any such parent, subsidiary or other affiliate of the Company without the necessity that this Agreement be re-signed at the time of such transfer.

17.4 Right of Set-Off. To the extent permitted by applicable law, the Company may at any time offset against any amounts owed to Executive hereunder or otherwise due or to become due to Executive, or anyone claiming through or under Executive, any debt or debts due or to become due from Executive to the Company.

17.5 Severability and Blue Penciling. If any provision of this Agreement is held to be invalid, the remaining provisions shall remain in full force and effect. However, if any court determines that any covenant in this Agreement, is unenforceable because the duration, geographic scope or restricted activities thereof are overly broad, then such provision or part thereof shall be modified by reducing the overly broad duration, geographic scope or restricted activities by the minimum amount so as to make the covenant, in its modified form, enforceable.

17.6 Choice of Law and Forum; *Jury waiver*; Attorneys' Fees. This Agreement shall be interpreted and enforced in accordance with the laws of the State of New York, without regard to its conflict-of-law principles. The Parties agree that any dispute concerning or arising out of this Agreement or Executive's employment hereunder (or termination thereof) shall be litigated exclusively in an appropriate state or federal court in or closest to New York County, New York and hereby consent, and waive any objection, to the jurisdiction of any such court. *In any such litigation, Executive and the Company each hereby waive the right to a trial by jury and agree that any such litigation shall not be heard by a jury*. In the event a litigation or other legal proceeding is commenced to resolve any such dispute, the prevailing party in such litigation or proceeding shall be entitled to recover from the non-prevailing party all of its costs, charges, disbursements and fees (including reasonable attorneys' fees) incurred in connection with such litigation or proceeding and the underlying dispute.

17.7 Notices.

(a) Any notice or other communication under this Agreement shall be in writing and shall be delivered by hand, email, facsimile or mailed by overnight courier or by registered or certified mail, postage prepaid:

(i) If to Executive, to Executive's address on the books and records of the Company.

(ii) If to the Company, to _____, or at such other mailing address, email address or facsimile number as it may have furnished in writing to Executive.

(b) Any notice so addressed shall be deemed to be given: if delivered by hand or email, on the date of such delivery; if by facsimile, on the date of such delivery if receipt on such day is confirmed and, if not so confirmed, on the next business day; if mailed by overnight courier, on the first business day following the date of such mailing; and if mailed by registered or certified mail, on the third business day after the date of such mailing.

17.8 Survival of Terms. All provisions of this Agreement that, either expressly or impliedly, contain obligations that extend beyond termination of Executive's employment hereunder, including without limitation Sections 9-14 and 17 hereof, shall survive the termination of this Agreement and of Executive's employment hereunder for any reason.

17.9 Interpretation. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. The language in all parts of this Agreement shall in all cases be construed according to its fair meaning, and not strictly for or against any Party. The Parties acknowledge that both of them have participated in drafting this Agreement; therefore, any general rule of construction that any ambiguity shall be construed against the drafter shall not apply to this Agreement. In this Agreement, unless the context otherwise requires, the masculine, feminine and neuter genders and the singular and the plural include one another.

17.10 Further Assurances. The Parties will execute and deliver such further documents and instruments and will take all other actions as may be reasonably required or appropriate to carry out the intent and purposes of this Agreement.

17.11 Voluntary and Knowing Execution of Agreement. Executive acknowledges that (i) Executive has had the opportunity to consult an attorney regarding the terms and conditions of this Agreement before executing it, (ii) Executive fully understands the terms of this Agreement including, without limitation, the significance and consequences of the post-employment restrictive covenants in Section 9 above, and (iii) Executive is executing this Agreement voluntarily, knowingly and willingly and without duress.

17.12 Entire Agreement. This Agreement constitutes the entire understanding and agreement of the Parties concerning the subject matter hereof, and it supersedes all prior negotiations, discussions, correspondence, communications, understandings and agreements regarding such subject matter. Each Party acknowledges and agrees that such Party is not relying on, and may not rely on, any oral or written representation of any kind that is not set forth in writing in this Agreement.

17.13 Waivers and Amendments. This Agreement may be altered, amended, modified, superseded or cancelled, and the terms hereof may be waived, only by a written instrument signed by the Parties or, in the case of a waiver, by the Party alleged to have waived compliance. Any such signature of the Company must be by an authorized signatory for the Company. No delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of any Party of any such right, power or privilege, nor any single or partial exercise of any such right, power or privilege, preclude any other or further exercise thereof or the exercise of any other such right, power or privilege.

17.14 Counterparts. This Agreement may be executed in counterparts, and each counterpart, when executed, shall have the efficacy of a signed original. Photographic copies, electronically scanned copies and other facsimiles of this Agreement (including such signed counterparts) may be used in lieu of the originals for any purpose.

[The remainder of this page is intentionally blank; signature page follows.]

IN WITNESS WHEREOF, the Parties have executed and delivered this Agreement as of the date first above written.

Carlo Russo

[Insert name of Genenta's US subsidiary]

By:
Name:
Title:

[Signature page to Employment Agreement.]

EXHIBIT A

LIST OF PRIOR INVENTIONS AND ORIGINAL WORKS OF AUTHORSHIP

Title	Date	Identifying Number or Brief Description

Exhibit 10.11

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT (this "Agreement"), dated as of [●], between **[Insert name of Genenta's US subsidiary]** (the "Company") and Richard B. Slansky ("Executive," together with the Company, the "Parties" and, each, a "Party").

WHEREAS, Genenta Science S.p.A. ("Parent") is the parent company of the Company;

WHEREAS, Parent is in the process of an initial public offering (the "IPO");

WHEREAS, the effectiveness of this Agreement is conditioned on the successful completion of the IPO; and

WHEREAS, effective on the later of the date of the IPO or July 1, 2021 (the "Commencement Date"), the Company desires to employ Executive, and Executive desires to accept such employment, on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, on the basis of the foregoing premises and in consideration of the mutual covenants and agreements contained herein, the Parties agree as follows:

1. Employment; Title; Duties and Location. Contingent on the successful completion of the IPO, the Company hereby agrees to employ Executive, and Executive hereby accepts employment with the Company, on the terms and subject to the conditions set forth herein. During the Employment Period (as defined in Section 2 below), Executive shall serve the Company as Chief Financial Officer ("CFO") and shall report exclusively and directly to the Chief Executive Officer of the Company (the "CEO"). Executive shall perform the duties consistent with Executive's title and position and such other duties commensurate with such position and title as shall be specified or designated by the CEO from time to time. Subject to Executive's appointment thereto, and without additional compensation, Executive shall hold such other or additional titles and serve, during the Employment Period, in such other or additional capacities to which Executive may be appointed from time to time in the Company and its affiliated companies, provided such titles and additional capacities are consistent with Executive's above-stated position and duties. The principal place of performance by Executive of Executive's duties hereunder shall be in California, although Executive may be required to travel to the Company's offices in New York City from time to time, as well as other reasonable travel in connection with the performance of Executive's duties.

2. Term. Executive's employment hereunder shall commence on the Commencement Date and continue until terminated pursuant to the terms of Section 6 below (the "Employment Period").

3. Compensation. During the Employment Period only (unless otherwise expressly provided for herein), Executive shall be entitled to the following compensation and benefits.

