# 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**
**of the Securities Exchange Act of 1934**

**For the month of October 2022**

**Commission File Number: 001-41115**

# GENENTA SCIENCE S.P.A.
**(Exact Name of Registrant as Specified in its Charter)**

**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): ☐

**Genenta Science S.p.A. Reports Financial Results for the Six Months Ended June 30, 2022**

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, 2022, and for the six months ended June 30, 2022, and June 30, 2021, 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, 2022, and for the six months ended June 30, 2022, and June 30, 2021, 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.

**EXHIBIT INDEX**

| Exhibit | Title |
|---|---|
| 99.1 | Unaudited Consolidated Financial Statements as of June 30, 2022, and for the six months ended June 30, 2022, and June 30, 2021. |
| 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, 2022, 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 Stockholders' 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 25, 2022

By */s/ Pierluigi Paracchi*

Pierluigi Paracchi, Chief Executive Officer

**Genenta Science S.p.A.**
**(formerly, Genenta Science S.r.l.)**
**Consolidated Statements of Operations and Comprehensive Loss**

| | Six Months Ended June 30, | |
|---|---|---|
| | **2022** | **2021** |
| | (Unaudited) | |
| Operating expenses | | |
| Research and development | € 1,640,579 | € 3,199,234 |
| General and administrative | 2,513,558 | 842,236 |
| Total operating expenses | 4,154,137 | 4,041,470 |
| | | |
| Loss from operations | (4,154,137) | (4,041,470) |
| | | |
| Other income (expense) | | |
| Other income | 215,486 | 2,679 |
| Unrealized exchange rate gain | 1,826,330 | (9,111) |
| Total other income (expense) | 2,041,816 | (6,432) |
| | | |
| Loss before income taxes | (2,112,321) | (4,047,902) |
| Income taxes benefit (expenses) | - | - |
| Net loss | (2,112,321) | (4,047,902) |
| | | |
| Net loss and comprehensive loss | € (2,112,321) | € (4,047,902) |
| | | |
| Loss per share: | | |
| Loss | € (2,112,321) | € (4,047,902) |
| Loss per share - basic | € (0.12) | € (0.27) |
| Weighted average number of shares outstanding - basic | 18,216,858 | 14,772,610 |

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

**Genenta Science S.p.A.**
**(formerly, Genenta Science S.r.l.)**
**Consolidated Balance Sheets**

| | At June 30, 2022 (Unaudited) | At December 31, 2021 |
|---|---|---|
| **Assets** | | |
| *Current assets* | | |
| Cash and cash equivalents | € 34,671,156 | € 37,240,162 |
| Prepaid expenses and other current assets | 2,737,108 | 1,519,023 |
| *Total current assets* | 37,408,264 | 38,759,185 |
| | | |
| *Non-current assets* | | |
| Property and equipment, net | 65,928 | 23,090 |
| Other non-current asset- related party | 3,350 | 3,350 |
| Other non-current assets | 800,000 | 1,241,215 |
| *Total non-current assets* | 869,278 | 1,267,655 |
| **Total assets** | € 38,277,542 | € 40,026,840 |
| | | |
| **Liabilities and stockholders' equity** | | |
| *Current liabilities* | | |
| Accounts payable | € 247,911 | € 164,819 |
| Accounts payable - related party | 277,654 | 25,047 |
| Accrued expenses | 382,862 | 712,313 |
| Accrued expenses - related party | 172,359 | 132,141 |
| Other current liabilities | 120,252 | 100,719 |
| *Total current liabilities* | 1,201,038 | 1,135,039 |
| | | |
| *Non-current liabilities* | | |
| Other non current liabilities | 32,407 | - |
| Retirement benefit obligation | 55,192 | 30,618 |
| *Total long-term liabilities* | 87,599 | 30,618 |
| | | |
| *Commitments and contingencies* | - | - |
| | | |
| *Stockholders' equity* | | |
| Common stock, no par value, 59,700,000 shares authorized and 18,216,858 shares issued and outstanding | 66,121,033 | 65,880,990 |
| Accumulated deficit | (29,132,128) | (27,019,807) |
| Total stockholders' equity | 36,988,905 | 38,861,183 |
| **Total liabilities and stockholders' equity** | € 38,277,542 | € 40,026,840 |

