UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the month of October 2024

Commission File Number: 001-41115

GENENTA SCIENCE S.P.A.
(Translation of Registrant's Name into English)

Via Olgettina No. 58
20132 Milan, Italy
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

This report on Form 6-K is incorporated by reference into the registrant's registration statement on Form F-3 (File No. 333-271901).

Genenta Science S.p.A. Reports Financial Results for the Six Months Ended June 30, 2024

Genenta Science S.p.A. ("Genenta") is furnishing this report on Form 6-K to provide its unaudited consolidated financial statements as of June 30, 2024, and for the six months ended June 30, 2024, and June 30, 2023, and to provide its Management's Discussion and Analysis of Financial Condition and Results of Operations with respect to such financial statements.

The unaudited consolidated financial statements as of June 30, 2024, and for the six months ended June 30, 2024, and June 30, 2023, are attached to this Form 6-K as Exhibit 99.1. Management's Discussion and Analysis of Financial Condition and Results of Operations is attached to this Form 6-K as Exhibit 99.2.

As described in more detail in Note 15, Subsequent events to the financial statements attached as Exhibit 99.1 hereto, on September 19, 2024, Genenta entered into an amendment to the Master Services Agreement with AGC Biologics S.p.A. ("AGC") to extend the term of the Master Services Agreement. Additionally, on October 14, 2024, Genenta entered into an *Agreement for the Conduct of Clinical Trials on Medical Products* with San Raffaele Hospital ("OSR") to conduct an open-label 1/2 clinical trial in Renal Cell Cancer. The descriptions of the amendment to the Master Services Agreement and the *Agreement for the Conduct of Clinical Trials on Medical Products* contained in this Form 6-K and in Exhibits 99.1and 99.2 hereto do not purport to be complete and are qualified in their entirety by reference to the complete text thereof, copies of which are filed as exhibits 10.1 and 10.2, respectively, to this Form 6-K.

EXHIBIT INDEX

Exhibit	Title
10.1	Amendment to the AGC Master Service Agreement dated September 19, 2024.
10.2	Agreement for the Conduct of Clinical Trials on Medicinal Products with OSR dated October 14, 2024.
99.1	Unaudited Consolidated Financial Statements as of June 30, 2024, and for the six months ended June 30, 2024, and June 30, 2023.
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations.
101	The following materials from Genenta's Report on Form 6-K for the six months ended June 30, 2023, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statements of Changes in Shareholders' Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENENTA SCIENCE S.P.A.

Date: October 29, 2024

By: */s/ Pierluigi Paracchi*
Pierluigi Paracchi, Chief Executive Officer

Amendment to Master Service Agreement

This Amendment (this "**Amendment**") to the Master Service Agreement (the "**Agreement**") is effective as of 05 March 2024 ("**Effective Date**") and entered into by and between **AGC Biologics S.p.A** (formerly Molecular Medicine (Molmed) S.p.A), a company organized and existing under Italian law, with registered offices at via Meucci 3 Bresso, Milan, Italy ("**AGC**") and **Genenta Science s.r.l.**, a company incorporated and existing under Italian law, with registered offices at via Olgettina 58, Milan, Italy ("**Customer**") (each a "**Party**" and collectively the "**Parties**").

WHEREAS, Molecular Medicine (Molmed) S.p.A. and Customer entered into the Agreement effective as of 06 March 2019, and the Parties now desire to amend the terms of the Agreement as set forth herein.

NOW THEREFORE, in consideration of the mutual promises herein, the Parties, intending to be legally bound, hereby agree as follows:

1. Definitions. Unless otherwise defined in this Amendment, initially capitalized terms used herein shall have the meanings given to them in the Agreement.

2. Extension of Term. The Term of the Agreement is amended to extend from 06 March 2019 to the new expiry date of 30 June 2025. The Parties may further extend the Term by mutual agreement in writing prior to the expiry of the Term.

3. Part of the Agreement. This Amendment forms part of the Agreement. Except as specifically set forth in this Amendment, the terms and conditions of the Agreement shall remain in full force and effect.

4. Execution and Counterparts. This Amendment may be executed by electronic signature and in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument. Any signature page delivered by electronic transmission shall be binding to the same extent as an original signature page.

The Parties intending to be bound have caused this Amendment to be executed by their duly authorized representatives effective as of the Effective Date.

Genenta Science s.r.l.		**AGC Biologics S.p.A.**	
By:	DocuSigned by: E9A8BB17C210468...	By:	DocuSigned by: Luca Alberici 0312CB4269524EE...
Print Name:	Pierluigi Paracchi	Print Name:	Luca Alberici
Title:	CEO	Title:	GM
Date:	19/09/2024	Date:	19 settembre 2024 | 05:47 PDT

Exhibit 10.2

****AGREEMENT FOR THE CONDUCT OF CLINICAL TRIALS ON MEDICINAL PRODUCTS****

[This constitutes an unofficial English translation of the original Italian document. The Italian document shall govern in all respects, including interpretation.]

"Open-label phase 1/2 study to evaluate the safety, biological response, and efficacy of a single dose of Temferon (autologous hematopoietic stem and progenitor cells enriched with CD34+ and genetically modified with human Interferon-α2) in patients with metastatic renal carcinoma."

****BETWEEN****

Ospedale San Raffaele S.r.l. (hereinafter referred to as the "Institution"), with registered office at 20132 **Milan (MI), via Olgettina no. 60**, registered with the Economic Administrative Registry at the Milan Chamber of Commerce under no. **MI-1972938**, with tax code, VAT number, and registration number with the Milan Companies Register **07636600962** (Share Capital € 60,817,200.00), a company with a single shareholder subject to the direction and coordination of Gruppo San Donato S.p.A., represented by the Director of Research, Dr. Anna Flavia d'Amelio Einaudi.

****AND****

Genenta Science S.p.A., with registered office at **Via Olgettina 58, 20132 Milan, VAT 08738490963**, represented by its legal representative **Dr. Pierluigi Paracchi** (CEO), acting as **Chief Executive Officer** (CEO) (hereinafter referred to as the "Sponsor").

Hereinafter individually/collectively referred to as "the Party/the Parties."

****Whereas**:**

A. The Sponsor intends to conduct, in accordance with Regulation (EU) No. 536/2014 (hereinafter "Regulation"), a clinical trial titled "Open-label phase 1/2 study to evaluate the safety, biological response, and efficacy of a single dose of Temferon (autologous hematopoietic stem and progenitor cells enriched with CD34+ and genetically modified with human Interferon-α2) in patients with metastatic renal carcinoma" (hereinafter "Trial"), concerning **Protocol version no. 1.0** dated **May 10, 2024**, and its duly approved subsequent amendments (hereinafter "Protocol"), EudraCT code no. **2024-512898-27-00**, at the Institution, under the responsibility of **Prof. Andrea Necchi**, as the scientific supervisor of the trial covered by this Contract (hereinafter "Principal Investigator"), in the Department of **Oncology, led by Prof. Michele Reni** (hereinafter "Trial Center"), and **Prof. Fabio Ciceri** as co-investigator, in the **Department of Hematology and Bone Marrow Transplant**.

B. The Sponsor has designated **Dr. Carlo Russo, Chief Medical Officer & Head of Development**, as the scientific reference for its scope. The Sponsor may change the scientific reference by written notice to the Institution.

C. The Trial Center possesses the technical and scientific expertise to conduct the Trial and is appropriately structured to conduct the trial in compliance with current regulations.

D. The Principal Investigator and their direct collaborators, qualified to exercise discretion in executing the Protocol (hereinafter "Co-investigators"), along with all other persons involved in any part of the Trial under the Principal Investigator's supervision, are competent to conduct the Trial in accordance with applicable regulations, are familiar with the Protocol and good clinical practice standards, and meet the necessary regulatory requirements, including compliance with applicable regulations regarding conflict of interest.

E. Except as may otherwise be agreed in writing by the Parties, the Institution shall conduct the Trial exclusively within its facilities.

F. The Institution is equipped with appropriate facilities for conducting the Trial as specified in the Protocol.

G. The Trial has been duly authorized in accordance with Chapter II of the Regulation, with a national authorization from AIFA uploaded on the EU portal pursuant to Article 80 of the Regulation on September 30, 2024, which includes the opinion issued by the National Ethics Committee for clinical trials on advanced therapies.

H. Pursuant to Article 76 of the Regulation and applicable national provisions, the Sponsor has taken out the insurance policy as specified in Article 8 of this Contract.

I. In negotiating this Contract, the Parties have based their agreement on the template approved by the National Coordination Center of Territorial Ethics Committees pursuant to Article 2, paragraph 6, of Law No. 3 of January 11, 2018, and, in compliance with the homogeneity of administrative, economic, and insurance aspects referred to therein, have agreed to supplement and/or modify the relevant provisions to govern the specificities and peculiarities of the Trial based on the following reasons, as specified below for each addition or modification:

- **Article 3 and following**: It is specified that, although Prof. Andrea Necchi (Medical Oncology) is the Principal Investigator, the study will take place at two separate operating units of the Institution: the Hematology and Bone Marrow Transplant Unit (where autologous transduced stem cell transplantation and Temferon administration and follow-up will take place) and the Medical Oncology Unit (responsible for the patient's oncological treatment).

- **Article 3.8**: Timelines for the delivery of Data Collection Forms and the resolution of clarification requests are specified.

- **Article 4 and following**: The method of providing study drugs is specified, with Temferon (proprietary IMP) provided for free and full reimbursement for the purchase of other IMPs (Plerixafor, Lenograstim, Busulfan, Cabozantinib, and Pembrolizumab). There are no auxiliary medications or background therapy.

- **Article 4.2**: The possibility of making the clinical trial drug available after the study, beyond the observation period, for patients who have obtained clinical benefit from the trial drug does not apply to the gene therapy in this study.

- **Article 5**: No loan for use is provided.

- **Article 7.2 (Duration, Termination, and Resolution)**: The clause regarding CRO (insolvency) has been removed as the study's financial management is fully managed by the Sponsor.

- **Article 9 (Final Report, Ownership, and Use of Results)**: The use of the Trial data and results by the Institution can occur only with the Sponsor's prior written authorization and once the goals of such use have been shared.

- **Article 10 (Confidentiality of Technical and Commercial Information and Disclosure of Results)**: The same principle applies to the Investigator, who may disclose and publish the Trial results only with the Sponsor's prior written authorization. Article 9.5 has been simplified, given it is a single-center study.

- **Annex A (Budget - omitted)**: The annex has been modified to adapt it to the specificities of the study.

The Parties agree and stipulate as follows:

Article 1 – Entirety of the Contract

1.1 The preamble, the Protocol, even if not physically attached, and all annexes, including the budget (Annex A - omitted) and the glossary related to personal data protection (Annex B - omitted), are integral and essential parts of this Contract.

Article 2 – Purpose

2.1 The Sponsor entrusts the Institution with the execution of the Trial under the conditions specified in this Contract, in accordance with the Protocol, any subsequent amendments, as well as with the modifications to this Contract/budget arising from these and formalized through the necessary, promptly signed amendment documents.

The Sponsor declares it has appointed the Contract Research Organization Alira Health S.r.l., based in Milan, Tax ID 03274820236, and VAT IT03274820236 (hereinafter referred to as "CRO"), which operates in compliance with the D.M. of November 15, 2011, and is registered with the National Observatory on Clinical Trials of Medicinal Products (OsSC), to carry out activities related to the Trial, granting it the necessary powers and related mandate with representation by agreement dated August 22, 2024. The Institution acknowledges being aware of this appointment.

2.2 The Trial must be conducted in strict compliance with the Protocol, in its current version, accepted by the Principal Investigator and approved by the Ethics Committee and Competent Authority, in accordance with the current regulations on clinical trials of medicinal products and the ethical and deontological principles that guide the medical professionals involved.

2.3 The Trial must also be conducted in accordance with the principles contained in the Convention on Human Rights and Biomedicine, the updated version of the Declaration of Helsinki, the current rules of Good Clinical Practice, and in compliance with the applicable transparency and anti-corruption laws, as well as personal data protection laws in accordance with the current regulations.

2.4 By signing this Contract, the Parties declare that they are aware of and accept the content mentioned above. To the extent necessary and to their knowledge, each Party declares that the activities provided for in this Contract do not violate any commitments it has made with third parties.

2.5 The Sponsor and the Principal Investigator, with an obligation to protect patient health, may, when circumstances arise, adopt urgent and appropriate measures to ensure patient safety, such as the temporary suspension of the study (discontinuation of treatment for patients already involved in the trial or the suspension of the inclusion of new subjects), following the procedures set forth in Article 38 of Regulation (EU) No. 536/2014, while the Sponsor is obliged to promptly inform the Ethics Committee, the Competent Authority, and the Trial Centers (who will then inform study participants) of any new events, measures taken, and a plan of actions to be taken, completing the procedures specified by current regulations in a timely manner. Upon notification from the investigator of a serious adverse event, the Sponsor promptly reports all suspected serious adverse reactions to the electronic database as per paragraph 2 of Article 42 of Regulation (EU) No. 536/2014, also by reporting under paragraph 3.

2.6 The Institution plans to enroll approximately 12 patients by December 31, 2025, though the inclusion period is subject to change based on enrollment progress, potential failure in identifying patients, or patients withdrawn from the study before treatment. The Parties acknowledge that any increase in the number of patients to be involved at the Institution's trial center must be pre-approved by the Parties and submitted to the Ethics Committee and Competent Authority with an appropriate amendment. It is understood that such an increase, conducted under the stated conditions, does not require an additional agreement to this Contract if the agreed economic conditions per patient apply to all additional patients.

2.7 The Institution and Sponsor will retain documentation related to the Trial (permanent file “investigator site file” for the Institution and “trial master file” for the Sponsor) for the period and under the specifications indicated by the current legislation (or for a longer period if required by other applicable laws or an agreement between the Institution and Sponsor). Upon expiration of this period, the Parties may agree on the terms of an extended retention period.

2.8 The Institution and Sponsor, each within its scope of competence, also undertake to retain the aforementioned documentation using forms of digitization (or dematerialization) in compliance with applicable regulations. Regardless of whether the documentation storage related to the Trial concerns personal data (either specific or not), as defined in Regulation (EU) No. 679/2016 (hereinafter “GDPR”), the Institution and Sponsor must adopt all physical and technical measures required by Article 32 of the GDPR and perform the necessary security checks as stipulated by current regulations, to protect data, information, and documents (both paper and electronic). The storage system used must guarantee not only the integrity of data, information, and documents in both paper and electronic formats but also their future readability for the entire duration of the retention obligation. For the fulfillment of this obligation, both the Sponsor and the Institution may engage external entities responsible for managing this storage obligation.

2.9 The Sponsor, Institution, and Principal Investigator must adhere to the guidelines, directives, instructions, and recommendations provided by the Ethics Committee and Competent Authority.

Article 3 – Principal Investigator and Co-Investigators

3.1 The Principal Investigator will be assisted in conducting the Trial by direct collaborators, qualified according to the Protocol to intervene with discretionary powers in its execution (hereinafter “Co-Investigators”), as well as by staff, both healthcare and non-healthcare, appointed by the Institution. Co-Investigators and other staff will operate under the Principal Investigator’s responsibility for aspects related to the Trial. The aforementioned individuals must be qualified to conduct the Trial and must have received adequate prior training on the Protocol, according to current regulations, from the Sponsor; each of them must have expressed their willingness to participate in the Trial. In particular, the Principal Investigator is required to monitor the proper conduct of the activities of the Co-Investigators and other staff participating in the Trial, with special reference to cases of radiation or suspension that may arise for some of them during the Trial.

It is emphasized that this Trial will be conducted in two separate units within the Institution, namely, the Hematology and Bone Marrow Transplantation unit (where the autologous transplant of transduced stem cells will be performed, and Temferon will be administered along with follow-up) and the medical oncology unit (which will be responsible for the patient’s oncology treatment).