3.1 Salary. Executive shall receive a base salary (the "Base Salary") payable in substantially equal installments in accordance with the Company's normal payroll practices and procedures in effect from time to time and subject to applicable withholdings and deductions. Executive's starting Base Salary shall be at the annual rate of $240,000. From time to time, the Company, at its sole discretion, may review and adjust Executive's Base Salary, except that Executive's Base Salary may only be decreased if the decrease is the same, on a percentage basis, for all similarly situated executives due to business conditions**.**

3.2 Discretionary Bonus. Executive shall be eligible to receive a discretionary bonus (a "Discretionary Bonus") with respect to each fiscal year of the Company (a "Fiscal Year") based on the terms and conditions hereof. The amount of any Discretionary Bonus for a Fiscal Year may be up to 30% of Executive's Base Salary as of the end of such Fiscal Year, based upon an individualized determination, by the CEO, of the achievement of objectives to be set from time to time by the CEO and approved by the Board of Directors of the Company (the "Board"). To be eligible for a Discretionary Bonus, Executive must be employed by the Company at the time such Bonus is paid. Any Discretionary Bonus for a given Fiscal Year shall be paid in the following Fiscal Year as soon as practicable after it is determined that such bonus has been awarded. The payment and amount of any Discretionary Bonus shall be determined in the sole discretion of the Company and is not guaranteed in any way.

3.3 Equity. Subject to the approval of the Board of Directors of Parent or its Compensation Committee, Executive will be granted an equity award (the "Equity Award") under an equity incentive plan to be adopted by Parent by no later than July 31, 2021 (the "Equity Plan"). The Equity Award will be subject to the terms and conditions of the Equity Plan and an applicable equity award agreement.

3.4 Benefits. Executive shall have the right to receive or participate in all employee benefit programs and perquisites generally established by the Company from time to time for employees similarly situated to Executive, subject to the general eligibility requirements and other terms of such programs and perquisites, and subject to the Company's right to amend, terminate or take other similar action with respect to any such programs and perquisites. Subject to the foregoing, the Company anticipates that such employment benefit programs will include, without limitation, medical insurance, dental insurance, vision insurance, and a 401K plan (with a minimal matching program).

3.5 Vacation and Other Paid Time Off. Executive shall be entitled to 20 days of paid vacation, as well as sick days and any other paid time off, each year in accordance with then current Company policy.

3.6 Required Taxes and Withholdings. The Company shall withhold from any payments made to Executive (including, without limitation, those made under this Agreement) all federal, state, local or other taxes and withholdings as shall be required pursuant to any law or governmental regulation or ruling.

4. Exclusivity and Best Efforts. During the Employment Period, Executive shall (i) in all respects conform to and comply with the lawful directions and instructions given to Executive by the Company; (ii) devote Executive's entire business time, energy and skill to Executive's services under this Agreement; (iii) use Executive's best efforts to promote and serve the interests of the Company and to perform Executive's duties and obligations hereunder in a diligent, trustworthy, businesslike, efficient and lawful manner; (iv) comply with all applicable laws and regulations, as well as the policies and practices established by the Company from time to time and made applicable to its employees generally or senior executives; (v) not engage in any other business, profession or occupation for compensation or otherwise; and (vi) not engage in any activity that, directly or indirectly, impairs or conflicts with the performance of Executive's obligations and duties to the Company, provided, however, that the foregoing shall not prevent the Executive from (i) continuing to serve on the boards of directors listed on Exhibit C, (ii) serving, with the prior written consent of the Board, as a member of the boards of directors or advisory boards (or their equivalents in the case of a non-corporate entity) of non-competing businesses and charitable organizations, (iii) managing Executive's personal affairs and passive personal investments, and (iv) participating in charitable, civic, educational, professional or community affairs, so long as, in the aggregate, any such activities do not unreasonably interfere or conflict with the Executive's duties hereunder or create a potential business or fiduciary conflict with the Company, as reasonably determined by the Company.

5. Reimbursement for Expenses. Executive is authorized to incur reasonable expenses in the discharge of the services to be performed hereunder in accordance with the Company's expense reimbursement policies, as the same may be modified by the Company from time to time in its sole and complete discretion (the "Reimbursement Policies"). Subject to the provisions of Section 17.2 below (Section 409A Compliance), the Company shall reimburse Executive for all such proper expenses upon presentation by Executive of itemized accounts of such expenditures in accordance with the terms of the Reimbursement Policies.

6. Termination.

6.1 Death. Executive's employment shall immediately and automatically be terminated upon Executive's death.

6.2 Disability. The Company may, subject to applicable law, terminate Executive's employment due to a Disability by providing written notice of such termination and its effective date to Executive. For purposes of this Agreement, "Disability" means a "disability" that entitles Executive to benefits under the applicable Company long-term disability plan covering Executive and, in the absence of such a plan, that Executive shall have been unable, due to physical or mental incapacity, to substantially perform Executive's duties and responsibilities hereunder for 120 days out of any 365 day period, whether or not consecutive. In the event of any question as to the existence, extent or potentiality of Executive's Disability upon which the Company and Executive cannot agree, such question shall be resolved by a qualified, independent physician mutually agreed to by the Company and Executive, the cost of such examination to be paid by the Company. If the Company and Executive are unable to agree on the selection of such an independent physician, each shall appoint a physician and those two physicians shall select a third physician who shall make the determination of whether Executive has a Disability. The written medical opinion of such physician shall be conclusive and binding upon each of the Parties as to whether a Disability exists and the date when such Disability arose. This section shall be interpreted and applied so as to comply with the provisions of the Americans with Disabilities Act (to the extent applicable) and any applicable state or local laws.

6.3 For Cause by the Company. The Company may terminate Executive's employment for Cause, at any time, upon written notice reasonably describing the nature of such Cause. For purposes of this Agreement, the term "Cause" means Executive's (i) willful misconduct; (ii) willful or gross neglect of Executive's job duties; (iii) material failure to materially perform Executive's job duties; (iv) refusal to follow a lawful directive of the Company that is materially related to and consistent with the provisions of Section 1 above; (v) material failure to materially comply with the Company's policies and practices; (vi) act of moral turpitude, theft, fraud or dishonesty; (vii) commission of any felony or misdemeanor (other than minor traffic violations or offenses of a comparable magnitude not involving dishonesty, fraud or breach of trust); (viii) material breach of any material term of a contractual agreement between Executive and the Company, including, without limitation, this Agreement; or (ix) willful act that is (or reasonably would be expected to be) materially damaging or detrimental to the Company; provided, however, that, in the event of conduct described in clauses (iii), (iv), (v) or (viii) that is capable of being cured, Cause shall exist only if the Company provides written notice to Executive reasonably detailing such grounds giving rise to Cause and Executive fails to cure such grounds for Cause to the reasonable satisfaction of the Company within two (2) business days after delivery to Executive of such written notice, if reasonably curable within two (2) business days, or, if not, then within such time as is reasonable under the circumstances, which in no event shall exceed twenty (20) business days. Notwithstanding the foregoing, notice and an opportunity to cure an event giving rise to Cause shall not be required for any event that is the same or of similar to an event that was the subject of a prior notice to cure. Executive's date of termination in the event Executive's employment is terminated for Cause shall be the date on which Executive is given notice of termination under this Section 6.3, except, if a notice period is required, Executive's date of termination shall be upon the expiration of said notice period if Executive fails to previously cure the grounds giving rise to Cause. If, subsequent to termination of Executive's employment for a reason other than for Cause, the Company learns that, during the Employment Period, Cause existed to terminate Executive's employment on a ground that would not have required notice and an opportunity to cure, the Company may retroactively designate Executive's termination of employment to be for Cause under this Section 6.3.