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

**Genenta Science S.p.A.**
**(formerly, Genenta Science S.r.l.)**
**Consolidated Statements of Changes in Stockholders' Equity**

| | Corporate capital | Additional paid-in capital | Common shares outstanding | Common stock, no par value | Accumulated deficit | Total |
|---|---|---|---|---|---|---|
| Balance at December 31, 2020 | € 37,056 | € 36,604,728 | - | € - | € (21,490,475) | € 15,151,309 |
| Capital increase from exercise of options on Quota B | 715 | | - | - | - | 715 |
| Share-based compensation | - | 497,104 | - | - | - | 497,104 |
| Quota B repurchased | (172) | - | - | - | - | (172) |
| Corporate capital adjustment from Srl to Spa | (37,599) | - | 11,279,700 | 37,599 | - | - |
| Capital increase related to SpA | - | (12,401) | 3,720,300 | 12,401 | - | - |
| Conversion adjustment from Srl to SpA | - | (37,089,431) | - | 37,089,431 | - | - |
| Net loss | - | - | - | - | (4,047,902) | (4,047,902) |
| Balance at June 30, 2021 (Unaudited) | € - | € - | 15,000,000 | € 37,139,431 | € (25,538,377) | € 11,601,054 |
| | | | | | | |
| Balance at December 31, 2021 | € - | € - | 18,216,858 | € 65,880,990 | € (27,019,807) | € 38,861,183 |
| | | | | | | |
| Share-based compensation | - | - | - | 240,043 | - | 240,043 |
| Net loss | - | - | - | - | (2,112,321) | (2,112,321) |
| Balance at June 30, 2022 (Unaudited) | € - | € - | 18,216,858 | € 66,121,033 | € (29,132,128) | € 36,988,905 |

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

**Genenta Science S.p.A.**
**(formerly, Genenta Science S.r.l.)**
**Consolidated Statements of Cash Flows**

| | Six Months Ended June 30, | |
|---|---|---|
| | **2022** | **2021** |
| | (Unaudited) | |
| **Cash flows from operating activities** | | |
| Net loss | € (2,112,321) | € (4,047,902) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation expense | 2,813 | 2,086 |
| Retirement benefit obligation | 24,574 | 4,256 |
| Share-based compensation | 240,043 | 497,104 |
| Changes in operating assets and liabilities | | |
| Prepaid expenses and other current assets | (1,218,085) | (263,548) |
| Other non-current assets | 443,114 | (217,757) |
| Accounts payable | 83,092 | (274,047) |
| Accounts payable - related party | 252,607 | 78,365 |
| Accrued expenses | (329,451) | 52,602 |
| Accrued expenses - related party | 40,218 | (549,586) |
| Other current liabilities | 7,203 | 27,558 |
| Other non current liabilities | - | - |
| Net cash used in operating activities | (2,566,193) | (4,690,869) |
| **Cash flows from investing activities** | | |
| Purchases of property and equipment | (2,813) | (3,727) |
| Net cash used in investing activities | (2,813) | (3,727) |
| **Cash flows from financing activities** | | |
| Proceeds from the exercise of stock options | - | 715 |
| Quota B repurchased | - | (172) |
| Prepaid offering costs | - | (217,284) |
| Net cash provided by financing activities | - | (216,741) |
| **Net increase (Net decrease) in cash and cash equivalents** | (2,569,006) | (4,911,337) |
| Cash and cash equivalents at beginning of period | 37,240,162 | 15,465,243 |
| **Cash and cash equivalents at end of period** | € 34,671,156 | € 10,553,906 |

The accompanying notes are an integral part of these 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" or "S.r.l," which is similar to a limited liability company in the United States) converted to an Italian joint stock company (a "società per azioni" or "S.p.A.") in June 2021, which is similar to a C corporation in the United States. 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. Quotaholder's and stockholder's equity.) New Bylaws were adopted, two new Board members were appointed, and the existing Board of Directors and Board of Statutory Advisors were re-appointed. The registered office remained 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., intended for future operations in the United States ("US Subsidiary"). The US Subsidiary operates in US Dollars ("USD" or "$").

On December 15, 2021, the Company completed an initial public offering ("IPO") of its ordinary shares and was listed on the Nasdaq Stock Capital Market ("Nasdaq"). 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).

Genenta is an early-stage company developing first-in-class cell and gene cancer therapies. The Company is initially developing its clinical leading product, Temferon™, to treat glioblastoma multiforme ("GBM"), a solid tumor affecting the brain. The Company intends to continue its clinical trials in Europe and eventually start a clinical trial in the United States to study Temferon™ in other cancers, possibly liver cancer.