3.2 The Parties acknowledge that the Principal Investigator, as the Institution’s general point of contact with the Sponsor, is responsible for complying with all obligations imposed on the Institution by the current regulations on clinical trials of medicinal products.

3.3 This relationship exists between the Sponsor and the Institution. Each of the Parties is not involved in the other’s relationships with its representatives and/or employees (particularly the Sponsor’s relationship with the Institution, Principal Investigator, Co-Investigators, and all other personnel participating in the Trial, and the Institution’s relationship with the Sponsor, the CRO, or any other representative and/or employee). Therefore, each is released from any claims that these individuals may make in connection with the Trial.

3.4 Concerning the Trial under this Contract, the Parties acknowledge that they have complied with the provisions of Article 7 of the Regulation and Article 6, paragraph 4 of Legislative Decree May 14, 2019, No. 52, as amended by Article 11-bis of Law July 17, 2020, No. 77, converting Decree-Law May 19, 2020, No. 34 ("Relaunch Decree").

3.5 If the relationship between the Principal Investigator and the Institution should end for any reason, the Institution must promptly inform the Sponsor in writing, indicating a replacement and reporting it in the European electronic database. The designation of the replacement must be approved by the Sponsor and the relevant Ethics Committee. The Institution guarantees that the new Principal Investigator meets the requirements to continue the study, accepts the terms and conditions of this Contract, and commits to following the Protocol in conducting the Trial. While waiting for the approval of the substantive amendment for changing the Principal Investigator, the Investigator appointed by the Institution ensures the necessary continuity of the trial activity.

If the Sponsor does not wish to accept the proposed replacement nominated by the Institution, or if the Institution does not propose a replacement, the Sponsor may withdraw from this Contract in accordance with Article 7.

3.6 The Principal Investigator or their delegate, before starting the Trial, must obtain the informed consent of the patient or their legal representative, as required by current regulations on clinical trials, and consent to the processing of personal data in accordance with the applicable national and EU regulations on data protection, as further outlined in Article 11.

3.7 The Principal Investigator is obliged to record and document in detail all adverse events and serious adverse events and to report them to the Sponsor within the deadlines specified by current legislation. Furthermore, the Principal Investigator must provide any other clinically relevant information specified in the Protocol (e.g., pregnancy) directly or indirectly related to conducting the Trial, as required by the Protocol, Good Clinical Practice standards, and applicable regulations on pharmacovigilance and clinical trials of medicinal products.

3.8 The Institution ensures the proper conduct of the Trial by the Principal Investigator and personnel under their responsibility according to the highest standards of diligence. In particular:

3.8.1 The Principal Investigator must deliver all Data Collection Forms (Case Report Forms - CRFs) correctly completed and pseudonymized, following the procedures and within fifteen (15) business days from the completion of each visit as defined by the Trial Protocol and applicable regulations, either in paper or electronic format, and in any case promptly as per GCP, within the deadlines set by the Trial Protocol.

3.8.2 The Principal Investigator also undertakes to resolve the clarification requests (queries) generated by the Sponsor within five (5) business days from the completion of each visit as provided in the Trial Protocol.

3.8.3 To verify the correspondence between the data recorded in the Data Collection Forms and those contained in the original documents (e.g., clinical records), the Institution and the Principal Investigator permit direct access to the original data during monitoring visits and any audits conducted by the Sponsor and inspections by the Competent Authorities, including remote procedures, provided that patient privacy and data protection laws are not violated.

3.8.4 The Institution and the Principal Investigator, after being given appropriate notice, must allow the proper conduct of monitoring, auditing, and inspection activities at the Trial Center, the medical oncology unit, and the Hematology and Bone Marrow Transplantation Department by the Sponsor's personnel and the Competent Authorities, to ensure the regular execution of the Trial.

3.8.5 The Sponsor acknowledges that the Institution may conduct internal quality checks (internal GCP audits) related to the Trial within its facilities, in accordance with its quality system and procedures.

3.9 The Institution will promptly inform the Sponsor if a Competent Authority notifies the Institution of an inspection/audit related to the Trial. If not expressly denied by the Competent Authority, the Institution will authorize the Sponsor to participate, sending to the Sponsor any written communication received and/or transmitted in connection with or as a result of the inspection/audit. These activities must not, in any way, prejudice the regular institutional activities of the Institution.

3.10 The Institution and the Sponsor ensure that biological samples (blood, urine, saliva, etc.) from patients involved in the Trial under this Contract, or any substudy included in the Protocol and subject to the patient's informed consent, will be used exclusively for the Trial under this Contract, according to the Protocol and current regulations. Any storage and subsequent use are subject to obtaining specific informed consent from the patient (or their parent/legal guardian), approval from the Ethics Committee, and must comply with the limits and safeguards provided by current laws and the guidelines specified in Article 1, paragraph 1, letter b, of Legislative Decree May 14, 2019, No. 52.

Article 4 – Investigational Medicinal Products, Materials, and Services

4.1 The Sponsor commits to provide the Institution, at no cost, with the investigational product (TemferonTM) in quantities deemed necessary and sufficient for the proper execution of the Trial throughout its duration (hereinafter "Investigational Medicinal Product"). Additionally, the Sponsor agrees to reimburse the Institution for other medicines outlined in the protocol, including Plerixafor, Lenograstim, Busulfan, Cabozantinib, and Pembrolizumab, in accordance with Annex 1, point 3, Table I of the Ministerial Decree of December 21, 2007 (hereinafter "Other Investigational Medicinal Products"). Quantities of the Investigational Medicinal Product and Other Investigational Medicinal Products provided by the Sponsor shall correspond to the study's case numbers and remain solely for Trial use. The Institution shall manage receipt, tracking through batch registration, labeling, and appropriate disposal as required. The Institution will bear the costs of background therapies excluded from comparative therapeutic strategies. The Sponsor further undertakes to supply, at its own expense, all additional materials required for the Trial (hereinafter, "Materials"), as well as laboratory, diagnostic, and monitoring tests necessary for the utilization of the Investigational Medicinal Product and Other Investigational Medicinal Products or for achieving the primary and secondary objectives of the Trial (hereinafter, "Services").

4.2 The Investigational Medicinal Product shall be dispatched by the Sponsor to the Institution's Pharmacy, which will manage its registration, appropriate storage, and distribution to the Principal Investigator, as per the Protocol and applicable regulations. The Other Investigational Medicinal Products shall be purchased directly by the Institution's Pharmacy, which will handle their registration, appropriate storage, and distribution to the Principal Investigator as stipulated by the Protocol and in line with prevailing regulatory standards.

4.3 The Investigational Medicinal Product must be accompanied by an appropriate delivery document addressed to the Pharmacy, specifying the drug type, quantity, batch number, storage requirements, expiration date, and Trial references (protocol code, Principal Investigator, and relevant Trial Center).

4.4 The Institution and the Principal Investigator are required to utilize the Investigational Medicinal Product, the Other Investigational Medicinal Products, and the Materials exclusively within the scope and for the purpose of the Trial. The Institution is prohibited from transferring or assigning to third parties the Investigational Medicinal Product, the Other Investigational Medicinal Products, and/or the Materials/Services provided by the Sponsor under this Agreement.

4.5 Any expired or otherwise unusable Other Investigational Medicinal Products, or those unused upon conclusion of the Trial, shall be disposed of by the Institution at the Sponsor's expense. The disposal fee set by the Institution's Pharmacy is €1,500.00 per disposal.

For the disposal of Temferon, the Sponsor shall issue a written disposal request to the Institution, with associated disposal costs also borne by the Sponsor. The Institution agrees to supply the Sponsor with duly certified proof of disposal in conformity with applicable regulations. For the disposal of unused Other Investigational Medicinal Products and related services, the Sponsor will compensate the Institution in accordance with the amount specified in Annex A (paragraph "Fees and Compensation" - part 1) of this Agreement. This amount will be invoiced with standard VAT by the Institution as an "ancillary consideration for the Trial, pertaining to the disposal of expired or unused Other Investigational Medicinal Products."

Article 5 – Loan for Use

The Parties acknowledge that no assets and/or equipment will be granted to the Institution on loan for use by the Sponsor.

Article 6 – Compensation

6.1 The agreed compensation, previously assessed by the Institution, per eligible, evaluable patient who has completed the experimental treatment in accordance with the Protocol and for whom the relevant CRF/eCRF has been duly completed, inclusive of all expenses incurred by the Institution for the execution of the Trial and all related activities, is detailed in Part 1 of Annex A – Budget "Fees and Compensation."

6.2 The Sponsor agrees to pay the amounts due under this article based on an adequate, justified accounting statement, agreed upon by the Parties. Payment of the above compensation will be made on a quarterly basis as indicated in the Budget (Annex A, paragraph "Payments and Invoices"), based on the number of patients involved in the respective period, treatments received according to Protocol, and completed and validated CRF/eCRFs, as approved by the Sponsor.

6.3 Plasma concentration monitoring of Busulfan (laboratory test) indicated in Annex A (paragraph "Fees and Compensation," part 1) and required by the Protocol, as approved by the Ethics Committee, will not incur any costs to the Institution as it will be performed centrally.

6.4 The Institution shall receive no compensation for patients deemed unevaluable due to non-compliance with the Protocol, violations of Good Clinical Practice, or failure to comply with current clinical trial regulations. Additionally, no compensation will be provided for patients included after notification of Trial interruption or completion by the Sponsor, or beyond the maximum number of subjects specified in this Agreement, unless previously agreed upon with the Sponsor.

6.5 The Sponsor will also reimburse the Institution, based on the trial rate in effect at the Institution, for any additional costs arising from medical/diagnostic activities, including possible hospitalizations, not provided for in the Protocol or its subsequent amendments, and not already covered by the above compensations, if these activities become essential for the proper clinical management of the trial participant. Reimbursement will only be made if these activities and their related costs are promptly communicated, justified, and documented in writing to the Sponsor and approved by the Sponsor in writing, while ensuring the codified form of the patient's personal data.

6.6 If, during the course of the Trial, it becomes necessary to increase financial support for the Institution, the Sponsor may supplement this Agreement with an addendum/amendment to provide for an adequate budget increase.

6.7 In compliance with regulations on mandatory electronic invoicing for the supply of goods and services, including private transactions, the Institution will issue invoices in XML format and send them through the Interchange System (SDI). For this purpose:

- the Sponsor provides its details:
    - COMPANY NAME: Genenta Science S.p.A.
    - DESTINATION CODE/PEC: genentascience@legalmail.it
    - VAT NUMBER: 08738490963
- the Institution provides its details:
    - OSPEDALE SAN RAFFAELE S.R.L., Via Olgettina, 60 – 20132 Milano, TAX CODE and VAT NUMBER 07636600962
      at UNICREDIT S.P.A., Largo Francesco Anzani, 13, 00153 Rome, ITALY
      IBAN: IT34 C 02008 05364 000101972801
      BIC CODE: UNCRITMMORR

6.8 Payments made for services provided by the Institution (i) represent the fair market value of such services, as they align with the applicable fee schedule at the Institution, (ii) have been negotiated on standard commercial terms, and (iii) are not based on the volume or value of prescriptions or any economic activities generated between the Parties. For activities performed or expenses incurred in relation to Patients participating in the Trial, for which the Sponsor is liable, neither the Institution nor the Principal Investigator shall seek other reimbursements or payments from third parties.

6.9 Within the limits and terms set forth in the Protocol and as approved by the Ethics Committee, the Sponsor makes available to Trial participants reimbursement for “out-of-pocket” expenses, provided these are actually incurred, documented, and associated with Trial participation at the Institution, following procedures previously approved by the Ethics Committee. Reimbursement will be physically provided to participants by an external, specialized organization (hereinafter referred to as “Service Provider”), which has been formally commissioned by the Sponsor and designated as the data processor for the patients’ personal data. The Institution will also enter into an agreement with the Service Provider as the data controller for the patients’ personal data. The Service Provider is compensated by the Sponsor but operates independently and may not in any way transfer patients’ personal data to the Sponsor, of which the Sponsor is not the data controller.

Costs related to items not specified in Annex A or not included in the Protocol will not be reimbursed.

The criteria and methods specified in paragraph 3 shall apply, where applicable, to other forms of outsourced services related to the Trial that are regulated by the Protocol and have received favorable evaluation by the Ethics Committee.

Article 7 – Duration, Withdrawal, and Termination

7.1 This Agreement will take effect on the date of its final signature ("Effective Date") and will remain in force until the actual completion of the Trial at the Institution, as specified in the Protocol, unless modified by mutual agreement between the Parties. Notwithstanding the foregoing, this Agreement will take effect following the issuance of formal authorization by the Competent Authority.

7.2 The Institution reserves the right to withdraw from this Agreement by providing written notice with a 30-day advance notice to the Sponsor via registered mail or PEC in the event of:

- Insolvency of the Sponsor, settlement agreements (even extrajudicial) with the Sponsor's creditors, or initiation of enforcement proceedings against the Sponsor.

- Transfer of all or part of the Sponsor's assets to creditors or an agreement with them for a debt moratorium.

The notice will take effect from the time the Sponsor receives it.

7.3 The Sponsor, pursuant to Article 1373, paragraph 2, of the Italian Civil Code, reserves the right to withdraw from this Agreement at any time for just cause by providing written notice via registered mail or PEC with a 30-day notice period. The notice will take effect from the time it is received by the Institution. In the event of Sponsor withdrawal, the obligations undertaken and expenses incurred by the Institution as of the withdrawal notice date will remain unaffected. In particular, the Sponsor shall reimburse the Institution for all documented, irrevocable expenses incurred to ensure the proper and effective execution of the Trial (including, where applicable, expenses incurred by the Institution on behalf of the patient-participants) and compensation accrued to that point. In the case of early termination, the Sponsor retains ownership of all data and results, even partial, obtained by the Institution during the Trial, as well as any subsequent data or results derived from or related to it.

7.4 In the event of an interruption of the Trial, pursuant to applicable regulations, the Sponsor will compensate the Institution for documented expenses and accrued compensation up to that point.

7.5 It is understood that early termination of the Agreement will not entitle either Party to seek indemnification or additional payment beyond what has been agreed.

7.6 The effects of this Agreement will automatically terminate under Article 1454 of the Italian Civil Code if one of the Parties fails to fulfill an obligation within 30 days of receiving a written demand for compliance from the other Party. The applicability of Articles 1218 and following of the Italian Civil Code remains unaffected.

7.7 In the event of termination of this Agreement due to reasons other than the Institution's breach, the Institution shall be entitled to reimbursement for expenses incurred for the Trial before receiving notice of termination and to compensation for services rendered in accordance with the Protocol and this Agreement, in proportion to the activities performed up to the termination date. The Institution agrees to return any amounts previously paid by the Sponsor for activities not yet performed.

7.8 In all cases of interruption or termination of this Agreement, all precautions will be taken to ensure the utmost protection of patients already involved, in accordance with the Protocol approved by the Ethics Committee, ensuring therapeutic continuity within the limits and methods provided in Article 4.2.

Article 8 - Insurance Coverage

8.1 The Sponsor is required to ensure, in accordance with current legislation, compensation for damages suffered by patients and attributable to their participation in the clinical trial as outlined in the Protocol, commensurate with the nature and scope of the resulting risks.

8.2 Without prejudice to the provisions of Article 76 of the Regulation for low-intervention trials, the insurance coverage provided by the Sponsor covers civil liability for the Sponsor, the Institution hosting the Trial, the Principal Investigator, and other Investigators involved at the Institution's Trial Center.

8.3 By signing this Agreement, the Sponsor declares that it has taken out appropriate third-party liability insurance (policy no. 390-76845879, with HDI-GLOBAL SE) to cover the risk of possible damages to patients arising from their participation in the Trial, as required by the Ministerial Decree of July 14, 2009. The insurance policy has been deemed legally compliant and adequately protective by the Ethics Committee for the subjects involved in the Trial.