6.4 Resignation by Executive for Good Reason. Executive may resign Executive's employment hereunder for Good Reason, at any time, provided that Executive provides the Company with ten (10) days' prior written notice of such resignation and such notice is given within thirty (30) days of when Good Reason first arises. For the purpose of this Agreement, "Good Reason" means (i) a material and substantial diminution in Executive's duties, authority, or responsibilities that would be inconsistent with Executive's position (other than while Executive is temporarily physically or mentally incapacitated, as permitted under Section 8 below or as required by applicable law), (ii) a material failure by the Company to pay Executive's compensation as provided for herein, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith; (iii) a change in the location of Executive's principal place of performance from other than that specified in Section 1 above; or (iv) other material breach by the Company of a material provision of this Agreement or any other agreement between the Company and Executive; provided (x) Executive has provided the Company with written notice reasonably detailing the grounds giving rise to Good Reason within thirty (30) days of the occurrence thereof or, if later, within thirty (30) days of the date upon which Executive first becomes aware of such grounds, and (y) the Company fails to cure such grounds within thirty (30) days after delivery to it of such written notice. Notwithstanding the foregoing, during the Employment Period, in the event that the Company reasonably believes that Executive may have engaged in conduct that could constitute Cause hereunder, the Company may, in its sole and absolute discretion, suspend Executive from performing Executive's duties hereunder for a period of up to sixty (60) days, and in such event such suspension shall not constitute an event pursuant to which Executive may terminate this Agreement with Good Reason; provided, however, that no such suspension shall alter the Company's obligations under this Agreement (including, without limitation, its obligations to provide Executive compensation and benefits) during such period of suspension. Executive's date of termination in the event Executive resigns Executive's employment for Good Reason shall be the effective date of Executive's notice of resignation for Good Reason, except that Company may waive all or any part of the above-referenced 10-day notice period or of the 30-day cure period, in which event Executive's date of termination shall be the last day of such notice or cure period that has not been waived or, if the entire notice or cure period has been waived, the date that Executive provided notice of the event giving rise to Good Reason or of Executive's resignation for Good Reason.

6.5 By the Company Without Cause or By Executive Without Good Reason. The Company may terminate Executive's employment without Cause, at any time, with or without prior notice, in its sole and complete discretion, by providing written notice of such termination and its effective date to Executive. Likewise, Executive may terminate Executive's employment without Good Reason upon at least sixty (60) days prior written notice to the Company without any liability. Termination of Executive's employment without Cause by the Company or without Good Reason by Executive shall not include termination of Executive's employment due to Executive's death or Disability.

6.6 Resignation from Other Positions. Upon termination of Executive's employment for any reason, Executive shall, upon request of the Company, immediately be deemed to have resigned from all boards, offices and appointments held by Executive in or on behalf of the Company. In furtherance hereof, upon Executive's termination of employment, Executive, at the direction of the Board, shall immediately submit to the Company letter(s) of resignation for any such boards, offices and appointments. If Executive fails to tender such letter(s) of resignation, then the governing body or person with respect to such boards, offices and appointments will be empowered to remove Executive from such boards, offices and appointments.

7. Effect of Termination of Employment.

7.1 Generally. In the event Executive's employment with the Company terminates, Executive shall have no right to receive any compensation, benefits or any other payments or remuneration of any kind from the Company, except as otherwise provided by this Section 7, in Section 12 below, in any separate written agreement between Executive and the Company or as may be required by law. In the event Executive's employment with the Company is terminated for any reason, Executive shall receive the following (collectively, the "Accrued Obligations"): (i) Executive's Base Salary through and including the effective date of Executive's termination of employment (the "Termination Date"), which shall be paid on the Termination Date; (ii) payment for accrued unused vacation time, subject to the Company's then current vacation policy, which shall also be paid on the Termination Date; (iii) payment of any vested benefit due and owing under any employee benefit plan, policy or program pursuant to the terms of such plan, policy or program; and (iv) payment for unreimbursed business expenses subject to, and in accordance with, the terms of Section 5 above, which payment shall be made within 30 days after Executive submits the applicable supporting documentation to the Company, and in any event no later than on or before the last day of Executive's taxable year following the year in which the expense was incurred.

7.2 Severance Benefits. In the event that Executive's employment is terminated by the Company pursuant to Section 6.5 above (without Cause) or by Executive pursuant to Section 6.4 hereof (Good Reason), in addition to the Accrued Obligations, Executive shall be entitled to receive severance benefits (the "Severance Benefits"), subject to and in accordance with the terms of this Section 7.2.

(a) Severance Benefits Not in Connection with a Change in Control. Except as provided in Section 7.2(b) below, the Severance Benefits shall consist of the payments and benefits provided by this Section 7.2(a).

(i) Executive shall receive payment of an amount (the "Severance Pay") equal to Executive's Base Salary immediately prior to the Termination Date (or, if Good Reason was attributable to the Company's failure to pay the minimum amount of Base Salary provided herein, such minimum amount) for the period of one year (the "Severance Period"). The Severance Pay shall be paid in the form of salary continuation pursuant to the terms and conditions of Section 3.1 above, commencing within ninety (90) days following the Termination Date on the first regularly scheduled payroll date of the Company that is practicable after the effective date of the Separation Agreement (defined in Section 7.2(c) below), *except* that, if the Separation Agreement may be executed and/or revoked in a calendar year following the calendar year in which the Termination Date occurs, the Severance Pay shall commence on the first regularly scheduled payroll date of the Company in the calendar year in which the consideration or, if applicable, release revocation period ends to the extent necessary to comply with Section 409A (as defined in Section 17.2 below). The first such payment shall include payment for any payroll dates between the Termination Date and the date of such payment.

(ii) Executive shall receive a Discretionary Bonus for the Fiscal Year in which the Termination Date occurs, pro-rated for the portion of such Fiscal Year Executive was employed hereunder. Any such Discretionary Bonus shall be determined and paid in accordance with the terms of Section 3.2 above.

(b) Severance Benefits in Connection with a Change in Control. In the event that Executive's employment is terminated by the Company pursuant to Section 6.5 above (without Cause) or by Executive pursuant to Section 6.4 hereof (Good Reason) within ninety (90) days prior to, or twelve (12) months after, a Change of Control (defined in Section 7.2(b)(iii) below), the Severance Benefits shall consist of the payments and benefits provided by this Section 7.2(b).

(i) Generally. Executive shall receive payment of an amount (the "Severance Pay") equal to Executive's Base Salary immediately prior to the Termination Date (or, if Good Reason was attributable to the Company's failure to pay the minimum amount of Base Salary provided herein, such minimum amount) for the period of two (2) years (the "Severance Period"). The Severance Pay shall be paid in the form of salary continuation pursuant to the terms and conditions of Section 3.1 above, commencing within ninety (90) days following the Termination Date on the first regularly scheduled payroll date of the Company that is practicable after the effective date of the Separation Agreement (defined in Section 7.2(c) below), *except* that, if the Separation Agreement may be executed and/or revoked in a calendar year following the calendar year in which the Termination Date occurs, the Severance Pay shall commence on the first regularly scheduled payroll date of the Company in the calendar year in which the consideration or, if applicable, release revocation period ends to the extent necessary to comply with Section 409A (as defined in Section 17.2 below). The first such payment shall include payment for any payroll dates between the Termination Date and the date of such payment.