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 €2.1 million and €4.0 million for the six months ended June 30, 2022, and June 30, 2021, respectively. In addition, at June 30, 2022, the Company had an accumulated deficit of €29.1 million. The Company has primarily funded these losses through the proceeds from sales of convertible debt and equity quotas, prior to the Company's conversion into an S.p.A., and then through the proceeds from its IPO. Although the Company has incurred recurring losses and expects to continue to incur losses for the foreseeable future, the Company expects that its existing cash and cash equivalents on hand as of June 30, 2022, of €34.7 million, will be sufficient to fund current planned operations and capital expenditure requirements for at least the next twelve months from the filing date of these consolidated financial statements. However, the future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company has evaluated whether there are conditions and events considered in the aggregate that raise substantial doubt about the Company's ability to continue as a going concern. The Company's business model, typical of biotechnology companies developing new therapeutic products that have not reached a balanced income and financial position, features negative cash flows. This is due to the fact that, at this stage, costs must be borne in relation to services and personnel, directly connected to research and development activities, and return for these activities is not certain and, in any case, it is expected in future years. Based on the accounting policies adopted, requiring full recognition of research and development costs in the statement of operations and comprehensive loss in the year they are incurred, the Company has reported a loss since its inception, and expects to continue to incur significant research and development and clinical costs 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 or debt securities. If adequate funds are not available in the future, the Company may be forced to delay, reorganize, or cancel research and development and/or clinical programs, or to enter into financing, licensing or collaboration agreements with unfavorable conditions or waive rights to certain products which otherwise it would not have waived, resulting in negative effects on the activity and on the economic, patrimonial and /or financial situation of the Company.

In February 2020, the COVID-19 pandemic commenced in Italy. Regulatory guidance was issued in March 2020 and updated in April 2020 relating to the management of clinical trials during the pandemic. As the global healthcare community continues to respond to the COVID-19 pandemic, many hospitals, including the Company's clinical sites, temporarily paused elective medical procedures, including dosing of new patients in clinical trials of our investigational gene therapies.

While dosing of new patients and data collection from enrolled patients has resumed at clinical sites, the extent to which clinical activities continue to be delayed or interrupted will depend on future developments that remain uncertain. The Company has not experienced significant interruptions related to COVID-19 or its variants.

The Company may find it difficult to enroll patients in its clinical trials, which could delay or prevent the Company from proceeding with clinical trials of its product candidates. The Company continues to closely monitor this evolving situation and the potential impact on the Company.

***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 and, therefore, the Company invests available cash mainly in bank deposits with reputable banks that have a credit rating of at least A-. Accordingly, a substantial majority of the Company's cash and cash equivalents is held in deposits that bear a small amount of interest. Given the current low rates of interest the Company receives, the Company will not be adversely affected if such rates are changed. The Company's 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***

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, 2022, the Company maintained $22.7 million in cash and cash equivalents.) Changes in the USD/EUR exchange rate could increase/decrease our operating expenses, especially as more costs are incurred in the United States 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 gain from exchange rate of €1.8 million. The Company has not yet determined to realize its gain from exchange rate, nor does it 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 of 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 May 2, 2022. The balance sheet as of December 31, 2021 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, 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 cash flow statements, 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 detailed as follows:

| | At June 30, 2022 | At December 31, 2021 |
|---|---|---|
| *(in Euros)* | (Unaudited) | |
| Cash in bank | € 34,667,138 | € 37,236,089 |
| Cash in hand & prepaid cards | 4,018 | 4,073 |
| Total | € 34,671,156 | € 37,240,162 |

***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, 2022, and June 30, 2021, the comprehensive loss was equal to 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 S.p.A. in June 2021, after the increase in capital to €50,000 required to be an S.p.A. by Italian law. The Company's shareholders authorized 59.7 million ordinary shares. The Company has 18,216,858 ordinary shares issued and outstanding at June 30, 2022 with 2.7 million ordinary shares reserved for the Company's Equity Incentive Plan 2021–2025. The Company has options on 147,783 shares outstanding at June 30, 2022. Diluted EPS is not relevant at June 30, 2022, as the effect of ordinary share equivalents, in the form of 23,502 underwriters' ordinary share warrants and options on 147,783 shares, would have been anti-dilutive. (See Note 10. Stockholders' 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 Company's Consolidated Statements of Operations and Comprehensive Loss. For financial reporting purposes, the assets and liabilities of the US subsidiary are translated into EUR using exchange rates in effect at the balance sheet date. The net loss of the US Subsidiary is translated into EUR using average exchange rates in effect during the reporting period. For the six months ended June 30, 2021, the currency translation impact was insignificant. During the six months ended June 30, 2022, foreign exchange gains unrealized were €1.8 million.