8.4 By signing this Agreement, the Sponsor agrees to bear the consequences of any inadequacies, including unforeseen ones, in the above-mentioned insurance coverage, supplementing it if necessary, in accordance with Article 7.1.

8.5 In particular, should the Sponsor intend to withdraw from the Agreement, it ensures that the insurance company will, in any case, provide coverage for individuals already included in the clinical trial, including the continuation of the Trial, in compliance with Article 2, paragraph 3 of the Ministerial Decree of July 14, 2009.

Article 9 - Final Report, Ownership, and Use of Results

9.1 The Sponsor undertakes to disclose, in accordance with legal requirements and upon completion of the Trial, all study results, even if negative.

9.2 The Sponsor is responsible for preparing the final clinical report and sending a summary of the Trial results to the Principal Investigator and the Ethics Committee within the legally specified timeframe. Regardless of the outcome of a clinical trial, the Sponsor will, within a year of its conclusion, submit a summary of the results to the EU database according to Article 37.4 of Regulation (EU) No. 536/2014.

9.3 All data, results, information, materials, discoveries, and inventions arising from the Trial's execution, in pursuit of its objectives, are the exclusive property of the Sponsor, except in cases where Investigators, if eligible, have rights to be recognized as authors. If the Sponsor initiates or plans to initiate a patent application process for inventions developed during the Trial, the Institution, and specifically the Principal Investigator, commits to providing the necessary support to the Sponsor, including documentation, at the Sponsor's expense.

9.4 The Institution may use the Trial's data and results, over which it is the autonomous data controller by law, solely for its institutional scientific and research purposes, with prior written authorization from the Sponsor. Such use should not, under any circumstances, compromise the confidentiality or patent protection of the Sponsor's intellectual property rights. The Institution must notify the Sponsor in writing of the purpose of its intended use of data and results.

The Parties mutually acknowledge their ownership of industrial and intellectual property rights related to their pre-existing knowledge (background knowledge).

9.5 The provisions of this article shall remain valid and effective even after the termination or cessation of this Agreement's effects.

Article 10 - Confidentiality of Technical and Commercial Information and Dissemination of Results

10.1 By signing this Agreement, each Party undertakes to maintain the confidentiality, for the entire duration of this Agreement (extendable through negotiation until the information becomes public domain), of all technical and/or commercial information provided by the other Party and/or developed during the course of the Trial and in pursuit of its objectives (including, but not limited to, the Investigator Brochure, information, data, and materials concerning the investigational medicinal product). Such information qualifies as "Trade Secrets" under Articles 98 and 99 of the Italian Industrial Property Code (Legislative Decree No. 30/2005, as amended by Legislative Decree No. 63/2018 implementing EU Directive 2016/943), adopting all appropriate contractual, technological, or physical measures to protect such information, including from its employees, collaborators, subcontractors, grantors, or successors.

Each Party further declares and guarantees that:

(i) its Trade Secrets have been lawfully acquired, used, and disclosed, with no known legal actions, disputes, or claims for damages or indemnification – even out of court – by third parties asserting ownership of such secrets.

(ii) it will indemnify and hold the other Party harmless from any legal actions, disputes, claims for damages, or indemnification claims, even if pursued out of court, by third parties asserting ownership of such Trade Secrets.

10.2 The Parties are required to ensure the proper and accurate dissemination and publication of the Trial results, as well as their appropriate communication to participating patients and patient representatives. The Sponsor is required, under applicable law, to promptly disclose the results, even if negative, upon completion of the Trial, once data from all participating Centers is available, and in any case, within the deadlines established by applicable EU provisions.

10.3 The Principal Investigator has the right, with prior written authorization from the Sponsor, to disseminate and publish, without limitation, the results of the Trial obtained at the Institution, in compliance with current provisions regarding the confidentiality of sensitive data, data protection, and intellectual property rights, as well as the terms and conditions outlined in this Agreement. To ensure the accuracy of data collection and the veracity of data and results processing from the Trial obtained at the Institution, at least 60 days before any presentation or publication, the Principal Investigator must submit the draft document to the Sponsor. Should issues arise concerning the scientific integrity of the document and/or regulatory, patent, or intellectual property matters, the Parties and the Principal Investigator shall review the document within the following 60 days. The Principal Investigator will consider the Sponsor's suggestions for presentation or publication, but only if necessary to protect the confidentiality of information, personal data, and intellectual property, provided they do not compromise data reliability or patient rights, safety, and well-being.

10.4 The Sponsor acknowledges it has no right to request the removal of information contained in the document, except when such requests and changes are necessary to protect data confidentiality, data protection, and intellectual property.

10.5 For the purpose of filing a patent application, the Sponsor may request the Principal Investigator to defer the publication or presentation of the document for an additional 90 days, if deemed necessary.

Article 11 - Personal Data Protection

11.1 The Parties, in carrying out the activities provided under this Agreement, agree to process any personal data they may become aware of during the clinical trial in compliance with the objectives stated in the previous articles and in accordance with Regulation (EU) 2016/679 of the European Parliament and Council of April 27, 2016 ("GDPR"), as well as related national legislative and administrative provisions in force, including any subsequent amendments and/or integrations (hereinafter collectively referred to as "Data Protection Laws"). Any institutional regulations of the Parties must be communicated to the Sponsor in advance and in detail.

11.2 The terms used in this article, in the Agreement, in the privacy notice and consent documentation, and in any other document used for the purposes of the clinical trial, must be understood and used in the manner defined in Annex B.

11.3 The Institution and the Sponsor qualify as independent data controllers under Article 4, paragraph 17 of the GDPR. Each Party shall, at its own cost, handle the appointment of Data Processors and assign functions and duties to designated persons operating under its authority in compliance with the GDPR and current legislation.

11.4 For the purposes of the Trial, personal data will be processed for the following categories of data subjects: participants in the trial and individuals working for the Parties. Such individuals are informed of the data processing through appropriate notification. For the purposes of the Trial, the following types of personal data will be processed: personal data as defined in Article 4, paragraph 1 of the GDPR; data falling under "special categories" of personal data, specifically health and sexual life data, and genetic data as per Article 9 of the GDPR. Such data will be processed in compliance with the principles of lawfulness, fairness, transparency, adequacy, relevance, and necessity as provided in Article 5, paragraph 1 of the GDPR.

11.5 The Sponsor may transfer data to affiliates of the Sponsor's group and third parties operating on its behalf, including entities outside the European Union, only in compliance with Articles 44 and following of the GDPR. In such cases, the Sponsor shall ensure an adequate level of data protection. If the Sponsor is located in a country outside the EU, and the European Commission has determined that such country does not provide an adequate level of protection per Articles 44 and 45 of the GDPR, the Sponsor and the Institution must complete and sign the Standard Contractual Clauses approved by the European Commission, provided in the absence of other legal provisions (this document is not attached to this Agreement).

11.6 The Parties guarantee that authorized personnel processing personal data for the Trial shall comply with principles protecting the right to data protection and confidentiality and that individuals accessing personal data are obliged to process it in accordance with the instructions provided by the data controller, consistent with this article.

11.7 The Principal Investigator is identified by the Institution as the individual authorized to process data under Article 29 of the GDPR and designated under Article 2-quaterdecies of the Italian Personal Data Protection Code (Legislative Decree 196/2003, as amended by Legislative Decree 101/2018).

11.8 The Principal Investigator must inform each patient, in a clear and comprehensive manner, before the start of the Trial (including preparatory and screening phases), about the nature, purpose, results, consequences, risks, and methods of personal data processing. Specifically, the patient must be informed that national and international authorities and the Ethics Committee may access the Trial-related documentation as well as the original medical records as part of monitoring, verification, and research control activities. These authorities, as well as Monitors and Auditors, may view such documents within the scope of their respective competencies.

11.9 The Principal Investigator must obtain from the duly informed patient the consent document not only for participating in the Trial but also for data processing. The Institution is responsible for storing this document.

11.10 Should either Party become aware of a personal data breach, it shall notify the other within 48 hours of discovering the breach. Each Party retains the authority to assess the existence of conditions for and fulfill its obligations under Articles 33 and 34 of the GDPR.

Article 12 - Amendments

12.1 This Agreement and its annexes/addendums, together with the Protocol as an integral part, constitute the entire agreement between the Parties.

12.2 This Agreement may be amended or supplemented only with the written consent of both Parties. Any modifications will be documented in an addendum to this Agreement and will take effect from the date of signing unless otherwise agreed upon by the Parties.

Article 13 - Anti-Corruption and Crime Prevention Regulations

13.1 The Institution and the Sponsor agree to comply with anti-corruption regulations applicable in Italy.

13.2 The Sponsor declares that it has adopted monitoring and control measures to comply with and implement the provisions of Legislative Decree 231 of June 8, 2001, as well as, where applicable and not in conflict with Italian law, the principles of the United States Foreign Corrupt Practices Act and their subsequent amendments. The Institution and its clinical and administrative structures agree to cooperate in good faith, within the limits of Italian law, with the Sponsor's personnel and management to facilitate the full and correct implementation of these obligations and the Sponsor's operational procedures for these purposes.

13.3 The Parties also acknowledge that both the Institution and the Sponsor have adopted an organizational, management, and control model in compliance with the principles outlined in the Decree (each a "Compliance Model"), a Code of Ethics (each a "Code of Ethics"), and an Anti-Corruption Policy, available on the Institution's website at https://www.hsr.it/strutture/ospedale-san-raffaele/trasparenza and on the Sponsor's website at https://ir.genenta.com/corporate-governance, to prevent liability for the commission of offenses specified by the Decree and the related sanctions.

13.4 The Institution and the Sponsor mutually agree to inform each other immediately of any potential violation of this article of which they become aware and to make all relevant data and documentation available for verification.

13.5 The Parties may disclose the terms of this Agreement or any amendment for any legitimate purpose, within the limits of data protection regulations.

13.6 A violation of the provisions of this article constitutes a material breach of this Agreement pursuant to Article 1456 of the Italian Civil Code, thereby undermining the trust relationship between the Parties.

Article 14 - Transfer of Rights, Assignment of the Agreement

14.1 This Agreement is fiduciary in nature; therefore, the Parties may not assign or transfer it, in whole or in part, to third parties without the prior written consent of the other Party. In any case, the assignee must explicitly accept all terms and conditions of this Agreement. Any transfer of rights not meeting these conditions will be considered null and void.

14.2 In the event of a name change by the Institution that does not alter its legal identity, an amendment to this Agreement will not be required. The Institution is still obliged to promptly notify the Sponsor of such a name change.

Article 15 - Signature and Tax Obligations

15.1 This Agreement is signed digitally in accordance with applicable regulations. Taxes and fees related to the execution of this Agreement, including the stamp duty on the electronic original under Article 2 of Annex A, Part I of DPR 642/1972, and the registration fee, must be paid in compliance with applicable laws. The Parties agree that the stamp duty shall be the exclusive responsibility of the Sponsor, while registration fees are borne by the Party requesting registration.

Article 16 - Governing Law and Jurisdiction

16.1 The law governing this Agreement is that of the Italian Republic.

16.2 For any disputes arising from the interpretation, application, and execution of this Agreement, while the Parties agree to attempt an out-of-court resolution, the exclusive jurisdiction shall be the Court of Milan.

Article 17 - Omitted

Article 18 - Acknowledgment and Acceptance of the Entire Agreement

The Parties acknowledge for mutual clarity that this Agreement, prepared based on the minimum content identified under Article 2, paragraph 6 of Law 3 of January 11, 2018, is considered known and accepted in its entirety by both Parties. Therefore, the provisions of Articles 1341 and 1342 of the Italian Civil Code do not apply.

Milan, on 14/10/2024

For the Sponsor:

The Legal Representative or their Delegate:

Dr. Pierluigi Paracchi
/s/ Pierluigi Paracchi 10/14/2024

Milan, on 21/10/2024

For the Institution:

Research Director
Dr. Anna Flavia d'Amelio Einaudi
/s/ Anna Flavia d'Amelio Einaudi

For acknowledgment of the provisions that concern him:

Principal Investigator
Prof. Andrea Necchi
/s/ Andrea Necchi

For acknowledgment of the provisions that concern him:

Co-Investigator
Prof. Fabio Ciceri
/s/ Fabio Ciceri

Exhibit 99.1

Genenta Science S.p.A.
Consolidated Statements of Operations and Comprehensive Loss

	Six Months Ended June 30,	
	2024	2023
	(Unaudited)	
Operating expenses		
Research and development	€ 2,040,390	€ 3,921,802
General and administrative	2,477,978	2,878,373
Total operating expenses	4,518,368	6,800,175
Loss from operations	(4,518,368)	(6,800,175)
Other income (expense)		
Other income	180,781	114,992
Finance income	145,290	77,999
Net exchange rate gain (loss)	153,791	(152,041)
Total other income, net	479,862	40,950
Loss before income taxes	(4,038,506)	(6,759,225)
Income tax benefit (expense)	-	-
Net loss	(4,038,506)	(6,759,225)
Net loss per share - basic	€ (0.22)	€ (0.37)
Weighted average number of shares outstanding - basic and diluted	18,256,622	18,216,858
Other comprehensive income (loss)		
Total change of marketable debt securities	(64,288)	-
Change in foreign currency translation	(16,081)	-
Total other comprehensive income	(80,369)	-
Comprehensive loss	€ (4,118,875)	€ (6,759,225)

The accompanying notes are an integral part of these consolidated financial statements.

Genenta Science S.p.A.
Consolidated Balance Sheets

	At June 30, 2024 (Unaudited)	At December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	€ 6,187,966	€ 3,691,420
Marketable securities	10,718,210	15,084,284
Prepaid expenses and other current assets	1,663,297	2,480,554
Total current assets	18,569,473	21,256,258
Non-current assets		
Fixed assets, net	€ 62,714	€ 82,977
Other non-current assets	381,670	1,004,560
Other non-current assets - related party	3,350	3,350
Total non-current assets	447,734	1,090,887
Total assets	€ 19,017,207	€ 22,347,145
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	€ 405,846	€ 294,975
Accounts payable - related party	189,762	170,888
Accrued expenses	260,051	153,136
Accrued expenses - related party	698,868	861,578
Other current liabilities	441,296	255,062
Total current liabilities	1,995,823	1,735,639
Non-current liabilities		
Other non current liabilities	7,981	14,594
Retirement benefit obligation	196,368	164,655
Total long-term liabilities	204,349	179,249
Commitments and contingencies	-	-
Shareholders' equity		
Ordinary shares, no par value, 59,700,000 shares authorized and 18,289,866 and 18,216,958 shares issued and outstanding, respectively	67,847,793	67,344,140
Accumulated deficit	(51,181,531)	(47,143,025)
Accumulated other comprehensive income	150,773	231,142
Total shareholders' equity	16,817,035	20,432,257
Total liabilities and shareholders' equity	€ 19,017,207	€ 22,347,145

The accompanying notes are an integral part of these consolidated financial statements.

Genenta Science S.p.A.
Consolidated Statements of Changes in Shareholders' Equity

	Common shares outstanding	Common stock, no par value	Accumulated deficit	Accumulated other comprehensive income	Total
Balance at December 31, 2022	€ 18,216,858	€ 66,603,725	€ (35,465,559)	€ -	€ 31,138,166
Share-based compensation	-	415,433	-	-	415,433
Cumulative translation adjustment	-	-	9,716	-	9,716
Net loss	-	-	(6,759,225)	-	(6,759,225)
Balance at June 30, 2023 (Unaudited)	€ 18,216,858	€ 67,019,158	€ (42,215,068)	€ -	€ 24,804,090
Share-based compensation	-	324,451	-	-	324,451
Capital increase ATM program	100	531	-	-	531
Cumulative translation adjustment	-	-	(9,716)	-	(9,716)
Other comprehensive income	-	-	(32,011)	231,142	199,131
Net loss	-	-	(4,886,230)	-	(4,886,230)
Balance at December 31, 2023	€ 18,216,958	€ 67,344,140	€ (47,143,025)	€ 231,142	€ 20,432,257
Share-based compensation	-	232,768	-	-	232,768
Capital increase ATM program	72,908	270,885	-	-	270,885
Other comprehensive income	-	-	-	(80,369)	(80,369)
Net loss	-	-	(4,038,506)	-	(4,038,506)
Balance at June 30, 2024 (Unaudited)	€ 18,289,866	€ 67,847,793	€ (51,181,531)	€ 150,773	€ 16,817,035

The accompanying notes are an integral part of these consolidated financial statements.