(ii) Section 280G. If (a) Executive's termination of employment giving rise Severance Benefits under this Section 7.2(b) results in a "Separation from Service" (within the meaning of Section 409A (defined in Section 17.2 below)) by the Executive, and (b) the Change in Control constitutes a change in ownership or effective control of Company or a change in the ownership of a substantial portion of the assets of the Company (within the meaning of Section 280G(b)(2)(i) of the Internal Revenue Code of 1986, as amended (the "Code"), the Severance Benefits shall be subject to mitigation as provided in Treasury Regulations Section 1.280G-1 Q&A 42(c)(5), or, in lieu of the Severance Benefits provided under this Section 7.2(b), Executive, in Executive's complete and sole discretion, may elect to receive an alternative severance payment (the "Alternative Payment"), not subject to mitigation, payable at the same time the Severance Benefits would otherwise have been paid. Executive must give written notice to Company of such election: (i) within fifteen (15) days prior to the end of the Notice Period after resignation with Good Reason; or (ii) within fifteen (15) days prior to the end of the Notice Period after termination by Company without Cause (each, an "Alternative Payment Notice"). For purposes of this Agreement, the "Alternative Payment" shall be a payment made by Company in the form provided for in Section 7.2(b)(i) above to Executive in an amount equal to the product of 2.99 (or, if Code Section 280G(b)(2)(A)(ii) is amended providing for a safe harbor multiple other than 3, then the multiple as amended, less 0.01) *multiplied by* Executive's "base amount" (as defined in Code Section 280G(b)(3)); provided, however, that the amount of the Alternative Payment shall be reduced by the value of acceleration (as determined under Code Section 280G and the regulations thereunder) of any equity, stock options, incentive compensation or deferred compensation accelerated by reason of termination to the extent required to be included in the Executive's "base amount" pursuant to Code Section 280G. The value (as determined under Code Section 280G and the regulations thereunder) of acceleration of vesting of equity, stock options, incentive compensation or deferred compensation shall be taken into account to the minimum extent necessary so as not to violate Treasury Regulations Section 1.280G-1 Q&A 42(c).

(iii) Definition of Change in Control. As used herein, "Change in Control" means the occurrence of any of the following events during the Employment Period: (i) any direct or indirect sale, lease, license, exchange or other transfer (in one transaction or a series of related transactions) of all, or substantially all of the business and/or assets of the Company and/or of Parent; (ii) a direct or indirect merger or consolidation of the Company and/or of Parent, and the Company and/or Parent is not the surviving entity; (iii) a direct or indirect reorganization or liquidation of the Company and/or Parent; (iv) a direct or indirect merger, consolidation, tender offer or any other transaction involving the Company and/or Parent if the equity holders of the Company and/or Parent, as applicable, immediately before such merger, consolidation, tender offer or other transaction do not own, directly or indirectly, immediately following such merger, consolidation, tender offer or other transaction, more than fifty percent (50%) of the combined voting power of the outstanding voting securities of the entity resulting from such merger, consolidation, tender offer or other transaction; (v) a change in the composition of the Company's and/or Parent's Board as a result of which fewer than a majority of the directors are Incumbent Directors (defined below); or (vi) the consummation of any other transaction involving a significant issuance of the Company's and/or Parent's securities, or other material event, that the Company's and/or Parent's Board determines to be a Change in Control. As used herein, "Incumbent Directors" means directors of the Company or Parent who either: (A) are directors of the Company or Parent as of the Commencement Date hereof; or (B) are nominated for election to the Board of the Company or Parent with the affirmative votes of at least a majority of the directors of the Company or Parent who are Incumbent Directors ("Approved Successors") described in (A) above at the time of such nomination; or (C) are nominated for election to the Board of the Company or Parent with the affirmative votes of at least a majority of the directors of the Company or Parent who are Incumbent Directors or their Approved Successors. Notwithstanding the foregoing, "Incumbent Directors" shall not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company or Parent.

(c) Separation Agreement and Other Conditions for Severance Benefits. Provision of the Severance Benefits is conditioned on (i) Executive's continued compliance in all material respects with Executive's continuing obligations to the Company, including, without limitation, the terms of this Agreement that survive termination of Executive's employment with the Company, and (ii) Executive signing (without revoking if such right is provided under applicable law) a separation agreement and release in a form of that provided to Executive by the Company on or about the Termination Date (the "Separation Agreement"). Executive must so execute the Separation Agreement within 60 days following the Termination Date (or such shorter time as may be set forth in the Separation Agreement).

8. Notice of Termination. In the event Executive elects to terminate Executive's employment hereunder by resigning with or without Good Reason under Sections 6.4 or 6.5 above, Executive shall provide the Company with the applicable prior written notice of termination required by such Sections (the "Notice Period"). The Company may, in its discretion, waive all or any portion of such Notice Period. The Company may require that, during the Notice Period, or part or parts thereof, Executive does not do any of the following: (i) enter the Company's premises; (ii) perform any work for the Company; (iii) undertake any work for any third party whether paid or unpaid and whether as an employee or otherwise; (iv) have any contact or communication with any client, customer or supplier of the Company; or (v) have any contact or communication with any employee, officer, director, agent or consultant of the Company. Additionally, during the Notice Period, or any part or parts thereof, the Company may require Executive to do any of the following: (i) perform special projects or perform duties not within Executive's normal duties (provided such duties are commensurate with Executive's position and title) or perform some but not all of Executive's normal duties; and (ii) keep the Company informed of Executive's whereabouts so that Executive can be contacted if the need arises for Executive to perform any duties provided by clause (i) of this sentence. The Company retains the right to terminate Executive's employment under Section 6.3 above during the Notice Period.

9. Confidential Information.

9.1 Protection of Confidential Information. For purposes of Sections 9-14 hereof, the term "Company" shall refer to not only the Company, but also, jointly and severally, any entity, directly or indirectly, through one or more intermediaries, controlled by, in control of, or under common control with, the Company (collectively, "Company Affiliates"). During the Employment Period and at all times thereafter, Executive will not, except to the extent necessary to perform Executive's duties hereunder or as required by law, directly or indirectly, use or disclose to any third person, without the prior written consent of the Company, any Confidential Information (defined 9.2 below) of the Company. If it is necessary for Executive to use or disclose Confidential Information so as to comply with any law, rule, regulations, court order, subpoena or other governmental mandate or investigation, Executive shall give prompt written notice to the Company of such requirement (to the extent legally permissible), disclose no more information than is so required, and cooperate with any attempts by the Company to obtain a protective order or similar treatment. In the event that the Company is bound by a confidentiality agreement or understanding with a customer, vendor, supplier or other party regarding the confidential information of such customer, vendor, supplier or other party, which is more restrictive than specified above in this Section 9, and of which Executive has notice or is aware, Executive shall adhere to the provisions of such other confidentiality agreement, in addition to those of this Section 9. Executive shall exercise reasonable care to protect all Confidential Information. Executive will immediately give notice to the Company of any unauthorized use or disclosure of Confidential Information. Executive hereby represents and warrants that it shall assist the Company in remedying any such unauthorized use or disclosure of Confidential Information.