***Emerging growth company status***

The Company is an "emerging growth company," as defined in the 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 tax credits, VAT credits, accounts payable, accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

***Segment information***

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company and its chief operating decision-maker view the Company's operations and manages its business in one operating segment, which is the research and development in the pharmaceutical sector with a focus on developing novel therapeutics to treat cancer.

***Tax credit on investments in research and development***

In line with the legislation in force at December 31, 2021, and for the financial year 2022, companies in Italy that invest in eligible research and development activities, regardless of the legal form and economic sector in which they operate, can benefit from a tax credit which can be used in order to reduce most taxes payable, including income tax or regional tax on productive activities, as well as social security contributions and payroll withholding taxes. For eligible research and development activities, the tax credit is equal to 20% both in fiscal year 2022 ("FY 2022") and fiscal year 2021 ("FY 2021") of the eligible costs incurred, with a maximum annual amount of €4.0 million both in FY 2022 and FY 2021.

The eligible activities consist of fundamental research, industrial research, and experimental development as defined respectively of the letters m), q) and j) of point 15, par. 1.3 of the Communication no. 198/2014 of the European Commission.

To determine the cost basis of the benefit, the following expenses are eligible:

- Personnel costs;
- Depreciation charges, costs of the financial or simple lease and other expenses related to movable tangible assets and software used in research and development projects;
- Expenses for extra-euro research contracts concerning the direct execution of eligible research and development activities by the provider;
- Expenses for consulting services and equivalent services related to eligible research and development activities; and,
- Expenses for materials, supplies, and other similar products used in research and development projects.

The Company, by analogy, 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 it 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 which reflects management's best estimate of the amount that is reasonably assured to be realized or utilized in the foreseeable future based on historical benefits realized, adjusted for expected changes, as applicable. The tax credits are recorded as an offset to research and development expenses in the Company's 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 Company's Board of Directors may approve, upon occasion, various share-based awards.

In May 2021, the Company's quotaholders adopted the Company's "Equity Incentive Plan 2021–2025" ("the Plan"); however, through December 31, 2021, no options or awards were granted and there were no outstanding options or awards. (See Note 11. Share-based compensation.)

In April 2022, the Company's Board of Directors, as administrator of the Plan, awarded nonqualified stock options ("NSOs") on 147,783 shares to its (former) Chairman according to the terms of a sub-plan called "2021-2025 Chairman Sub-Plan" (the "Sub-Plan") attached to the Plan.

Currently, the Company has authorized options on 1,821,685 ordinary shares (i.e., 10% of the number of shares outstanding, which are currently 18,216,858 ordinary shares outstanding); however, at the quotaholders' meeting held on May 20, 2021, the quotaholders approved an increase to the Plan of up to a maximum of options on 2,700,000 ordinary shares. Therefore, as the Company raises additional capital, the Board of Directors has authority to issue options on 1,821,685 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 applies the provisions of *ASC 718, Compensation—Stock Compensation ("ASC 718")*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including stock options, in the statements of operations.

Under paragraphs 718-10-30-7 and 30-9 of Topic 718, there are two ways to determine the fair value of an equity share option (or similar award) at the grant date:

1. If there is an observable market price for an option with the same or similar terms and conditions, that market price shall be the fair value.

2. Otherwise, the fair value of an equity share option or similar instrument (i.e., an instrument with the same time value) must be estimated using a proper valuation technique.

In paragraph 718-10-30-8, the FASB indicates that market prices for equity share options and similar instruments are not currently available but could become available in the future. Therefore, in practice, equity share options and similar awards currently are valued using valuation models and techniques.

In Section 718-10-55, the FASB explains that the issuer may select from one of the following types of valuation models in determining the fair value of an equity share option:

- A closed-form model that uses an equation to produce an estimated fair value, such as the Black-Scholes-Merton formula;
- A non-closed-form model that produces an estimated fair value on the assumed changes in the prices of a financial instrument over successive periods of time, such as the binomial model or other forms of a lattice model; or
- Other valuation techniques that are not based on a closed-form model, such as a Monte Carlo simulation technique.

Topic 718 does not indicate that one valuation technique is better than any other. The FASB hopes this lack of preference will not hinder the future development of better valuation models and techniques. Rather, the FASB explains (in paragraph 718-10-55-17) that each issuer must select an appropriate valuation technique or model depending on the substantive characteristics of the instrument being valued.

The SEC reinforced the point that no particular valuation technique or model is preferred in SEC Staff Accounting Bulletin (SAB) Topic 14, "Share-Based Payment" (Codification Section 718-10-S99).