Genenta Science S.p.A.
Consolidated Statements of Cash Flows

	Six Months Ended June 30,	
	2024	**2023**
	(in Euros)	
Cash flows from operating activities		
Net loss	€ (4,038,506)	€ (6,759,225)
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange adjustment	-	9,716
Depreciation expense	22,132	21,143
Retirement benefit obligation	31,713	40,486
Share-based compensation	232,768	415,433
Net gain (loss) on purchase of marketable securities	-	(9,517)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	817,258	(377,721)
Other non-current assets	622,890	(502,229)
Accounts payable	110,871	(692,780)
Accounts payable - related party	18,874	(21,768)
Accrued expenses	106,915	245,976
Accrued expenses - related party	(162,710)	143,174
Other current liabilities	186,234	(86,603)
Other non-current liabilities	(6,613)	(6,214)
Net cash used in operating activities	(2,058,174)	(7,580,129)
Cash flows from investing activities		
Purchases of marketable securities	(8,998,556)	(9,989,030)
Proceeds from maturities of marketable securities	13,300,341	-
Purchases of fixed assets	(1,869)	(12,437)
Net cash (used in) provided by investing activities	4,299,916	(10,001,467)
Cash flows from financing activities		
Proceeds from ATM program	270,885	-
Net cash provided by financing activities	270,885	-
Effect of exchange rate changes	(16,081)	-
Net increase (decrease) in cash and cash equivalents	2,496,546	(17,581,596)
Cash and cash equivalents at beginning of period	3,691,420	29,794,856
Cash and cash equivalents at end of period	€ 6,187,966	€ 12,213,260

The accompanying notes are an integral part of these consolidated financial statements.

Genenta Science S.p.A.
Notes to the Consolidated Financial Statements

1. Nature of business and history

Genenta Science S.p.A. (the "Company" or "Genenta") – formerly Genenta Science S.r.l., a "società a responsabilità limitata" ("S.r.l."), which is similar to a limited liability company in the United States ("U.S.") converted to a "società per azioni" ("S.p.A."), an Italian corporation in June 2021, which is similar to a C corporation in the U.S. The Company was founded in Milan, Italy by San Raffaele Hospital ("OSR"), Pierluigi Paracchi, Luigi Naldini and Bernhard Gentner, and was incorporated in July 2014. On May 20, 2021, the quotaholders (owners of the Company) resolved that the Company convert from an S.r.l. to an S.p.A. and determined that the outstanding quota be converted to 15 million ordinary shares at no par value. (See Note 10. Shareholders' equity.) The registered office (or headquarters) is located in Milan, Italy. The Company's reporting currency is Euros ("EUR" or "€"). In May 2021, the Company formed a wholly owned, Delaware incorporated subsidiary, Genenta Science, Inc. ("U.S. Subsidiary"), intended to support U.S. employees and future operations in the U.S.. The U.S. Subsidiary operates in U.S. Dollars ("USD" or "$").

On December 17, 2021, the Company completed an initial public offering ("IPO") of its shares. The shares began trading on the Nasdaq Stock Capital Market ("Nasdaq") on December 15, 2021. Through the IPO, 3,120,114 new ordinary shares with no par value were issued. 720,114 ordinary shares were subscribed by the Company's existing shareholders through a reserved offering, while 2,400,000 American Depository Shares ("ADSs"), each representing one of the Company's ordinary shares, were offered to the public and listed on Nasdaq. Subsequently, on December 27, 2021, the Company's underwriter exercised a portion of its "green shoe" allotment for an additional 96,744 ADSs. The total number of shares outstanding resulting at December 31, 2021 was 18,216,858. Through the IPO, approximately €29 million was raised, net of listing costs (approximately €3.9 million).

On May 12, 2023, the Company filed with the Securities and Exchange Commission (the "SEC") a shelf registration statement that was subsequently declared effective on May 24, 2023. It permits the Company to sell from time-to-time ordinary shares, including ordinary shares represented by ADSs, or rights to subscribe for ordinary shares or ordinary shares represented by ADSs in one or more offerings in amounts, at prices, and on the terms that the Company will determine at the time of offering for aggregate gross sale proceeds of up to $100 million, subject currently to the limits set forth in Instruction I.B.6(a) of Form S-3 (referred to as "baby shelf" rules).

In June 2023, the Company's shareholders reduced the number of directors from seven (7) to five (5).

In July 2023, the Company issued 100 ADSs for net proceeds of approximately €531 (or $582), increasing the total number of shares outstanding to 18,216,958, pursuant to a Controlled Equity Offering^{SM} Sales Agreement, dated May 12, 2023 (the "Prior Sales Agreement"), between the Company and Cantor Fitzgerald & Co. ("Cantor"), as agent, subject to the terms and conditions described in the Prior Sales Agreement and SEC rules and regulations (the "Prior ATM Offering").

In March 2024, the Company issued 72,908 ADSs for net proceeds of approximately €270,885 (or $293,328), bringing the total number of ordinary shares outstanding to 18,289,866, pursuant to the Prior Sales Agreement. On March 28, 2024, the Company and Cantor mutually agreed to terminate the Prior Sales Agreement.

On April 26, 2024, the Company entered into an ATM Sales Agreement (the "Current Sales Agreement") with Capital One Securities, Inc. and Virtu Americas LLC (the "Sales Agents"), pursuant to which the Company may offer and sell ADSs, for an aggregate offering price of up to $16,362,816 from time to time through or to the Sales Agents, acting as sales agents or principals, subject to the terms and conditions described in the Current Sales Agreement and SEC rules and regulations (the "Current ATM Offering").

In May 2024, the Company's shareholders approved an amendment of article 9 of the Company's Bylaws, introducing increased voting rights by introducing a mechanism whereby each ordinary share owned by the same subject (either an entity or an individual) for a continuous period of not less than twenty-four months entitles the holder to a double vote and therefore to an increase from one to two votes per share. In addition, a further vote is attributed at the end of each twelve-month period, following the first vesting period of twenty-four months, in which the ordinary share has belonged to the same entity or individual, up to a total maximum of 10 votes per ordinary share. The amendment applies to only ordinary shares, not ADSs.

Genenta is an early-stage company developing first-in-class cell and gene therapies to address unmet medical needs in cancerous solid tumors. 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 continue its clinical trials in Italy, and eventually start a clinical trial in Europe and the U.S. to study Temferon™ in other cancers. In June 2023, the Company's Board of Directors (the "Board") selected Renal Cell Cancer ("RCC") as the second solid tumor indication for Temferon. The Company is currently finalizing a clinical plan for RCC.

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 and profit from operations.

Liquidity and risks

The Company has incurred losses since its inception, including a net loss of €4.0 million and €6.8 million for the six months ended June 30, 2024, and June 30, 2023, respectively. In addition, at June 30, 2024, the Company had an accumulated deficit of €51.2 million. The Company has primarily funded these losses through the proceeds from sales of convertible debt and equity quotas, before the Company's conversion into an S.p.A., and then through the proceeds from its IPO. The Company has incurred recurring losses and expects to continue to incur losses for the foreseeable future. In addition, the Company expects that its existing cash and cash equivalents on hand of €6.2 million, together with the other short-term marketable securities of €10.7 million as of June 30, 2024 will be sufficient to fund current planned operations and capital expenditure requirements for at least the next twelve months. 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 continue as a going concern, as well the 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'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 because, 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 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, debt or convertible securities through public offerings or private placements, including sales of ADSs pursuant to the Current ATM Offering. 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 and /or financial situation of the Company.

The Company's ability to raise additional capital may be adversely impacted by the potential worsening of global economic and political conditions and volatility in the credit and financial markets in the U.S. and worldwide. This could be exacerbated by, among other factors, the war between Russia and Ukraine, the ongoing conflict in the Middle East or other macroeconomic conditions. The Company's failure to raise capital as and when needed, or on acceptable terms could have a negative impact on the Company's financial condition, its ability to continue as a going concern, and its ability to pursue its business strategy, and the Company may have to delay, reduce the scope of, suspend or eliminate one or more of its research-stage programs, clinical trials, or future commercialization efforts.

Quantitative and qualitative disclosure about market risk

The Company is exposed to market risks in the ordinary course of its business. Market risk represents the risk of loss that may impact the Company's financial position due to adverse changes in financial market prices and rates. The Company's current investment policy is conservative due to the need to support operations. The Company invests available cash in Italian and U.S. government treasury bills and notes with short-term maturities. A minority of the Company's cash and cash equivalents and marketable securities are held in deposits that bear a small amount of interest. The Company's market risk exposure is primarily a result of foreign currency exchange rates, which is discussed in detail in the following section.

The Company is an early-stage cell and gene therapy company commercializing technology licensed from OSR. The Company intends to continue to conduct its operations so that neither it nor its subsidiary is required to register as an investment company under the Investment Company Act of 1940, as amended, and the rules and regulations promulgated thereunder (the "'40 Act"). To ensure that the Company does not become subject to regulation under the '40 Act, the Company may be limited in the type of assets that it may own or acquire. If the Company were to become inadvertently subject to the '40 Act, any violation of the '40 Act could subject the Company to material adverse consequences.

Foreign currency exchange risk

The Company's results of operations and cash flow may be subject to fluctuations due to changes in foreign currency exchange rates. The Company's liquid assets and expenses are denominated in EUR and USD. At June 30, 2024, the Company maintained €6.2 million in cash and cash equivalents and €10.7 million in marketable securities. Changes in the USD/EUR exchange rate could increase/decrease the Company's operating expenses, especially as more costs are incurred in the U.S. or, as USD are exchanged for EUR to cover European operating costs. As the Company continues to grow its business, the Company's results of operations and cash flows might be subject to significant fluctuations due to changes in foreign currency exchange rates, which could adversely impact the Company's results of operations.

Currently, the Company has recorded an unrealized net gain from exchange rate of approximately €0.2 million. The Company does not currently hedge its foreign currency exchange risk. In the future, the Company may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of its principal operating currencies. These measures, however, may not adequately protect the Company from the material adverse effects of such fluctuations.

2. Summary of significant accounting policies

Basis of presentation

The consolidated financial statements of the Company are unaudited and have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial reporting and in accordance with Regulation S-X, Rule 10-01 promulgated by the Securities and Exchange Commission ("SEC"). Accordingly, the financial statements may not include all the information and footnotes required by U.S. GAAP for complete financial statements. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 20-F filed with the SEC on March 29, 2024, as amended by Amendment No. 1 of Form 20-F/A filed with the SEC on April 1, 2024. The balance sheet as of December 31, 2023 was derived from audited consolidated financial statements included in the Company's Annual Report but does not include all disclosures required by U.S. GAAP.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from these interim financial statements. However, these interim financial statements include all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of the Company's management, necessary to fairly state the results of the interim period. The interim results are not necessarily indicative of results to be expected for the full year.

A summary of the significant accounting policies applied in the preparation of these consolidated 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.

Principles of consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

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 consolidated financial statements include but are not limited to, the accrual for research and development and clinical expenses and related milestone payments, share-based compensation expense, valuation of research and development 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 consolidated 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 like short-term marketable securities, which amounts may at times exceed federally insured limits. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk. In the Consolidated Statements of Cash Flows, cash and cash equivalents include cash on hand, deposits held with banks, and other short-term highly liquid investments. In the consolidated balance sheets, bank overdrafts, if any, are shown in current liabilities. Cash and cash equivalents are reported at fair value and are detailed as follows:

	At June 30, 2024	At December 31, 2023
	(Unaudited)	
Cash in bank	€ 3,945,143	€ 3,687,402
Cash in short-term marketable securities	2,238,823	-
Cash in hand & prepaid cards	4,000	4,018
Total cash and cash equivalents	€ 6,187,966	€ 3,691,420

Marketable securities

The Company's marketable securities are maintained by management and investment managers and consist of highly rated domestic and foreign government debt securities. Debt securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of shareholders' equity until realized. Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Amortization and accretion of premiums and discounts are recorded in interest income, net. Realized gains and losses on debt securities are determined using the specific identification method and are included in other income(expense), net.

The Company classifies marketable securities with a remaining maturities when purchased of greater than three months as available-for-sale. Marketable securities with a remaining maturity date greater than one year are classified as non-current assets.

Effective January 1, 2023, the Company adopted ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements* ("ASU 2016-13" or "ASC 326"), using the effective date method. As the Company had never recorded any other-than-temporary-impairment adjustments to its available-for-sale debt securities prior to the effective date, no transition provisions are applicable to the Company.

The Company assesses its available-for-sale debt securities under the available-for-sale debt security impairment model in ASC 326 as of each reporting date to determine if a portion of any decline in fair value below carrying value recognized on its available-for-sale debt securities is the result of a credit loss. The Company records credit losses in the Consolidated Statements of Operations and Comprehensive Loss as credit loss expense within other income (expense), net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit loss on its available-for-sale debt securities.

Accrued interest receivable related to the Company's available-for-sale debt securities is presented within receivables and other current assets on the Company's Consolidated Balance Sheets. The Company has elected to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write-offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivables associated with its marketable securities.

Net loss and comprehensive loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. ASC 220 Comprehensive Income requires that an entity records all components of comprehensive (loss) income, net of their related tax effects, in its financial statements in the period in which they are recognized. For the six months ended June 30, 2024, the net loss was equal to €4.0 million and the comprehensive loss was equal to €4.1 million. At June 30, 2023, the comprehensive loss was equal to the net loss.

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 ordinary shares outstanding during the period. Diluted EPS reflects potential dilution and is computed by dividing net loss by the weighted average number of ordinary shares outstanding during the period increased by the number of additional ordinary shares that would have been outstanding if all potential ordinary shares had been issued and were dilutive.

The EPS calculation was applied at the Company conversion to an S.p.A. in June 2021. Prior to the conversion to an S.p.A., the Company's equity ownership interests were represented by quotas, as opposed to shares, and accordingly, an EPS calculation was not possible. The Company's shareholders have authorized 59.7 million ordinary shares. In July 2023, in the Prior ATM Offering, 100 new ADSs were issued. In March 2024, 72,908 additional ADSs were issued in the Current ATM Offering. At June 30, 2024, the Company had 18,289,866 ordinary shares issued and outstanding, with approximately 1.8 million ordinary shares reserved for the Company's Equity Incentive Plan 2021–2035.

At June 30, 2024 and June 30, 2023, the Company had options on 280,033 and 318,459 ordinary shares outstanding, respectively, and 23,502 ordinary share equivalents in the form of underwriters' ordinary share warrants. Dr. Squinto, the Company's former Chairman of the Board, held options on 147,783 shares that expired unexercised as of April 2024.

Diluted EPS was not relevant at June 30, 2024 and June 30, 2023, as the effect of ordinary share equivalents, in the form of 23,502 underwriters' ordinary share warrants, and options on 280,033 and 318,459 ordinary shares, respectively, would have been anti-dilutive. (See Note 10. Shareholders' equity and Note 11. Share-based compensation.)