9.2 Confidential Information Defined. For purposes of this Agreement, "Confidential Information" means all information of a confidential or proprietary nature regarding the Company, its business or properties that the Company has furnished or furnishes to Executive, whether before or after the date of this Agreement, or is or becomes available to Executive by virtue of Executive's employment with the Company, whether tangible or intangible, and in whatever form or medium provided, as well as all such information generated by Executive that, in each case, has not been published or disclosed to, and is not otherwise known to, the public. Confidential Information includes, without limitation, customer lists, customer requirements and specifications, designs, financial data, sales figures, costs and pricing figures, marketing and other business plans, product development, marketing concepts, personnel matters (including employee skills and compensation), drawings, specifications, instructions, methods, processes, techniques, computer software or data of any sort developed or compiled by the Company, formulae or any other information relating to the Company's services, products, sales, technology, research data, software and all other know-how, trade secrets or proprietary information, or any copies, elaborations, modifications and adaptations thereof. For the avoidance of doubt, Executive acknowledges and agrees that Confidential Information protected under this Agreement includes information regarding pay, bonuses, benefits and perquisites offered to or received by employees of the Company, as well as non-public information regarding the unique and special skills of specific employees and how such skills are valuable and integral to the Company's operations. Notwithstanding the foregoing, Confidential Information shall not include any information (i) that is generally known to the industry or the public other than as a result of Executive's breach of this covenant; (ii) that is made available to Executive by a third party without that party's breach of any confidentiality obligation; or (iii) which was developed by Executive outside or independent of Executive's performance of Executive's obligation to render services on behalf of the Company.

9.3 Immunity for Certain Limited Disclosures. Executive acknowledges that Executive has been notified in accordance with the federal Uniform Trade Secrets Act (18 U.S. Code § 1833(b)(1)) that an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; ***and*** (ii) solely for the purpose of reporting or investigating a suspected violation of law; ***or*** (b) is made in a complaint or other document filed in a lawsuit or other proceeding, ***if*** such filing is made under seal.

9.4 Permitted Disclosures. Executive also acknowledges that nothing in this Agreement shall be construed to prohibit Executive from reporting possible violations of law or regulation to any governmental agency or regulatory body or making other disclosures that are protected under any law or regulation, or from filing a charge with or participating in any investigation or proceeding conducted by any governmental agency or regulatory body.

10. Intellectual Property.

10.1 The Company's Proprietary Rights. Executive acknowledges and agrees that all Intellectual Property (defined below) created, made or conceived by Executive (solely or jointly) during Executive's employment by the Company (regardless of whether such Intellectual Property was created, conceived or produced during Executive's regular work hours or at any other time) that relates to the actual or anticipated businesses of the Company or results from or is suggested by any work performed by employees or independent contractors for or on behalf of the Company ("Company Intellectual Property") shall be deemed "work for hire" and shall be and remain the sole and exclusive property of the Company for any and all purposes and uses whatsoever as soon as Executive conceives or develops such Company Intellectual Property, and Executive hereby agrees that its assigns, executors, heirs, administrators or personal representatives shall have no right, title or interest of any kind or nature therein or thereto, or in or to any results and proceeds therefrom. If for any reason such Company Intellectual Property is not deemed to be "work-for-hire," then Executive hereby irrevocably and unconditionally assigns all rights, title, and interest in such Company Intellectual Property to the Company and agrees that the Company is under no further obligation, monetary or otherwise, to Executive for such assignment. Executive also hereby waives all claims to any moral rights or other special rights ("Moral Rights"), including, without limitation, all rights of paternity, integrity, disclosure and withdrawal and any other rights that may be known as or referred to as "moral rights," "artist's rights," "droit moral" or the like, that Executive may have or may accrue in any Company Intellectual Property. To the extent that any such Moral Rights cannot be assigned under applicable law, Executive hereby ratifies and consents to any action that may be taken with respect to such Moral Rights by or on behalf of the Company and waives and agrees not to enforce any and all such rights, including, without limitation, any limitation on subsequent modification, to the extent permitted under applicable law. Executive shall promptly disclose in writing to the Company the existence of any and all Company Intellectual Property. As used in this Agreement, "Intellectual Property" shall mean and include any ideas, inventions (whether or not patentable), designs, improvements, discoveries, innovations, patents, patent applications, trademarks, service marks, trade dress, trade names, trade secrets, works of authorship, copyrights, copyrightable works, films, audio and video tapes, other audio and visual works of any kind, scripts, sketches, models, formulas, tests, analyses, software, firmware, computer processes, computer and other applications, creations and properties, Confidential Information and any other patents, inventions or works of creative authorship.

10.2 Waiver. In the event that Executive owns or claims any rights to Company Intellectual Property that cannot be assigned to the Company, Executive irrevocably waives all claims and the enforcement of all such rights against the Company, and their respective officers directors, assigns and licensees, and agrees, at the Company's request and expense, to consent to and join in any action to enforce the Company's interests in such Company Intellectual Property. As to any rights to Company Intellectual Property that cannot be assigned to the Company or waived by Executive, Executive irrevocably grants to the Company an exclusive, irrevocable, perpetual, worldwide, fully paid and royalty-free license, with rights to license and sublicense, to reproduce, create derivative works, distribute, publicly perform and publicly display by all means now known or later developed, any and all such Company Intellectual Property.

10.3 Cooperation Regarding Intellectual Property. Executive agrees to assist the Company, and to take all reasonable steps, with securing patents, registering copyrights and trademarks, and obtaining any other forms of protection for the Company Intellectual Property in the United States and elsewhere. In particular, at the Company's expense (except as noted in clause (i) below), Executive shall forthwith upon request of the Company execute all such assignments and other documents (including applications for patents, copyrights, trademarks, and assignments thereof) and take all such other action as the Company may reasonably request in order (i) to vest in the Company all of Executive's right, title, and interest in and to such Company Intellectual Property, free and clear of liens, mortgages, security interests, pledges, charges, and encumbrances ("Liens") (and Executive agrees to take such action, at Executive's expense, as is necessary to remove all such Liens) and (ii), if patentable or copyrightable, to obtain patents or copyrights (including extensions and renewals) therefor in any and all countries in such name as the Company shall determine. In the event that Executive is unable or unavailable or shall refuse to sign any lawful or necessary documents required in order for the Company to apply for and obtain any copyright or patent with respect to any work performed by Executive in the course of his employment with the Company (including applications or renewals, extensions, divisions or continuations), Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agents and attorneys-in-fact to act for and in Executive's behalf, and in Executive's place and stead, to execute and file any such applications or documents and to do all other lawfully permitted acts to further the prosecution and issuance of copyrights and patents with respect to such Company Intellectual Property with the same legal force and effect as if executed or undertaken by Executive.

10.4 No infringement. Executive represents and warrants to the Company that all Intellectual Property Executive delivers to the Company shall be original and shall not infringe upon or violate any patent, copyright or proprietary right of any person or third party.

10.5 License to Prior Invention. If Executive in the course of Executive's employment for the Company incorporates into a Company product Intellectual Property that Executive has, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of Executive's employment with the Company in which Executive has a property right (each, a "Prior Invention"), Executive hereby grants to the Company a perpetual, nonexclusive, royalty-free, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use and sell such Prior Invention. Executive hereby represents and warrants that all Prior Inventions have been listed by Executive on Exhibit A hereto or, if no such list is attached, that there are no Prior Inventions. Executive will not incorporate any Intellectual Property owned by any third party into any Company Intellectual Property without the Company's prior written permission.