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 consolidated 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 date(s) of the transaction(s) or valuation where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the Consolidated Statements of Operations and Comprehensive Loss. For financial reporting purposes, the assets and liabilities of the U.S. Subsidiary are translated into EUR using exchange rates in effect at the balance sheet date. The net income/(loss) of the U.S. Subsidiary is translated into EUR using average exchange rates in effect during the reporting period. The resulting currency translation impact is recorded in the Consolidated Statements of Changes in Shareholders' Equity as a cumulative translation adjustment. At June 30, 2024 and June 30, 2023, the currency translation impact was not material.

During the six months ended June 30, 2024, the unrealized foreign exchange net gain was €0.2 million. During the six months ended June 30, 2023, the unrealized foreign exchange net loss was €0.2 million. The minimal change in the net foreign exchange rate effect was due to the fluctuation in the USD exchange rate with the Euro.

Emerging growth company status

The Company is an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act (the "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, because of this election, its consolidated 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 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 ("R&D") tax credits, VAT credits, accounts payable, accrued expenses and other current liabilities were evaluated and determined to approximate their fair values due to the short-term nature of these assets and liabilities.

	June 30, 2024			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	€ 6,187,966	6,187,966	€ -	€ -
Marketable securities	10,718,210	10,718,210	-	-
Total cash and cash equivalents and marketable securities	**€ 16,906,176**	**€ 16,906,176**	**€ -**	**€ -**

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	3,691,420	3,691,420		
Marketable Securities	€ 15,084,284	15,084,284	€ -	€ -
Total cash and cash equivalents and marketable securities	**€ 18,775,704**	**€ 18,775,704**	**€ -**	**€ -**

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 R&D

In line with the legislation in force at December 31, 2023, and for the fiscal year 2024, companies in Italy that invest in eligible R&D 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 social security contributions and payroll withholding taxes.

Starting with the fiscal year 2023 ("FY 2023"), for eligible R&D activities, the tax credit is equal to 10% of the eligible costs incurred, with a maximum annual amount of €5.0 million. In addition, the law extended the measure up to the tax period ended December 31, 2031.

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 R&D projects;
- Expenses for extra-euro research contracts concerning the direct execution of eligible R&D activities by the provider;
- Expenses for consulting services and equivalent services related to eligible R&D activities; and,
- Expenses for materials, supplies, and other similar products used in R&D 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 has elected to present net of the related expenditure on the Consolidated Statements of Operations and Comprehensive Loss.

While these tax credits can be carried forward indefinitely, the Company recognized an amount that 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 Consolidated Statements of Operations and Comprehensive Loss.

Share-based compensation

To reward the efforts of employees, officers, directors, and certain consultants, and to promote the Company's growth and development, the Board may approve, upon occasion, various share-based awards. The Company's stock option plan (the "Equity Incentive Plan 2021–2025" or the "Plan"), pursuant to which stock options are granted, was originally approved on May 20, 2021.

In June 2023, the Company's shareholders modified the Plan to extend the final deadline for the issuance of the ordinary shares until December 31, 2035, to allow all stock options granted during the term of the Plan could provide for an exercise period of 10 years starting from the date of grant. (See Note 11. Share-based compensation.)

Currently, the Company has authorized options on 1,828,986 ordinary shares (i.e., 10% of the number of shares outstanding, which was 18,289,866 ordinary shares outstanding at June 30, 2024); however, as provided by the Plan, the Company may increase the authorized shares under the Plan up to a maximum of 2,700,000 ordinary shares without further shareholder approval. Therefore, as the Company raises additional capital, the Board has the authority to issue options on 1,828,986 to 2,700,000 ordinary shares, as the number of issued and outstanding ordinary shares grows, i.e., the Company does not have to obtain further authorization from shareholders to increase the number of ordinary shares available for equity grants until the outstanding ordinary shares exceed 27,000,000.

The Company measures its stock option awards granted to employees, officers, directors, and consultants under the Plan based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is normally 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 stock-based compensation expense in its Consolidated Statement 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.

The Company chose the Black-Scholes-Merton model because it is considered easier to apply and it is a defined equation and incorporates only one set of inputs. As a result, it is the model most commonly in use.

Representative warrants

Upon the closing of the Company's IPO, the Company issued 23,502 warrants to the underwriters of the offering ("Warrants"). The Warrants are exercisable at a per share exercise price equal to 125% of the public offering price (i.e., $14.375) per ADS sold in the IPO. The 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 June 13, 2022. The Warrants will provide for adjustment in the number and price of the Warrants and the ADSs underlying such Warrants in the event of recapitalization, merger, stock split, or other structural transaction, or a future financing undertaken by the Company. The Warrants were evaluated under applicable guidance and accordingly classified as equity in the consolidated financial statements.

Non-current assets right-of-use ("ROU")

Upon commencement of a contract containing a lease, the Company classifies leases other than short-term leases as either an operating lease or a finance lease according to the criteria prescribed by ASC 842. The Company recognizes both lease liabilities and ROU assets on the balance sheet for all leases, except for short-term leases (those with a lease term of 12 months or less). Lease liabilities are initially measured at the present value of the future lease payments over the lease term, discounted at the rate implicit in the lease or, if that rate is not readily determinable, the Company's incremental borrowing rate. The ROU assets represent the lessee's right to use the underlying asset for the lease term and are initially measured at the same amount as the corresponding lease liability. For finance leases, the Company recognizes interest expense on the lease liability and amortization expense on the ROU asset. For operating leases, lease expense is recognized on a straight-line basis over the lease term.

In February 2022, the Company entered into a four-year (i.e., 48-month) lease of an automobile, with an ending date of January 2026. The "base" annual lease payment is €13,967 payable monthly in the amount of €1,164. The lease payment will remain fixed for the four (4) years. The automobile lease was identified and accounted for as a finance-type lease.

For the initial measurement, the calculation of the net present value of the ROU asset and liability was made by using the discounted rate of 6.25% and was determined to be approximately €49,320. Lessee initial direct costs were deemed not material. Other non-lease component costs for lease insurance were accounted for separately from the lease. At June 30, 2024, the net present value of the ROU asset and liability amounted to approximately €21,004. The liability was determined to be €13,023 as a current liability and €7,981 as a long-term liability.

Fixed Assets

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. Depreciation is systematically recorded in the consolidated financial statements by taking into consideration the use, purpose, and financial-technical duration of the assets, based on their estimated useful economic lives. Leasehold improvement depreciation is recorded based on the shorter of: (i) the life of the leasehold improvement; or, (ii) the remaining term of the lease.

Ordinary maintenance costs are expensed to the Consolidated Statements of Operations and Comprehensive Loss 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 purpose of economic productivity of the Company, are attributed to the asset to which they refer and depreciated based on its estimated useful economic life. Amortization of leasehold improvements is computed using the straight-line method based on 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 for the six months ended June 30, 2024, and June 30, 2023.

Deferred offering costs

Deferred offering costs, which primarily consist of direct, incremental legal and accounting fees relating to fundraising activities (e.g., an IPO or other fundraising activities), are capitalized within prepaid expenses and other current assets before the offering and netted or offset with the offering proceeds upon closing of the offering.

For the six months ended June 30, 2024, the Company incurred approximately €0.2 million of ATM offering costs that were fully expensed as general and administrative costs in the Consolidated Statement of Operations and Comprehensive Loss.

For the six months ended June 30, 2023, the Company incurred approximately €0.3 million of ATM offering costs that were fully expensed as general and administrative costs in the Consolidated Statement of Operations and Comprehensive Loss.

Recently issued accounting pronouncements

In November 2023, the FASB issued ASU 2023-07 which amends ASC 280 to improve the information that a public entity discloses about its reportable segments and to address investor requests for more information about reportable segment expenses by requiring incremental disclosures for segment reporting. The effective date for ASU 2023-07 is for fiscal years beginning after December 15, 2023 and interim periods with fiscal years beginning after December 15, 2024. The amendment requires companies to disclose more information about their reportable segments, including: (1) significant segment expenses, (2) ‘other’ segment items, (3) the title and position of the chief operating decision maker (“CODM”), (4) how the CODM uses the reported measure(s) of segment profit or loss and (5) annual disclosures about a reportable segment’s profit or loss and assets. The Company will be providing the enhanced reportable segment financial disclosures effective with its Annual Report on Form 20-F for the year ending December 31, 2024.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which modifies the rules on income tax disclosures to require disaggregated information about a reporting entity’s effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. The Company is currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

In March 2024, the FASB issued ASU 2024-01, Scope Application of Profits Interest and Similar Awards, which clarifies how an entity determines whether a profits interest or similar award (hereafter a “profits interest award”) is (1) within the scope of Accounting Standards Codification (ASC) 718, Compensation — Stock Compensation, or (2) not a share-based payment arrangement and therefore within the scope of other guidance. For public business entities, ASU 2024-01 is effective for annual periods beginning after December 15, 2024, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after December 15, 2025, and interim periods within those annual periods. The Company currently expects that this ASU will not have a material impact on its consolidated 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, 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 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 annually 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 at 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 disclosures in Note 12. Accumulated Other Comprehensive Income 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, and the U.S., through the U.S. Subsidiary. Taxation in Italy includes the standard corporate income tax ("IRES") and a regional business tax ("IRAP"). Taxation in the U.S. includes federal corporate income tax ("IRS"), as well as state and local taxes. 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. In the future, the Company may be taxed in various other countries where it may have permanent establishments, as applicable. Due to the tax loss position reported, no income taxes were accrued for the six months ending June 30, 2024, and June 30, 2023, in Italy or the U.S. At June 30, 2024, the U.S, subsidiary had an immaterial amount of other state taxes.

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.

At each reporting date, the Company considers existing evidence, both positive and negative, that could impact its view with regard to future realization of deferred tax assets. In consideration of the start-up status of the Company, a valuation allowance has been established to offset the deferred tax assets, as the related realization is currently uncertain. In the future, should the Company 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 Consolidated Statements 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 consolidated financial statements. For the Company, the prior five years of tax returns (2019-2023) are potentially subject to audit. For the U.S. Subsidiary, the open years for tax examination are 2021, 2022, and 2023.

At June 30, 2024, and June 30, 2023, the Company believes there were no significant differences with regard to its deferred tax assets and its relevant components, compared to the computations of the preceding periods.

In 2011, the Italian tax authorities issued a set of rules that modified the previous treatment of tax loss carryforwards. According to DL 98/2011, at the end of 2011, all existing tax loss carryforwards will never expire but they can offset only 80% of the taxable income of the year.

The Company has analyzed its tax position by determining the amount of tax losses that can be carried forward indefinitely and has decided to accrue an allowance for related deferred tax assets as the Company is in a situation of pre-revenues that is destined to remain in the long run and there is no certainty of the future recoverability of such tax losses through tax relevant incomes. Future taxable profits for the Company depend on the manufacture of marketable drugs following the successful completion of the applicable clinical trial. Since the GBM clinical trial is still in Phase 1/2a status, the time frame and uncertainties regarding the outcome of the completion justify the full allowance of deferred tax assets.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	At June 30, 2024	At December 31, 2023
(in Euros)	(Unaudited)	
Value added tax (VAT)	€ 420,366	€ 1,170,634
Research and development tax credit	766,680	833,000
Advances payments to suppliers	34,439	34,108
Other current assets	247,946	64,664
Other prepaids	193,866	378,148
Total	€ 1,663,297	€ 2,480,554

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 2024 and 2023 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. During the six months ended June 30, 2024, the Company received a VAT refund of approximately €1.7 million, of which approximately €1.3 million related to short-term VAT and approximately €0.4 million related to VAT that was classified as long-term at December 31, 2023. The amount of VAT as of June 30, 2024 is related to the VAT accrued in the same period.

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. The Company has a total research and development tax credit available to be used of approximately €4.0 million at June 30, 2024, 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 that represents the Company's best estimate of the amount of tax credit that can be used in offsetting taxes payable by the fourth quarter of 2025. This estimate is consistent with the Company's most updated cash budget utilization projections approved by the Board in March 2024 and the revised cash forecast as of October 2024. According to the revised cash forecast dated October 2024, the Company's available cash as of June 30, 2024, together with our investment in short-term marketable securities, is deemed more than sufficient to cover the operating activities through at least November 2025, without additional financing or other management plans.

During the six months ended June 30, 2024 and 2023, the Company utilized approximately €0.4 million to offset certain social contributions and taxes payable. In addition, the recorded benefit for the six months ended June 30, 2024, and June 30, 2023, was approximately €0.4 million, respectively, to offset research and development expenses.

The advance payments to suppliers mainly refer to an advance payment to a supplier whose activities are still ongoing based on a service agreement that provides for a discount on this advance payment on the last invoice that will be issued at the end of the works.

As of June 30, 2024, other current assets were primarily composed of tax credits amounting to approximately €0.2 million and financial claims for accrued interest on ongoing investments, amounting to approximately €53,000. The change compared to the previous period balance was due to the reclassification from long-term to short-term of a €180,000 of tax credit related to Italian Additional Corporate Tax (the "ACE tax") which, based on the latest updates received from the Italian Revenue Agency, will be recovered in the short term.

The prepaids refer to accrual adjustments for services that have already been fully invoiced and paid, but whose economic usefulness is distributed over multiple periods beyond the current closing period. These costs mainly concern IT services, licenses, insurance, and manufacturing activities. The change in the prepaid balance is primarily influenced by the trend in manufacturing activities performed by the Company's manufacturing vendor, AGC Biologics, and the amount of the premium for the directors' and officers' insurance policy. The most recent renewal of this policy specifically resulted in a significant cost saving, which consequently led to a reduction in the balance of the related prepaid from approximately €0.2 million at June 30, 2023 to approximately €0.1 million at June 30, 2024.

7. Fixed assets, net

Fixed assets consist of the following:

	At June 30, 2024	At December 31, 2023
	(Unaudited)	
Software (ERP Implementation)	€ 87,800	€ 87,800
Computers	37,840	35,971
Furniture and fixtures	13,005	13,005
Total fixed assets	138,645	136,776
Less: accumulated depreciation	(75,931)	(53,799)
Fixed assets, net	€ 62,714	€ 82,977

For the period ended June 30, 2024 and June 30, 2023, software was €87,800 and includes software customization and development costs related to information technology security infrastructure and the new ERP system.

Equipment consists of computers, and furniture and fixtures of our office space in Milan, Italy. There were no significant purchases, disposals or impairments 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. No significant purchases occurred during the six months ended June 30, 2024.

8. Other non-current assets

Other non-current assets consist of the following:

	At June 30, 2024	At December 31, 2023
	(Unaudited)	
Value added tax (VAT)	€ 110,774	€ 630,342
Research and development tax credit	249,892	167,000
Other non-current assets	21,004	207,218
Total	€ 381,670	€ 1,004,560

The balance of long-term VAT credit is what remains outstanding after the refund of €0.4 million already received during the six months ended June 30, 2024.

The R&D tax credit long-term portion at June 30, 2024 was approximately €250,000 as compared to €167,000 at December 31, 2023 due to the expected utilization period for the R&D tax credit being adjusted to a timeframe ending November 30, 2025 as per the contingent financial cash projections.

Other non-current assets include the ROU asset for the car lease in the amount of €21,004. The main change in the Other non-current assets balance, compared to the previous period, was due to the reclassification of the €180,000 of ACE tax credit from long-term to short-term following a recent update from the Italian Revenue Agency regarding the expected timing of the related refund.

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 are accounted for under the provisions of ASC 715, Compensation – Retirement Benefits.

The amount of the obligation at June 30, 2024 and December 31, 2023 was €196,368 and €164,655, respectively. The increase was due to the increase in personnel costs and as a result of new hires.

10. Shareholders' equity

The number of the Company's outstanding ordinary shares at December 31, 2022, was 18,216,858, no par value. All ordinary shares outstanding are held in ledger form with some of the ordinary shares represented by ADSs.

For the six-month period ended June 30, 2023, the Company accrued €415,433 as the fair value of stock options granted as per the Plan. (See Note 11. Share-based compensation for more details.)

In July 2023, 100 new ADSs were issued in the Prior ATM Offering, and the Company recorded an increase in the ordinary shares, no par value of €531.

For the six-month period from July 1, 2023 to December 31, 2023, the Company accrued €324,451 to update the fair value of the granted stock options.

At December 31, 2023, the Company had 18,216,958 ordinary shares issued and outstanding with approximately 1.8 million ordinary shares reserved for the Plan.

In March 2024, 72,908 new ADSs were issued in the Prior ATM Offering and the Company recorded an increase in the ordinary shares, no par value of €270,885.

For the six-months ended June 30, 2024, the Company accrued €232,768 as the fair value of stock options granted as per the Plan. (See Note 11. Share-based compensation for more details)

At June 30, 2024, the Company had 18,289,866 ordinary shares issued and outstanding with approximately 1.8 million ordinary shares reserved for the Plan.

11. Share-based compensation

As mentioned in Note 2. Summary of significant accounting policies, to reward the efforts of employees, officers, directors, and certain consultants, and to promote the Company's growth and development, the Board may approve, upon occasion, various share-based awards.

The Plan was originally approved on May 20, 2021 and was subsequently modified, in June 2023, to extend the final deadline for the issuance of the ordinary shares until December 31, 2035, to allow that all stock options granted during the term of the Plan could provide for an exercise period of 10 years starting from the date of grant.

At January 1, 2023, there were 540,523 granted stock options and 1,281,162 stock options remaining available for grant.

In March 2023, the Board, as administrator of the Plan, awarded non-qualified stock options ("NSOs") on 46,400 shares to the Company's directors. The NSOs vested monthly over a one (1) year period with a 10-year term. All NSOs were priced based on a 30-day volume weighted average formula, adjusted with the Black-Scholes method, which was determined to be $5.62 per share.

At December 31, 2023, there were 586,923 granted stock options and 1,234,772 stock options remaining available for grant.

In April 2024, NSOs on 147,783 shares expired. These options had a two (2) year term and were awarded to the Company's former Chairman in April 2022, according to the terms of a sub-plan called the "2021-2025 Chairman Sub-Plan" (or the "Sub-Plan") attached to the original Equity Incentive Plan 2021–2025.

At June 30, 2024, there were 439,140 stock options granted and 1,389,846 options available for grant.

The Company calculates the fair value of stock option awards granted to employees and non-employees using the Black-Scholes option-pricing method. If the Company determines that other methods are more reasonable, or other methods for calculating these assumptions are prescribed by regulators, the fair value calculated for the Company's stock options could change significantly. Higher volatility and longer expected lives would result in an increase to share-based compensation expense to non-employees determined at the date of grant. Share-based compensation expense to non-employees affects the Company's general and administrative expenses and research and development expenses.

The Company calculated the share compensation expense for the options granted by utilizing the Black-Scholes method with the following inputs for each of the stock grants:

- The option's exercise price.
- The option's expected term.

- The underlying share's current price.
- The underlying share's expected price volatility during the option's expected (or in certain cases, contractual) term, or in cases where calculated value is used, the historical volatility of an appropriate industry sector index.
- The underlying share's expected dividends during the option's expected (or in certain cases, contractual) term except cases, such as when dividend protection is provided; and,
- The risk-free interest rate during the option's expected (or in certain cases, contractual) term.

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2023	540,523	€ 4.99	7.3	€ 272,480
Granted	46,400	5.30	9.17	-
Vested and exercised	-	-	-	-
Cancelled or forfeited	-	-	-	-
Outstanding as of December 31, 2023	586,923	€ 4.84	6.53	€ 67,596
Exercisable as of December 31, 2023	382,785	€ 5.11	5.44	€ 33,796
Outstanding, expected to vest as of December 31, 2023	**204,138**	**€ 4.34**	**8.58**	**€ 33,800**
Outstanding as of January 1, 2024	586,923	€ 4.84	6.53	€ 67,596
Granted	-	-	-	-
Vested and exercised	-	-	-	-
Cancelled or forfeited	(147,783)	-	-	-
Outstanding as of June 30, 2024	439,140	€ 4.53	8.12	€ -
Exercisable as of June 30, 2024	280,033	€ 4.58	8.16	€ -
Outstanding, expected to vest as of June 30, 2024	159,107	**€ 4.44**	**8.05**	€ -

The Company's share-based compensation expense for the period ended June 30, 2024 and June 30, 2023 is represented by the following table:

	Six Months Ended June 30,	
	2024	**2023**
Research & development expense	€ 37,173	€ 36,718
Research & development expense - related party	-	-
General & administrative expense	114,219	298,333
General & administrative expense- related party	81,376	80,381
Total	€ 232,768	€ 415,433
Unrecognized expense	€ 747,043	€ 1,471,743

For the six months ended June 30, 2024, and June 30, 2023, the Company recorded €232,768 and €415,433, respectively, as the fair value of the stock options granted. The amount of unrecognized expense at June 30, 2024 and June 30, 2023 was €747,043 and €1,471,743, respectively.

There were no options granted during the six months ended June 30, 2024. The weighted average grant date fair value of the options granted during the six months ended June 30, 2023 was €5.30 per share.

Weighted average shares

The calculation was performed by taking the number of shares outstanding during a given period and weighting them for the number of days that number of shares were outstanding. For the six months ended June 30, 2024, and June 30, 2023, there was a weighted average of 18,256,622 and 18,216,858 shares, respectively, of the Company's ordinary shares, no par value.

12. Accumulated Other Comprehensive Income

	Changes in Accumulated Other Comprehensive Income For the Period Ending June 30, 2024		
	Unrealized gains and losses on available-for-sale debt securities	Foreign Currency Translation Adjustments	Total
Beginning Balance	€ 214,984	€ 16,158	€ 231,142
Adjustment for net gain on marketable securities	(190,228)		(190,228)
Change in fair value of marketable securities	125,940		125,940
Cumulative translation adjustment	-	(16,081)	(16,081)
Total	€ 150,696	€ 77	€ 150,773

Accumulated Other Comprehensive Income relates to marketable securities fair value measurement reserve and cumulative translation adjustment reserve as reported in the above table.

The net realized gain in the six months ended June 30, 2024 from the Company's investing activity was approximately €0.2 million. The unrealized net gain on marketable securities not matured at June 30, 2024, was approximately €0.1 million. Translation adjustments on investment transactions expressed in U.S. dollars were not material.

The cumulative translation adjustments reserve was not material, and it mainly included the effect of the translation of U.S. dollars held by the U.S. Subsidiary into Euros as the consolidated financial statements currency.

13. Related parties

The Company's R&D expenses are a combination of third-party expenses, and related party expenses, as detailed below:

	Six Months Ended June 30, 2024		
	Third Parties	Related Parties	Total
Consultants & other third parties	€ 113,498	€ 303,298	€ 416,796
Materials & supplies	911,246	-	911,246
Compensation (including share-based)	349,839	329,227	679,066
Travel & entertainment	17,589	-	17,589
Other	15,693	-	15,693
Total	€ 1,407,865	€ 632,525	€ 2,040,390

	Six Months Ended June 30, 2023		
	Third Parties	Related Parties	Total
		(Unaudited)	
Consultants & other third parties	€ 150,402	€ 72,500	€ 222,902
Materials & supplies	2,464,107	660,863	3,124,970
Compensation (including share-based)	212,003	330,796	542,799
Travel & entertainment	27,892	-	27,892
Other	3,239	-	3,239
Total	€ 2,857,643	€ 1,064,159	€ 3,921,802

Related party R&D expenses for consultants & other third parties refer mainly to the costs of preclinical and clinical activities charged by OSR. R&D costs for materials & supplies relate mainly to manufacturing costs charged by the Company's main manufacturing vendor, AGC Biologics. Compensation costs relate to R&D personnel wages, salaries, and share-based compensation including social contribution and other related personnel costs. Travel & entertainment expenses relate mainly to business trips and scientific conferences. Other R&D expenses relate to minor general operating costs.

The Company's general and administrative expenses are also a combination of third-party and related-party expenses, as detailed below:

	Six Months Ended June 30, 2024		
	Third Parties	Related Parties	Total
Compensation (including share-based)	€ 451,903	€ 698,620	€ 1,150,523
Accounting, legal & other professional	557,049	-	557,049
Communication & IT related facility	85,277		85,277
Facility & insurance related	984	8,120	9,104
Consultants & other third parties	324,306	-	324,306
Other	350,752	967	351,719
Total	€ 1,770,271	€ 707,707	€ 2,477,978

	Six Months Ended June 30, 2023		
	Third Parties	Related Parties	Total
	(Unaudited)		
Compensation (including share-based)	€ 697,228	€ 673,795	€ 1,371,023
Accounting, legal & other professional	720,989	-	720,989
Communication & IT related facility	-	-	-
Facility & insurance related	2,868	8,171	11,039
Consultants & other third parties	314,059	-	314,059
Other	460,320	943	461,263
Total	€ 2,195,464	€ 682,909	€ 2,878,373

The Company's accounts payable to related parties are comprised as follows:

	At June 30, 2024	At December 31, 2023
	(Unaudited)	
San Raffaele Hospital	€ 189,762	€ 170,888

The Company's accrued expenses to related parties are comprised as follows:

	At June 30, 2024	At December 31, 2023
	(Unaudited)	
San Raffaele Hospital	€ 34,306	€ 413,935
Pierluigi Paracchi	252,000	175,254
Richard Slansky	176,812	116,738
Carlo Russo	235,750	155,651
Total	€ 698,868	€ 861,578

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 chair of the Scientific Advisory Board);
- Bernard Rudolph Gentner (co-founder of the Company and member of Scientific Advisory Board);
- Carlo Russo (Chief Medical Officer and Head of Development);
- Richard Slansky (Chief Financial Officer); and,
- Ospedale San Raffaele (co-founder of the Company, shareholder, main service provider for clinical activity and licensor of brands of any product that can be obtained through research).

These parties could exercise significant influence on the Company's strategic decisions, behavior, and future plans.

The following is a description of the nature of the transactions between the Company and these related parties:

Pierluigi Paracchi

Mr. Pierluigi Paracchi, is the Company's Chief Executive Officer, Chairman, as well as co-founder. His current employment arrangement with the Company provides an annual gross salary of €420,000 plus a 40% annual bonus subject to Board approval. Mr. Paracchi also has use of a Company car, for which the Company entered an operating lease agreement that started in 2022.

In March 2023, Mr. Paracchi was paid a bonus of approximately €112,000 (gross amount), related to the activity performed in 2022 and accrued in the same period.

At December 31, 2023, the Company accrued €168,000 for Mr. Paracchi's bonus (of which €84,000 accrued in the first six months ended June 30, 2023) to reward the activity performed in the same year. At June 30, 2024, the bonus accrued in 2023 was not paid yet. For the six months ended June 30, 2024 the Company accrued €84,000 for Mr. Paracchi bonus for his performance in 2024.

For the six months ended June 30, 2024 and June 30, 2023, the Company expensed approximately €300,000, related to compensation for Mr. Paracchi.

Luigi Naldini/Bernard Rudolph Gentner

Drs. Luigi Naldini and Bernhard Gentner are co-founders of Genenta and part of the Scientific Advisory Board ("SAB"), with Dr. Naldini as Chairman, and Dr. Gentner as a member. The Company has consulting agreements with each of Drs. Naldini and Gentner.

Dr. Naldini has an advisory agreement approved by the Board and he and his staff perform the pre-clinical studies for the Company. The latest consulting agreement with Dr. Naldini was signed on June 20, 2022, which includes an annual fee of €100,000 starting July 1, 2022. As of June 30, 2024, Dr. Naldini billed €50,000 and all the issued invoices were paid before June 30, 2024.

Dr. Gentner, like Dr. Naldini, oversees pre-clinical research related to the Company's platform technology and analyzes clinical biological data. The consulting agreement with Dr. Gentner started on July 1, 2022, and provides fees in the amount of €45,000 per year. As of June 30, 2024, Dr. Gentner billed €22,500 and all the issued invoices were paid.

In February 2024, Dr. Gentner entered into an addendum to the consulting agreement in which the Company agrees to pay a total one-time fee of up to €15,000 to conduct research and write and submit a scientific research paper. The agreement provides the fees to be billed progressively if and when the expected research steps are met. At June 30, 2024, only the first step was achieved, billed, and paid in the amount of €5,000.

Carlo Russo

Dr. Carlo Russo serves the Company as Chief Medical Officer and Head of Development and is responsible for the clinical development of Temferon™, the Company's gene therapy platform. His current employment arrangement is in place with the U.S. Subsidiary, and it provides for an annual gross salary of $500,000, plus a 30% bonus, subject to Board approval.

In March 2023, Dr. Russo was paid a bonus of approximately €112,000 (gross amount), related to the activity performed in 2022 and accrued in the same period.

At December 31, 2023, the Company accrued €156,000 for Dr. Russo's bonus (of which approximately €84,000 was accrued in the first six months ended June 30, 2023) to reward the activity performed in the same year. At June 30, 2024, the bonus accrued for 2023 was not paid yet. For the six months ended June 30, 2024, the Company accrued €70,000 for Dr. Russo's bonus for his performance in 2024.

For the six months ended June 30, 2024, and June 30, 2023, the Company expensed approximately €329,000 and €331,000, respectively, related to compensation for Dr. Russo.

Richard Slansky

Mr. Richard Slansky is the Chief Financial Officer of the Company. His current employment arrangement is in place with the U.S. Subsidiary, and it provides an annual gross compensation of $375,000 plus a 30% bonus subject to Board approval.

At December 31, 2023 the Company accrued €116,000 for Mr. Slansky's bonus (of which approximately €63,000 accrued in the first six months ended June 30, 2023) to reward the activity performed in the same year. At June 30, 2024 the bonus for 2023 was not paid yet. For the six months ended June 30, 2024, the Company accrued €53,000 for Mr. Slansky's bonus for his performance in 2024.

For the six months ended June 30, 2024, and June 30, 2023, the Company expensed approximately €243,000 and €253,000, respectively, related to compensation for Mr. Slansky.

OSR – San Raffaele Hospital

OSR - San Raffaele Hospital is a co-founder of the Company, and the Company is a corporate and research spin-off of OSR. OSR 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 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 located in an OSR facility.

Amended and Restated OSR License Agreement

The Company entered into an amended and restated license agreement (the "ARLA") with OSR in March 2023. The ARLA replaced the Company's original license agreement originally entered into with OSR on December 15, 2014, as subsequently amended on March 16, 2017, February 1, 2019, December 23, 2020, September 28, 2021, January 22, 2022, September 29, 2022, and December 22, 2022 (the "Original OSR License Agreement").

The effectiveness of the ARLA was subject to Italy's Law Decree No. 21 of March 15, 2012 (i.e., the Italian Golden Power regulations), as subsequently amended and supplemented and would not become effective until the applicable Italian governmental authority consented to the ARLA. On April 20, 2023, such consent was received, and the ARLA became effective.

Pursuant to the terms of the ARLA, OSR has granted the Company an exclusive, royalty-bearing, non-transferrable (except with the prior written consent of OSR), sublicensable, worldwide license, subject to certain retained rights, to (1) certain patents, patent applications and existing know-how for the use in the field(s) of Interferon ("IFN") gene therapy by lentiviral based-hematopoietic stem and progenitor cells ("HSPC") gene transfer with respect to any solid cancer indication (including glioblastoma and solid liver cancer) and/or any lympho-hematopoietic indication for which the Company exercises an option (described below); and, (2) certain gene therapy products (subject to certain specified exceptions related to replication competent viruses) developed during the license term for use in the aforementioned field(s) consisting of any lentivirals or other viral vectors 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 indication means any indication related to lympho-hematopoietic malignancies and solid cancer indication means any solid cancer indication (e.g., without limitation, breast, pancreas, colon cancer), with each affected human organ counting 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, the right to use the licensed technology within the field(s) of use other than in relation to the licensed products, 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, the Company granted OSR a perpetual, worldwide, royalty-free, non-exclusive license to any improvement generated by the Company with respect to the licensed technology, to conduct internal research within the field(s) of use directly, or in or with the collaboration third parties; and, for any use outside the field(s) of use, in which case the license is sublicensable by OSR. Finally, the worldwide rights for the field(s) of use granted to the Company 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.