10.6 Severability. The Company and the Executive acknowledge that any provision in this Agreement requiring Executive to assign his rights in any Company Intellectual Property does not apply to Intellectual Property which otherwise qualifies under the provisions of Section 2870 of the California Labor Code or any such equivalent statute from another state. By signing this Agreement, Executive acknowledges receipt of a copy of this Agreement and of written notification of the provisions of Section 2870 (which is attached hereto as Exhibit B).

11. Non-Disparagement. During and after the Employment Period, Executive shall not make any disparaging statement (verbal, written or otherwise) about the Company or its financial status, business, personnel, directors, officers, consultants, services or business methods. This Section does not apply to (i) truthful statements made in connection with legal proceedings, governmental and regulatory investigations and actions; (ii) any other truthful statement or disclosure required by law; or (iii) business-related intra-Company communications.

12. Cooperation. During and after the Employment Period, Executive shall assist and cooperate with the Company in connection with the defense or prosecution of any claim that may be made against or by the Company, or in connection with any ongoing or future investigation or dispute or claim of any kind involving the Company, including any proceeding before any arbitral, administrative, judicial, legislative, or other body or agency, including testifying in any proceeding to the extent such claims, investigations or proceedings relate to services performed or required to be performed by Executive, pertinent knowledge possessed by Executive, or any act or omission by Executive. Executive will also perform all acts and execute and deliver any documents that may be reasonably necessary to carry out the provisions of this paragraph. The Company will reimburse Executive for reasonable expenses Executive incurs in fulfilling Executive's obligations under this Section 12. Notwithstanding the foregoing, this Section shall not be applicable to any claim by the Company against Executive or by Executive against the Company.

13. Company Property. Executive agrees that all Confidential Information, trade secrets, drawings, designs, reports, computer programs or data, books, handbooks, manuals, files (electronic or otherwise), computerized storage media, papers, memoranda, letters, notes, photographs, facsimile, software, computers, smart phones and other documents (electronic or otherwise), materials and equipment of any kind that Executive has acquired or will acquire during the course of Executive's employment with the Company are and remain the property of the Company. Upon termination of employment with the Company, or sooner if requested by the Company, Executive agrees to return all such documents, materials and records to the Company and not to make or take copies of the same without the prior written consent of the Company. With regard to such documents, materials and records in electronic form, Executive shall first provide a copy to Company, and then irretrievably delete such electronic information from her electronic devices and accounts, including but not limited to computers, phones, personal email accounts, cloud storage accounts, and removable storage media. Executive agrees to provide the Company access to Executive's system as reasonably requested to verify that the necessary copying and/or deletion is completed. Executive acknowledges and agrees that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets, and other work areas, is subject to inspection by personnel of the Company at any time with or without notice. Executive acknowledges and agrees that Executive has no expectation of privacy with respect to the Company's telecommunications, networking or information processing systems (including, without limitation, files, e-mail messages and voice messages) and that Executive's activity and any files or messages on or using any of those systems may be monitored at any time without notice. Notwithstanding anything in this Agreement to the contrary, Executive shall be entitled to retain, following Executive's termination of employment, information showing Executive's compensation or relating to reimbursement of business expenses incurred by Executive, and copies of this Agreement, any other agreement between Executive and the Company and any Company benefit programs in which Executive participated.

14. Injunctive Relief and Other Remedies. Executive acknowledges that a breach of Sections 9 through 13 of this Agreement will result in material irreparable injury to the Company for which there is no adequate remedy at law, that it will not be possible to measure damages for such injuries precisely and that, in the event of such a breach or threat thereof, the Company shall be entitled to obtain a temporary restraining order and/or a preliminary and/or permanent injunction, without the necessity of posting a bond or of proving irreparable harm or injury as a result of such breach or threatened breach of Sections 9 through 13, restraining Executive from engaging in activities prohibited by Sections 9 through 13 and such other relief as may be required specifically to enforce any of the provisions in Sections 9 through 13. Executive further agrees that, if Executive breaches any of the provisions in Sections 9 through 13 of this Agreement, to the extent permitted by law, Executive shall (i) forfeit Executive's right to receive the balance of any compensation and/or benefits due Executive under this Agreement; (ii) pay over to the Company all compensation, profits, monies, accruals, increments or other benefits derived or received by Executive as the result of any action or transaction constituting a breach of any provision thereof; and (iii) pay over to the Company all costs and expenses incurred by the Company resulting from Executive's breach (including, without limitation, reasonable attorneys' fees and expenses in dealing with Executive's breach or any suits or actions with regard thereto) and for all damages (compensatory, along with punitive) that may be awarded in connection therewith. The provisions of this section shall not limit any other remedies available to the Company as a result of a breach of the provisions of this Agreement or otherwise. Additionally, each of the covenants and restrictions to which Executive is subject under this Agreement, including, without limitation those in Section 9 above, shall each be construed as independent of any other provision in this Agreement, and the existence of any claim or cause of action by Executive against the Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement by the Company of such covenants and restrictions.

15. Representations Regarding Prior Work and Legal Obligations.

15.1 Executive represents and warrants that Executive has no agreement or other legal obligation with any prior employer, or any other person or entity, that restricts Executive's ability to accept employment with the Company. Executive further represents and warrants that Executive is not a party to any agreement (including, without limitation, a non-competition, non-solicitation, no hire or similar agreement) and has no other legal obligation that restricts in any way Executive's ability to perform Executive's duties and satisfy Executive's other obligations to the Company, including, without limitation, those under this Agreement.

15.2 Executive represents and acknowledges that Executive has been instructed by the Company that at no time should Executive divulge to or use for the benefit of the Company or any Company Affiliates any trade secret or confidential or proprietary information of any previous employer or entity with which Executive was affiliated or of any other third-party. Executive expressly represents and warrants that Executive has not divulged or used any such information for the benefit of the Company or Company Affiliates and will not do so.

15.3 Executive represents and agrees that the Executive has not and will not misappropriate any intellectual property belonging to any other person or entity.

15.4 Executive acknowledges that the Company is basing important business decisions on these representations, agreements and warranties, and Executive affirms that all of the statements included herein are true. Executive agrees that Executive shall defend, indemnify and hold the Company harmless from any liability, expense (including attorneys' fees) or claim by any person in any way arising out of, relating to, or in connection with a breach and/or the falsity of any of the representations, agreements and warranties made by Executive in this Section 15.

16. D&O Insurance. During the Employment Period and for a reasonable period thereafter, the Company or any successor to the Company (and it shall be a condition of any agreement by the Company with any such successor that such successor) shall purchase and maintain, at its own expense, directors' and officers' liability insurance providing coverage to Executive on terms that are no less favorable than the coverage provided to other managers, directors and senior officers of the Company.

17. Miscellaneous Provisions.

17.1 IRCA Compliance. This Agreement, and Executive's employment with the Company, is conditioned on Executive's establishing Executive's identity and authorization to work as required by the Immigration Reform and Control Act of 1986 (IRCA).