Pursuant to the ARLA, the Company has an exclusive option exercisable until April 20, 2026 to any OSR product improvements at no additional cost, which could be useful for the development and/or commercialization of licensed products in the field of use. The Company also has an exclusive option exercisable until April 20, 2026 (the "LHI Option Period") to any lympho-hematopoietic indication(s) 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:

- €1.0 million for the first lympho-hematopoietic indication;
- €0.5 million for the second lympho-hematopoietic indication; and
- €0.3 million for the third lympho-hematopoietic indication.

No option fee is due for the fourth lympho-hematopoietic indication and any subsequent lympho-hematopoietic indications.

The Company has the right to extend the LHI Option Period twice for additional 12-month periods, subject to the payment of specified extension fees.

Prior to the effective date of the ARLA, the Company paid OSR an upfront fee in an amount equal to €250,000 pursuant to the Original OSR License Agreement.

Pursuant to the ARLA, as consideration, the Company agreed to pay OSR additional license fees equal to up to €875,000 in total, which are payable on April 20, 2023, December 31, 2023, and upon the Company entering into a sublicense agreement with a third party sublicensee (pursuant to which the Company is entitled to receive an upfront payment in an amount exceeding a specified threshold from such sublicensee) during the period between September 30, 2022 and April 20, 2028 (with most of these additional license fees being triggered upon the Company entering into such a sublicense agreement). In addition, the Company has 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. The Company 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, market authorization application ("MAA") approval by a major market country, MAA approval in the U.S., the first commercial sale of a licensed product in the U.S. and certain E.U. countries, and achievement of certain net sales levels.

As part of the ARLA, the Company has agreed to use reasonable efforts to involve OSR in Phase I clinical trials for 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. The Company is also obligated to carry out its development activities using qualified and experienced professionals and sufficient level of resources. In particular, consistent with the terms of the Original OSR License Agreement, the ARLA continues to require the Company 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). (See Note 14. Commitments and contingencies.)

OSR maintains control of the preparation, prosecution, and maintenance of the patents licensed. The Company is 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 the Company, the Company has the right to enforce the licensed technology within the field of use. Both the Company and OSR must consent to settlement of any such litigation, and all monies recovered will be shared, after reimbursement for costs, in relation to the damages suffered by each party, or failing a bona fide agreement between the Company and OSR, on a 50% - 50% basis.

The ARLA expires upon the expiry of the "Royalty Term" for all licensed products and all countries, unless terminated earlier. The Royalty Term begins on the first commercial sale of a licensed product in each country, on a country by country basis, and ends upon the later of the (a) expiration of the commercial exclusivity for such product in that country (wherein the commercial exclusivity refers to any remaining valid licensed patent claims covering such licensed product, any remaining regulatory exclusivity to market and sell 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 in such country.

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 the Company fails to pay any of the upfront payments, additional license fees, sublicensing income or milestone payments within 30 days of due dates for each. In addition, OSR may terminate (with a 60-business day prior written notice) the Company's rights as to certain fields of use for the Company's failure to achieve certain development milestones for specified licensed products within certain time periods, which may be subject to extension. In addition, OSR may terminate the agreement in the event that commercialization of a licensed product is not started within 24 months from the grant of both (i) the MAA approval and (ii) the pricing approval of such licensed product, provided that such termination will relate solely to such licensed product and to such country or region to which both such MAA approval and pricing approval were granted.

Amendment to OSR Amended and Restated License Agreement

On September 28, 2023, the Company and OSR entered into an amendment to the ARLA, whereby the Company and OSR agreed that the Company had fulfilled the obligations as set forth in the ARLA specific to Candidate Products 1 pursuant to the CP1 SRA (each as defined below). Furthermore, the amendment provides that the Company and OSR have no further obligations to negotiate and execute a sponsored research agreement for the performance of feasibility studies related to certain gene therapy products consisting of any lentiviral vectors 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 cytokines and their variants (other than IFN or in addition to IFN) under the control of a Tie2 promoter, either alone or in combination with any immunotherapy ("Candidate Products 2"). Notwithstanding the removal of the obligation to enter into a sponsor research agreement with regards to Candidate Products 2, OSR granted the Company an exclusive option, to be exercised by sending written notice to OSR on or before September 30, 2025, to include certain intellectual property related to Candidate Products 2 and Candidate Products 2 as part of the licensed patents and licensed products under the ARLA. The option fee and the Company's fee to extend the option period, if necessary, remain consistent with the prior fees to those costs reflected in the ARLA specific to Candidate Products 2. OSR will also have the right to prepare, file and prosecute patents and patent applications with respect to the results of Candidate Products 2. The amendment provides that the costs of the foregoing activities will be borne by the Company.

At June 30, 2024, the cumulative total amount of expenses for the OSR clinical trial activity from inception amounted to approximately €11.0 million and includes the cost for the exercise of the first and the second solid cancer indication option fee of €1.0 million as well as the cost for ARLA fees of €0.4 million.

At June 30, 2024, there were no pending activities with OSR related to any agreement in place prior to the ARLA effective date, except for the project called "TEM-MM unspent budget reallocated to the TEM-GBM study", for which the last tranche of activities corresponding to the 20% of the total project approximately amounting to €0.2 million, as a whole, is still to be completed.

OSR Sponsor Research Agreement

On August 1, 2023, the Company entered into a Sponsored Research Agreement ("CP1 SRA"), which was contemplated under the ARLA, pursuant to which the Company will fund feasibility studies for certain gene therapy products consisting of any lentiviral vectors 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, in combination with any immunotherapy ("Candidate Products 1"), along with three additional research projects, to be conducted at OSR. If OSR determines that additional funds are needed, OSR will inform the Company and provide an estimate for completing the research.

During the period from the date of execution from the CP1 SRA until six months from the last report delivered to the Company under the CP1 SRA (the "CP1 Option Period"), the Company has the exclusive option to include certain intellectual property related to Candidate Products 1 and Candidate Products 1 as part of the licensed patents and licensed products under the ARLA. To exercise this option, the Company must pay an option exercise fee. The Company also has the right to extend the CP1 Option Period twice for an additional 24-month period. The extension requires payment of an extension fee for each 24-month extension.

At June 30, 2024 the Company recorded and paid approximately €0.3 million for the CP1 SRA studies.

Operating leases

The Company entered into a non-cancelable lease agreement for office space in January 2020. (See Note 14. Commitments and contingencies.)

14. 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 the Company's obligations by contractual maturity on June 30, 2024:

	Payments by Period				
	Total	Less than a year	1 to 3 years	4 to 5 years	More than 5 years
OSR operating leases and office rent	€ 21,267	€ 15,012	€ 6,255	€ -	€ -
OSR- ARLA	166,700	166,700	-	-	-
AGC manufacturing	75,985	75,985	-	-	-
Insurance policies	11,095	6,996	4,099	-	-
Total	€ 275,047	€ 264,693	€ 10,354	€ -	€ -

The commitments with OSR relate to the office rent agreement and the ARLA while the commitments with AGC Biologics ("AGC") relate to product manufacturing and biologic stability studies on plasmid batches. Insurance on operating leases arise related to the non-lease insurance component of the Company's auto lease agreement, which was entered into in February 2022 and has a term of four (4) years.

The Company has not included future milestones 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.

CMO and CRO agreements

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

As part of the ARLA, the Company is obligated to carry out development activities using qualified and experienced professionals and a sufficient level of resources. In particular, consistent with the terms of the Original OSR License Agreement, the ARLA continues to require the Company 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).

The Company incurred €0.9 million and €1.6 million of manufacturing expenses during the first six months ended June 30, 2024, and June 30, 2023, respectively. The cumulative expense to date is €10.1 million, and there is no residual commitment for the Company at June 30, 2024.

The Company has agreed to pay OSR royalties for 4% 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. The Company also agreed to pay OSR a royalty of the Company's 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, market authorization application ("MAA") approval by a major market country, MAA approval in the United States, the first commercial sale of a licensed product in the U.S. and certain E.U. countries, and achievement of certain net sales levels.

No events have occurred or have been achieved (and none are considered probable) to trigger any contingent payments under the ARLA during the six months ended June 30, 2024.

AGC Biologics S.p.A.

The AGC agreement dated March 6, 2019 (the "Master Service 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. Under the Master Service 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 Master Service 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 October 2022, the Company entered into Side Letter to the Master Service Agreement dated March 6, 2019 to negotiate a technology transfer agreement regarding the transfer and implementation of the manufacturing process in the AGC facility located in Bresso, Italy, including timeline, budget and the technology transfer protocol (the "Tech Transfer") and AGC agreed with the Company to procure raw materials to be used under the Tech Transfer.

In December 2022, the Company signed respectively: (i) the Amendment No. 1 to the Master Service Agreement mainly to update the definition of raw materials; and (ii) a Process Transfer Agreement to agree on producing the raw materials necessary for the performance of the services related to the Tech Transfer for a total commitment of €405,000 for raw materials, €40,500 for handling and €24,000 for the stability timepoints. As of June 30, 2024, the project was completed.

In January 2023, the Company entered into a new Development and Manufacturing Service Agreement providing the framework under which AGC will provide services pursuant to one or more work statements to be entered into from time to time during the agreement term.

In February 2023, the Company entered into work statements Nos. 1 and 2 to produce Lentiviral Vector ("LVV") for ex-vivo application (TIA-126-LV) for an estimated amount, including raw material and third-party costs, of approximately €0.7 million and €1.5 million respectively. At June 30, 2024 the work statement No. 1 was completed, while the work statement No. 2 had approximately €0.2 million to be performed.

In December 2023, the Company entered into purchase orders Nos. 41 and 42 under the Master Service Agreement, for a total amount of approximately €0.2 million. At June 30, 2024, the production activity was completed.

In January 2024, the Company entered into a new project change order No. 1 "For the Process Transfer Agreement," governed by the term and conditions of the Process Transfer Agreement, to update stage 3 of the Process Transfer Agreement to extend Temferon shelf-life up to 18 months, for a total cost of €8,000.

During the six months ended June 30, 2024, the Company entered into purchase orders Nos. 43, 44 and 45 under the Master Service Agreement, for a total amount of approximately €0.3 million. At June 30, 2024, the production activity was not completed for purchase order No. 43 and not begun for purchase orders Nos. 44 and 45, and was subsequently cancelled in July 2024 as explained below in Note 15. Subsequent events.

In June 2024, the Company entered into a work order for the development studies on frozen apheresis and liquid cultures implementation for an estimated amount including raw materials of approximately €0.3 million.

Operating lease - office rent

On January 1, 2020, the Company began a six-year non-cancelable lease agreement for office space with OSR. Withdrawal is allowed from the fourth year with a notice of 12 months. Since the annual rent amounts approximately €15,150, at June 30, 2024, outstanding minimum payments amount to €7,575 through December 2024.

Finance lease

On February 11, 2022, the Company entered a four (4) year auto lease. This lease has been recognized as a finance lease. The automobile underlying the lease agreement is fully covered by insurance policies for the duration of the lease agreement, for a total amount of €27,985. This insurance policy is considered a non-lease component since it represents services provided separately from the auto lease agreement. Therefore, it is accounted for in insurance expense in the Consolidated Statement of Operations and Comprehensive Loss when occurred. At June 30, 2024, the outstanding payments for insurance expenses related to the automobile under lease amounted to approximately €11,000.

Legal proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of ASC 450, Contingencies.

15. Subsequent events.

AGC Biologics S.p.A.

In July 2024:

- the Company signed a purchase order with AGC, named 'Bresso Preparatory Activities', specifically for a one-time fee applicable to all ongoing activity programs and intended for the performance of the same manufacturing activities for €0.1 million;

- the Company signed a purchase order with AGC, No.46, for a total amount of approximately €0.1 million for manufacturing activity;

- the Company cancelled purchase orders with AGC, Nos. 44 and 45, and, as a consequence, the Company will incur a cancellation fee of approximately €112,000; and

- on September 19, 2024, an Amendment to the Master Service Agreement was signed with AGC. The purpose of the amendment was to extend the term of the Master Service Agreement to June 30, 2025. The amendment was considered effective retroactive from March 5, 2024, the day on which the Master Service Agreement expired, to cover the preceding period during which the same MSA continued to be operating.

In September 2024:

- the Company signed two purchase orders with AGC, GU_01 and GU_02, for approximately €159,000 total, for the manufacturing activity scheduled for November to be performed by AGC for the first two patients of the new TEM-GU study.

In October 2024:

- the Company signed a purchase order with AGC, No.47, for a total amount of approximately €0.1 million for manufacturing activity.

Share-based compensation

In July 2024, the Board, as the administrator of the Equity Incentive Plan 2021-2025, awarded NSOs on 577,884 shares to the Company's directors, officers, and employees. The director NSOs vest immediately with a 10-year term. The officer and employee NSOs have a 10-year term and vest monthly over three years, except that employees with less than one year of service have a one-year cliff vesting from the date of hire, and then monthly vesting thereafter. All options have an exercise price utilizing the stock price at the date of grant of $3.083 per share.

Status of proposed Renal Cell Cancer trials

In October 2024, the Company announced that the Agenzia Italiana del Farmaco approved a new Phase 1 clinical trial for metastatic Renal Cell Cancer. The Company expects to commence the trial in the fourth quarter of 2024.

In October 2024, the Company also entered into an agreement with OSR to conduct an open-label phase 1/2 clinical trial in Renal Cell Cancer. The study is designed to evaluate the safety, biological response, and efficacy of a single dose of Temferon (autologous hematopoietic stem and progenitor cells enriched with CD34+ and genetically modified with human Interferon-α2) in patients with metastatic renal carcinoma.

Exhibit 99.2

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 in Exhibit 99.1 to the report on Form 6-K (the "Form 6-K") to which this Exhibit 99.2 relates. This discussion and other parts of this Exhibit 99.2 and the Form 6-K may 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 our annual report on Form 20-F for the year ended December 31, 2023, filed with the Securities and Exchange Commission (the "SEC") on March 29, 2024, as amended by Amendment No. 1 on Form 20-F/A filed with the SEC on April 1, 2024 (our "2023 20-F"). References to "we," "Genenta," "us," "our," "the Company," or "our company" herein are to Genenta Science S.p.A., including its subsidiary.

Our reporting currency and functional currency is the Euro. Unless otherwise expressly stated or the context otherwise requires, references in this Exhibit 99.2 to "dollars," "USD" or "$" are to U.S. dollars, and references to "euros," "EUR," "Euros," or "€" are to European Union euros.

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 or 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 June 30, 2024, aggregated gross cash proceeds of approximately €67.3 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 six months ended June 30, 2024, and June 30, 2023 were approximately €4.0 million and approximately €6.8 million, respectively. As of June 30, 2024, and December 31, 2023, we had an accumulated deficit of approximately €51.2 million and €47.1 million, respectively. 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, debt and convertible securities in public offerings and private placements, including the net proceeds from our initial public offering ("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 June 30, 2024, we had cash and cash equivalents of approximately €6.2 million and marketable securities of approximately €10.7 million. We believe that our existing cash and cash equivalents and marketable securities, as of June 30, 2024, 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 may need to raise additional capital, which cannot be assured.

Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of our patients, business partners, employees, and other stakeholders. As a result, cybersecurity risk management is an integral part of our overall risk management and compliance program, and our current cybersecurity risk management processes are modeled after industry best practices, such as the National Institute of Standards and Technology Cybersecurity Framework, for handling cybersecurity threats and incidents, including threats and incidents associated with the use of applications developed by third-party service providers, and facilitate coordination across different departments of our Company

Our Board of Directors has overall oversight responsibility for our cybersecurity risk management; however, it delegates cybersecurity risk management oversight to our management and Board of Statutory Auditors. Our management and Board of Statutory Auditors is responsible for ensuring that we have processes in place designed to identify and evaluate cybersecurity risks to which we are exposed and implement processes and programs to manage cybersecurity risks and mitigate cybersecurity incidents.

These processes include steps for assessing the severity of a cybersecurity threat, identifying the source of the threat, including whether the cybersecurity threat is associated with a third-party service provider, implementing cybersecurity countermeasures and mitigation strategies, and informing management and our Board of Directors of material cybersecurity threats and incidents. Our information technology consultant is responsible for assessing our cybersecurity risk management program, and we currently do not engage other third parties for such assessment.

Our cybersecurity program is under the direction of our Chief Financial Officer and Finance Director, who receive reports from our information technology consultant and monitors the prevention, detection, mitigation, and remediation of cybersecurity incidents. Our Chief Financial Officer and Finance Director together have over 50 years of information technology experience in various roles of increasing importance. Their experience includes overseeing and supervising information technology risk management processes. Among their other duties as Chief Financial Officer and Finance Director, respectively, they manage our cybersecurity consultant, who is a certified and experienced information security professional and implements and monitors of our various cybersecurity systems and tools.

Management is responsible for identifying, considering, and assessing material cybersecurity risks on an ongoing basis, establishing processes to ensure that such potential cybersecurity risk exposures are monitored, putting in place appropriate mitigation measures and maintaining cybersecurity programs, including:

- implementing a comprehensive, cross-functional approach to identifying, preventing and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner;

- deploying technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence;

- establishing and maintaining comprehensive incident response and recovery plans that fully address our response to a cybersecurity incident, and such plans are tested and evaluated on a regular basis; and

- providing regular, mandatory training for personnel regarding cybersecurity threats as a means to equip our personnel with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices

Management, including our Chief Financial Officer and Finance Director, regularly update our Board of Statutory Auditors on our cybersecurity processes, material cybersecurity risks, and mitigation strategies. Our Board of Statutory Auditors, in coordination with our management, reports all material cybersecurity risks to our Board of Directors.

Although we are subject to ongoing and evolving cybersecurity threats, we are not aware of any material risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

Components of Operating Results

Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products until we obtain regulatory approval for, and commercialize, our product candidate(s).

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 ("CROs"), contract manufacturing organizations ("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 to manage 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 in the Consolidated Statements of Operations and Comprehensive Loss. However, some of our research and development expenses are allocated by program:

	Six Months Ended June 30,	
	2024	2023
	(Unaudited)	
Direct research and development expenses by program:		
TEM-GBM Phase 1	€ 643,460	€ 660,863
TEM-GBM Phase 2	2,500	-
TEM-GU Phase 1	282,250	-
Unallocated costs:		
Personnel (including share-based compensation)	679,066	542,799
Consultants and other third party	190,998	222,902
Materials & supplies	209,025	2,464,107
Travel & entertainment	17,592	27,892
Other	15,499	3,239
Total research and development expenses	€ 2,040,390	€ 3,921,802

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, clinical costs, 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;
- 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 European Medicines Agency ("EMA"), United States ("U.S.") Food and Drug Administration ("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, 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 expenses for individuals on our Board of Directors and 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 the development of our product candidates. We also anticipate that we will continue to incur additional accounting, audit, legal, regulatory, compliance, directors and officers' insurance costs as well as investor and public relations expenses associated with being a public company. Additionally, when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other expenses 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 gain (loss) from sale or maturity of available for sale debt securities.

Income Taxes

We are subject to taxation in Italy and the U.S. Taxes are recorded on an accrual basis. Taxes 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 six months ended June 30, 2024, and June 30, 2023.

As of each reporting date, we consider existing evidence, both positive and negative, that could impact our view regarding 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 June 30, 2024. 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 Consolidated Statements of Operations and Comprehensive Loss.

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, as updated by the Italian Budget Law 2022, companies in Italy that invested in eligible research and development activities, regardless of the legal form and economic sector in which they operate, can benefit from a tax credit up to 10% of the increase of annual research and development expenses incurred, up to a maximum of €5.0 million, which can 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. In addition, the tax credit due can only be used as compensation in three equal annual installments. The measure is provided up to the tax period ending December 31, 2031.

The Italian Budget Law 2023 established that the actual support of eligible expenses and its correspondence with the accounting documents must result from a specific certification issued by the person responsible for the legal audit and, in addition to the audit report, a technical report is also required.

Results of Operations

Comparison of the Six Months Ended June 30, 2024 to the Six Months Ended June 30, 2023

The following table summarizes our results of operations for the six months ended June 30, 2024, and June 30, 2023:

	Six Months Ended June 30,	
	2024	2023
	(Unaudited)	
Operating expenses		
Research and development	€ 2,040,390	€ 3,921,802
General and administrative	2,477,978	2,878,373
Total operating expenses	4,518,368	6,800,175
Loss from operations	(4,518,368)	(6,800,175)
Other income (expense)		
Other income	180,781	114,992
Finance income	145,290	77,999
Net exchange rate gain (loss)	153,791	(152,041)
Total other income, net	479,862	40,950
Loss before income taxes	(4,038,506)	(6,759,225)
Income tax benefit (expense)	-	-
Net loss	(4,038,506)	(6,759,225)
Net loss per share - basic	€ (0.22)	€ (0.37)
Weighted average number of shares outstanding - basic and diluted	18,256,622	18,216,858
Other comprehensive income (loss)		
Change in fair value of marketable debt securities fair value measurement	(64,288)	-
Change in foreign currency translation	(16,081)	-
Total other comprehensive income	(80,369)	-
Comprehensive loss	€ (4,118,875)	€ (6,759,225)

Research and Development Expenses

Research and development expenses were approximately €2.0 million for the six months ended June 30, 2024, as compared to approximately €3.9 million for the six months ended June 30, 2023. The decrease of €1.9 million was mainly due to: (1) the substantial completion of manufacturing activities related to the preparation of Lentiviral Vector ("LVV") starting material in 2023, [incurring approximately €0.7 million]; (2) in 2023, we entered the final manufacturing phase with our manufacturing partners for the scale-up of LVV for gene therapy with residual cost in 2024, [incurring approximately €0.4 million]; (3) the completion of our technology transfer activities from AGC Biologics' Olgettina facility to its Bresso site for drug product manufacturing, which we were obligated by contract to support, [incurring approximately €0.3 million]; (4) the last cohort of our TEM-GBM Phase 1 dose-ranging study was completed in May 2024, [incurring approximately €0.3 million more patient costs in the six months ended June 30, 2023 compared to the six months ended June 30, 2024]; (5) a reduction in fees to OSR (San Raffaele Hospital) [of approximately €0.1 million]; and (6) a reclassification of patent-related legal fees in 2024 from research and development expenses to general and administrative expenses, [incurring approximately €0.1 million].

General and Administrative Expenses

General and administrative expenses were approximately €2.5 million for the six months ended June 30, 2024, as compared to approximately €2.9 million for the six months ended June 30, 2023. The decrease of approximately €0.4 million was primarily due to: (1) lower stock compensation expenses accrued in the first six months ended June 30, 2024, [amounting to approximately €0.2 million]; (2) lower audit fees since a different auditing firm was engaged for 2024, [amounting to approximately €0.1 million]; and, (3) insurance costs decreased in the first six months ended June 30, 2024, mainly due to a reduction in our directors' and officers' limited liability insurance policy that was renegotiated at the end of 2023 resulting in a premium reduction [of approximately €0.1 million].

Other Income (Expenses) and Finance Income (Expenses)

Other net income and net finance income, mainly relate to financial interests and capital gain from short-term liquidity investments and amounted to approximately €0.3 million at June 30, 2024, and €0.2 million at June 30, 2023. The increase was due to the positive performance of our investment portfolio.

Foreign Exchange Gains

For the first six months ended June 30, 2024, the foreign exchange net gain was approximately €0.2 million, while for the six months ended June 30, 2023, we recorded a net foreign exchange loss of approximately €0.2 million. The increase in foreign exchange net gain was due to the strengthening of the U.S. dollar against the Euro in the six months ended June 30, 2024.

Net Loss

Our net loss was approximately €4.0 million for the six months ended June 30, 2024, as compared to approximately €6.8 million for the six months ended June 30, 2023. The decrease in our loss of approximately €2.8 million was primarily due to the reduction in overall research and development activity, as well as a decrease in professional fees, especially legal fees and audit fees as explained above.

Liquidity and Capital Resources

Overview

Since 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, in prior years as an S.r.l., and through our shares, in our IPO and follow on offerings as an S.p.A. We received gross cash proceeds of approximately €33.6 million from sales of quotas prior to our IPO, approximately €32.7 million of gross proceeds from the IPO and approximately €0.3 million from our at-the-market ("ATM") offerings. As of June 30, 2024, we had approximately €6.2 million in cash and cash equivalents and €10.7 million in marketable securities maturing short term.

	Six Months Ended June 30, (Unaudited)	
	2024	**2023**
Net cash used in operating activities	€ (2,058,174)	€ (7,580,130)
Net cash (used in) provided by investing activities	4,299,916	(10,001,467)
Net cash provided by financing activities	270,885	-
Effect of exchange rate changes	(16,081)	-
Net (decrease) increase in cash and cash equivalents	€ 2,496,546	€ (17,581,597)
Cash and cash equivalents at beginning of year	3,691,420	29,794,856
Cash and cash equivalents at end of year	€ 6,187,966	€ 12,213,259

Operating Activities

During the six months ended June 30, 2024, and June 30, 2023, operating activities used approximately €2.0 million and €7.6 million, respectively, of cash and cash equivalents, resulting mainly from our loss during the period. The net change in our operating assets and liabilities was primarily due to the decrease in payments to third-party vendors for manufacturing and clinical trial activities, due to the reduction of research and development activity.

The non-cash charges primarily included approximately €0.2 million of stock-based compensation expense and other minor amounts of depreciation and retirement benefit obligation expense.

Investing Activities

During the six months ended June 30, 2024, we purchased approximately €9.0 million of marketable securities, while the proceeds from maturities of marketable securities were approximately €13.3 million.

Financing Activities

During the six months ended June 30, 2024, we raised approximately €0.3 million from the sale of ADSs representing our shares through our ATM offerings.

Current Outlook

To date, we have not generated revenue and do not expect to generate significant revenue from the sale of any product candidate in the near future.

As of June 30, 2024, our cash and cash equivalents and marketable securities were approximately €16.9 million. Our primary cash obligations relate to payments to personnel, OSR for clinical trial costs, and other providers for other clinical trial related services and manufacturing activities.

Based on our estimates, operating and financial plans, our existing cash, we estimate that our funds will be sufficient to fund our operations and capital expenditure requirements for more than the next twelve months. 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 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 agreements with existing or new contract manufacturing organizations;
- 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, short-term deposits, and short-term marketable securities, as well as through additional financings, which we may seek through a combination of private and public equity offerings, debt financings and collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships.

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.

This expected use of cash and cash equivalents represents our intentions based on 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 available cash and cash equivalents to in-license, acquire, or invest in additional businesses, technologies, products, or assets.

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 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 shareholder, 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 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 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

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 way 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 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.

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 recognize an amount that reflects management's best estimate of the amount 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 U.S. Jumpstart Our Business Startups Act ("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 are 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 are 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 can be subject to significant fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. Our functional currency is the Euro. Exposure to foreign currently exchange risk is derived from transactions between the Company and the U.S. Subsidiary for which the functional currency is the U.S. dollar, as well as transactions with suppliers outside the euro zone.

The following table shows the impact of up to a 10% increase in the exchange rate between the Euro and the U.S. dollar. A deterioration of the U.S. dollar versus the 1.07132 closing rate at June 30, 2024 could impact the expenses as follows:

	At June 30, 2024		Sensitivity		
	USD	EUR	+1%	+5%	+10%
USD Expenses	$ 1,176,430	€ 1,098,112	€ (10,872)	€ (52,291)	€ (99,828)

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.

Other Events

Appointment of the New Board of Directors

As previously reported in our Form 6-K furnished to the SEC on April 8, 2024, on April 5, 2024, Mark A. Sirgo, Anthony Marucci, Roger Abravanel, and Guido Guidi resigned as directors of the Board of Directors, noting unease with the Company's strategic approach as well as a disagreement related to the proposal of a loyalty share program through a proposed amendment to the Company's Bylaws.

Further, as previously reported in our Form 6-K furnished to the SEC on May 3, 2024 (our "May Form 6-K"), on May 2, 2024, at the Ordinary and Extraordinary Shareholders' Meeting of the Company (the "2024 Shareholders' Meeting"), the Company's shareholders approved the appointment of five directors to the Company's Board of Directors, effective as of May 2, 2024, four of whom are new directors. The new members of the Board are: John L. Cantello, Ph.D., Lauren H. Chung, Ph.D., Armon R. Sharei, Ph.D., and Todd Wider, M.D. Pierluigi Paracchi, Chief Executive Officer, will continue to serve on the Board of Directors as Chairman. For more information regarding our new directors, see our May Form 6-K.

The term of office of the new directors is one year and the aggregate annual directors' compensation is €213,000.

The newly appointed directors met immediately following the 2024 Shareholders' Meeting and appointed Mr. Paracchi as Chief Executive Officer of the Company and allocated €37,500 as compensation for each director, excluding the Chairman and Chief Executive Officer who is already remunerated in his capacity as executive.

Appointment of the New Board of Statutory Auditors

As previously reported in our May Form 6-K, at the 2024 Shareholders' Meeting, the Company's shareholders approved also the appointment of the new Board of Statutory Auditors for the three-year period of 2024-2026, consisting of: Carlo Alberto Nicchio (Chairman), Jacopo Doveri, Giuseppe Gentile, while Luca Domenico and Adalberto Adriano were appointed as alternates. The annual Board of Statutory Auditor compensation is €18,000 for the chairman and €12,000 for each active member while no compensation is provided for the alternates unless they replace an active member. For more information regarding the new members of our Board of Statutory Auditors, see our May Form 6-K.

Full Effectiveness of Loyalty Share Program

As previously reported in our May Form 6-K, at the 2024 Shareholders' Meeting, the Company's shareholders approved an amendment to the Company's Bylaws that established a loyalty share program. Following such approval, no shareholder of the Company exercised rights of withdrawal. As result, the loyalty share program is fully effective. Accordingly, each ordinary share of the Company held in registered form entitles the shareholder to a double vote (i.e. two votes for each ordinary share) if the ordinary share has been held by the same shareholder for a continuous period of not less than twenty-four months from the date of its registration in the special list maintained by the Company, and an additional vote is also granted upon the expiration of each 12-month period, following the expiration of the period referred to above, in which such ordinary share has been held by the shareholder, up to a total maximum of ten votes per ordinary share. For more information, see our May Form 6-K.

Status of Proposed Renal Cell Cancer Trials

In October 2024, we announced that the Agenzia Italiana del Farmaco had approved a new Phase 1 clinical trial for metastatic Renal Cell Cancer. We expect to commence the trial in the fourth quarter of 2024. Also, in October 2024, we entered into an agreement with OSR to conduct an open-label phase 1/2 clinical trial. The study is designed to evaluate the safety, biological response, and efficacy of a single dose of Temferon (autologous hematopoietic stem and progenitor cells enriched with CD34+ and genetically modified with human Interferon-α2) in patients with metastatic renal carcinoma.

Supplementary Risk Factor Disclosure

In addition to the risks related to healthcare legislative and regulatory changes that are discussed in our 2023 20-F in Item 3.D "Key Information—Risk Factors," recently, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.