17.2 Section 409A Compliance. To the extent applicable, it is intended that this Agreement comply with the provisions of Section 409A of the Internal Revenue Code and the guidance promulgated thereunder ("Section 409A"). This Agreement shall be administered in a manner consistent with this intent, and any provision that would cause the Agreement to fail to satisfy Section 409A shall have no force and effect until amended by the parties to comply with Section 409A (which amendment may be retroactive to the extent permitted by Section 409A). Unless otherwise expressly provided, any payment of compensation by Company to Executive, whether pursuant to this Agreement or otherwise, shall be made no later than the 15th day of the third month (*i.e.*, 2½ months) after the later of the end of the calendar year or the Company's fiscal year in which Executive's right to such payment vests (*i.e.*, is not subject to a "substantial risk of forfeiture" for purposes of Code Section 409A). For purposes of this Agreement, "Separation from Service" shall have the meaning given to such term under Section 409A. Each payment and each installment of any severance payments provided for under this Agreement shall be treated as a separate payment for purposes of application of Section 409A. To the extent that any severance payments come within the definition of "short term deferrals" or "involuntary severance" under Section 409A, such amounts shall be excluded from "deferred compensation" as allowed under Section 409A, and shall not be subject to the following Section 409A compliance requirements. All payments of "nonqualified deferred compensation" (within the meaning of Section 409A) are intended to comply with the requirements of Section 409A, and shall be interpreted in accordance therewith. Neither party individually or in combination may accelerate, offset or assign any such deferred payment, except in compliance with Section 409A. No amount shall be paid prior to the earliest date on which it is permitted to be paid under Section 409A and Executive shall have no discretion with respect to the timing of payments except as permitted under Section 409A. Any payments to which Section 409A applies which are subject to execution of a waiver and release which may be executed and/or revoked in a calendar year following the calendar year in which the payment event (such as Separation from Service) occurs shall commence payment only in the calendar year in which the release revocation period ends as necessary to comply with Section 409A. In the event that Executive is determined to be a "key employee" (as defined and determined under Section 409A) of the Company at a time when its stock is deemed to be publicly traded on an established securities market, payments determined to be "nonqualified deferred compensation" payable upon separation from service shall be made no earlier than (i) the first day of the seventh (7th) complete calendar month following such termination of employment, or (ii) Executive's death, consistent with the provisions of Section 409A. Any payment delayed by reason of the prior sentence shall be paid out in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule. All expense reimbursement or in-kind benefits subject to Section 409A provided under this Agreement or, unless otherwise specified in writing, under any Company program or policy, shall be subject to the following rules: (i) the amount of expenses eligible for reimbursement or in-kind benefits provided during one calendar year may not affect the benefits provided during any other year; (ii) reimbursements shall be paid no later than the end of the calendar year following the year in which the Executive incurs such expenses, and the Executive shall take all actions necessary to claim all such reimbursements on a timely basis to permit the Company to make all such reimbursement payments prior to the end of said period, and (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit. Notwithstanding anything herein to the contrary, no amendment may be made to this Agreement if it would cause the Agreement or any payment hereunder not to be in compliance with Section 409A.

17.3 Assignability and Binding Effect. This Agreement shall inure to the benefit of and shall be binding upon the heirs, executors, administrators, successors and legal representatives of Executive, and shall inure to the benefit of and be binding upon the Company, the Company Affiliates and their successors and assigns, but the obligations of Executive are personal services and may not be delegated or assigned. Executive shall not be entitled to assign, transfer, pledge, encumber, hypothecate or otherwise dispose of this Agreement, or any of Executive's rights and obligations hereunder, and any such attempted delegation or disposition shall be null and void and without effect. This Agreement may be assigned by the Company to a person or entity that is an affiliate or a successor in interest to substantially all of the business operations of the Company. Upon such assignment, the rights and obligations of the Company hereunder shall become the rights and obligations of such affiliate or successor person or entity. Further, in the event Executive becomes employed by a parent, subsidiary or other affiliate of the Company, this Agreement shall thereupon automatically be assigned to such parent, subsidiary or other affiliate and Executive consents to be bound by the provisions of this Agreement for the benefit of the Company and/or any such parent, subsidiary or other affiliate of the Company without the necessity that this Agreement be re-signed at the time of such transfer.

17.4 Right of Set-Off. To the extent permitted by applicable law, the Company may at any time offset against any amounts owed to Executive hereunder or otherwise due or to become due to Executive, or anyone claiming through or under Executive, any debt or debts due or to become due from Executive to the Company.

17.5 Severability and Blue Penciling. If any provision of this Agreement is held to be invalid, the remaining provisions shall remain in full force and effect. However, if any court determines that any covenant in this Agreement, is unenforceable because the duration, geographic scope or restricted activities thereof are overly broad, then such provision or part thereof shall be modified by reducing the overly broad duration, geographic scope or restricted activities by the minimum amount so as to make the covenant, in its modified form, enforceable.

17.6 Choice of Law and Forum; Attorneys' Fees. This Agreement shall be interpreted and enforced in accordance with the laws of the State of California, without regard to its conflict-of-law principles, except to the extent that Section 17.7 below is governed by the Federal Arbitration Act. The Parties agree that any dispute concerning or arising out of this Agreement or Executive's employment hereunder (or termination thereof) that is not subject to the arbitration provisions of Section 17.7 below shall be litigated exclusively in an appropriate state or federal court in or closest to San Diego County, California, and hereby consent, and waive any objection, to the jurisdiction of any such court. In the event a litigation or other legal proceeding is commenced to resolve any such dispute, the prevailing party in such litigation or proceeding shall be entitled to recover from the non-prevailing party all of its costs, charges, disbursements and fees (including reasonable attorneys' fees) incurred in connection with such litigation or proceeding and the underlying dispute.

17.7 Arbitration.

(a) Any claim, dispute, or controversy between the Executive and the Company (which, for this purpose, shall include including any of the Company's partners, affiliated companies, successors, assigns, owners, directors, officers, shareholders, employees, managers, members and agents), including without limitation, those arising out of or relating to this Agreement, Executive's employment with the Company or the termination thereof shall be submitted to final and binding arbitration pursuant to the Federal Arbitration Act ("FAA"). Notwithstanding the foregoing, the following shall not be subject to mandatory arbitration pursuant to this provision: (i) applications by any Party for temporary or preliminary injunctive relief in aid of arbitration or for the maintenance of the status quo pending arbitration; (ii) claims for workers' compensation benefits; (iii) claims for unemployment insurance compensation benefits; (iv) to the extent required by law, administrative claims or charges before applicable federal and state administrative agencies (such as the Equal Employment Opportunity Commission, the Department of Fair Employment and Housing, and any unfair labor charge which is to be brought under the National Labor Relations Act); and (v) claims that are not legally subject to pre-dispute mandatory arbitration agreements. For avoidance of doubt, nothing in this Agreement prevents or excuses a Party from satisfying any conditions precedent and/or exhausting administrative remedies under applicable law before bringing a claim in arbitration.

(b) To the maximum extent permitted by applicable law, the Parties agree that any claim each brings may not be initiated, maintained, heard or determined on a class action, collective action, or representative action basis either in court or in arbitration, and that each is not entitled to serve or participate as a class, collective or representative action member or representative or to receive any recovery from a class, collective or representative action involving a claim against the other Party either in court or in arbitration. Any claim brought by one Party may not be joined or consolidated with any other claim that does not involve precisely the same parties. If a Party is included within any class action, collective action, or representative action in court or in arbitration involving a claim against the other Party, such Party will take all steps necessary to opt-out of the action or refrain from opting in, as the case may be. Insofar as any claim between the Parties is permitted to proceed on a class action, collective action, or representative action basis, notwithstanding this Section 17.7 it must do so in court pursuant to Section 17.6 above.

(c) The arbitration process shall be confidential and private and administered by JAMS pursuant to its Employment Arbitration Rules & Procedures in effect at the time the dispute is submitted (the "Arbitration Rules"), which can be found at http://www.jamsadr.com, a copy of which will be provided to Executive upon Executive's request. Claims must be submitted to JAMS for arbitration in accordance with the Arbitration Rules for commencing an arbitration, and within the applicable statute of limitations. The Parties may file and the arbitrator shall hear and decide at any point in the proceedings any motion permitted by the Federal Rules of Civil Procedure, including but not limited to motions to compel discovery, motions for protective orders, motions to dismiss, motions for summary judgment, and motions in limine. In addition, the arbitration shall be subject to the same burdens of proof and statutes of limitations as if the claim at issue was being heard in the federal or state court provided by Section 17.6 above. The arbitration proceedings will be held before a single, neutral arbitrator in Orange County, California. The fees of the arbitrator and all other costs that are unique to the arbitration process shall be paid by the Company to the extent required by law. Otherwise, each party shall be solely responsible for paying his/her/its own costs for the arbitration, including, but not limited to attorneys' fees, except to the extent provided under Section 17.6 above. The arbitrator shall have the authority to award any damages or relief authorized by law. The award of the arbitrator shall be in writing and shall contain the arbitrator's factual findings, legal conclusions and reasons for the award. The award may be entered as a judgment in any court with jurisdiction over either Executive or the Company. Either Party may bring an action in any court of competent jurisdiction to compel arbitration under this Agreement, to enforce an arbitration award and to vacate an arbitration award. However, in actions seeking to vacate an award, the standard of review to be applied by said court to the arbitrator's findings of fact and conclusions of law will be the same as that applied by an appellate court reviewing a decision of a trial court sitting without a jury. To the extent any of the terms, conditions or requirements of this Agreement conflict with the Arbitration Rules, the terms, conditions or requirements of this Agreement shall govern.

(d) Notwithstanding any provision of the Arbitration Rules to the contrary, any issue concerning the validity or enforceability of any of the class action, collective action, and representative action waivers contained in this Agreement ("Waivers") shall be governed by and determined under and in accordance with the FAA and shall be decided by a court of competent jurisdiction pursuant to Section 17.6 above. Any issue concerning arbitrability of a particular issue or claim pursuant to this Agreement (except for issues concerning the validity or enforceability of the class action, collective action, or representative action Waivers) must be resolved by the arbitrator, not the court.

17.8 Notices.

(a) Any notice or other communication under this Agreement shall be in writing and shall be delivered by hand, email, facsimile or mailed by overnight courier or by registered or certified mail, postage prepaid:

(i) If to Executive, to Executive's address on the books and records of the Company.

(ii) If to the Company, to _____, or at such other mailing address, email address or facsimile number as it may have furnished in writing to Executive.

(b) Any notice so addressed shall be deemed to be given: if delivered by hand or email, on the date of such delivery; if by facsimile, on the date of such delivery if receipt on such day is confirmed and, if not so confirmed, on the next business day; if mailed by overnight courier, on the first business day following the date of such mailing; and if mailed by registered or certified mail, on the third business day after the date of such mailing.

17.9 Survival of Terms. All provisions of this Agreement that, either expressly or impliedly, contain obligations that extend beyond termination of Executive's employment hereunder, including without limitation Sections 9-14 and 17 hereof, shall survive the termination of this Agreement and of Executive's employment hereunder for any reason.

17.10 Interpretation. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement. The language in all parts of this Agreement shall in all cases be construed according to its fair meaning, and not strictly for or against any Party. The Parties acknowledge that both of them have participated in drafting this Agreement; therefore, any general rule of construction that any ambiguity shall be construed against the drafter shall not apply to this Agreement. In this Agreement, unless the context otherwise requires, the masculine, feminine and neuter genders and the singular and the plural include one another.

17.11 Further Assurances. The Parties will execute and deliver such further documents and instruments and will take all other actions as may be reasonably required or appropriate to carry out the intent and purposes of this Agreement.

17.12 Voluntary and Knowing Execution of Agreement. Executive acknowledges that (i) Executive has had the opportunity to consult an attorney regarding the terms and conditions of this Agreement before executing it, (ii) Executive fully understands the terms of this Agreement, and (iii) Executive is executing this Agreement voluntarily, knowingly and willingly and without duress.

17.13 Entire Agreement. This Agreement constitutes the entire understanding and agreement of the Parties concerning the subject matter hereof, and it supersedes all prior negotiations, discussions, correspondence, communications, understandings and agreements regarding such subject matter. Each Party acknowledges and agrees that such Party is not relying on, and may not rely on, any oral or written representation of any kind that is not set forth in writing in this Agreement.

17.14 Waivers and Amendments. This Agreement may be altered, amended, modified, superseded or cancelled, and the terms hereof may be waived, only by a written instrument signed by the Parties or, in the case of a waiver, by the Party alleged to have waived compliance. Any such signature of the Company must be by an authorized signatory for the Company. No delay by any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of any Party of any such right, power or privilege, nor any single or partial exercise of any such right, power or privilege, preclude any other or further exercise thereof or the exercise of any other such right, power or privilege.

17.15 Counterparts. This Agreement may be executed in counterparts, and each counterpart, when executed, shall have the efficacy of a signed original. Photographic copies, electronically scanned copies and other facsimiles of this Agreement (including such signed counterparts) may be used in lieu of the originals for any purpose.

[The remainder of this page is intentionally blank; signature page follows.]

IN WITNESS WHEREOF, the Parties have executed and delivered this Agreement as of the date first above written.

Richard B. Slansky

[Insert name of Genenta's US subsidiary]

By:
Name:
Title:

[Signature page to Employment Agreement.]

EXHIBIT A

LIST OF PRIOR INVENTIONS AND ORIGINAL WORKS OF AUTHORSHIP

Title	Date	Identifying Number or Brief Description

EXHIBIT B

INVENTION ASSIGNMENT NOTICE

In accordance with Section 2872 of the California Labor Code, you are hereby notified that the invention assignment provisions of the Confidentiality, Assignment of Inventions and Non-Solicitation Agreement which you have signed do not apply to an invention which qualifies fully under the provisions of Section 2870 of the California Labor Code, which provides in pertinent part:

> Any provision in an employment agreement which provides that an employee shall assign, or offer to assign, any of his or her rights in an invention to his or her employer shall not apply to an invention which was developed entirely on his or her own time without using the employer's equipment, supplies, facilities or trade secret information except for those inventions that either:
>
> (1) Relate at the time of conception or reduction to practice of the invention to the employer's business, or actual or demonstrably anticipated research or development of the employer, or
>
> (2) Result from any work performed by the employee for the employer.

RECEIPT ACKNOWLEDGED

Signed: _____ Dated: _____

EXHIBIT C

OUTSIDE BOARDS AND MEMBERSHIPS

Board Seat

1. Matterhorn Shoppes, Inc. – commercial real estate leasing (Director and Secretary/Treasurer)
2. Hypnoz Therapeutic Devices, Inc. – airway device company (Director and Secretary/Treasurer)
3. Nuclear RNA Networks, Inc. – small biopharma company (Director and Assistant Secretary/Treasurer)
4. Parabilis Space Technologies, Inc. – small aerospace company (Board Chair and Secretary)

Member

1. Sky View Inn, LLC – family country inn (Member)