Furthermore, FAS 123(R) states that an entity should measure the fair value of a stock option as of the grant date "based on the observable market price of an option with the same or similar terms and conditions, if one is available," but the FASB further notes that market prices generally are not available. In the absence of such prices, fair value must be "estimated using a valuation technique such as an option-pricing model." The standard identifies a "lattice model" (e.g., a binomial model) and a "closed-form model" (e.g., the Black-Scholes Merton formula) as acceptable option pricing models and a Monte Carlo simulation technique as another type of acceptable valuation technique. An entity must choose an appropriate valuation technique on the basis of the substantive characteristics of the options it is valuing.

The Company chose The Black-Scholes-Merton model because it is considered easier to apply and also 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.

***Property and equipment***

Property and equipment are stated at cost, including any accessory and direct costs that are necessary to make the assets fit for use, and adjusted by the corresponding accumulated depreciation. The depreciation rates recorded in the consolidated financial statements have been calculated by taking into consideration the use, purpose, and financial-technical duration of the assets, on the basis of their estimated useful economic lives. The Company believes the above criteria to be represented by the following estimated useful lives:

- Equipment & furniture: 15 years;
- Electronic office equipment: 10 years; and,
- Leasehold improvements: based on the shorter of the life of the leasehold improvement or 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 on the basis of its estimated useful economic life. Amortization of leasehold improvements is computed using the straight-line method based upon the terms of the applicable lease or estimated useful life of the improvements, whichever is less.

***Impairment of long-lived assets***

In accordance with ASC Topic 360-10-20, "Property, Plant and Equipment," the Company performs an impairment test whenever events or circumstances indicate that the carrying value of long-lived assets with finite lives may be impaired. Impairment is measured by comparing the carrying value of the long-lived assets to the estimated undiscounted pre-tax cash flows expected to result from the use of such assets and their ultimate disposition. In circumstances where impairment is determined to exist, the Company will write-down the asset to its fair value based on the present value of estimated cash flows. To date, no impairments have been identified for the six months ended June 30, 2022, and June 30, 2021.

***Recently issued accounting pronouncements***

In April 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than when public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, unless the Company elects early adoption of any standards, will adopt the new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies.

In December 2019, the FASB issued ASU 2019-12, Income Taxes: Simplifying the Accounting for Income Taxes. The new standard intended to simplify the accounting for income taxes by eliminating certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. For non-public entities, the standard is effective for annual periods beginning after December 15, 2021, with early adoption permitted. Adoption of the standard requires certain changes to primarily be made prospectively, with some changes to be made retrospectively. The Company adopted this guidance for the reporting period beginning January 1, 2022, which did not have a material impact on its financial statements or disclosures.

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance. The aim of ASU 2021-10 is to increase the transparency of government assistance including the disclosure of (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. Diversity currently exists in the recognition, measurement, presentation, and disclosure of government assistance received by business entities because of the lack of specific authoritative guidance in U.S. GAAP. The ASU will be effective for annual reporting periods after December 15, 2021, and early adoption is permitted. Upon implementation, the Company may use either a prospective or retrospective method of adoption when adopting the ASU. The Company adopted this guidance for the reporting period beginning January 1, 2022, which did not have a material impact on its financial statements or disclosures.

In August 2020, the FASB issued ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023, and interim periods within those annual periods and early adoption is permitted in fiscal periods ending after December 15, 2020. Upon implementation, the Company may use either a modified retrospective or full retrospective method of adoption. The Company is evaluating the impact of adopting the new ASU.

**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 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 with the addition of the Company's wholly owned subsidiary in the United States, the Company is subject to taxation in the United States. Taxation in Italy includes the standard corporate income tax ("IRES") and a regional business tax ("IRAP"). Taxation in the United States 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, 2022, and June 30, 2021, in Italy or the United States.

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 regards 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. The prior five years of tax returns (2017-2021) are potentially subject to audit.

At June 30, 2022 and June 30, 2021, the Company believes there were no significant differences with regards 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 the DL 98/2011, at the end of 2011, all existing tax loss carryforwards will never expire but they can off-set only 80% of the taxable income of the year. The rules do not affect the tax loss carryforward that refer to the start-up period, defined as the first three (3) years of operations starting from the inception of the Company. The impact of the updated calculation of tax losses carryforward at December 31, 2021 and 2020 is deemed not significant with respect of the preceding periods.

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 clinical trial. Since the clinical trial is still in Phase I/2a, 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, 2022 | At December 31, 2021 |
|---|---|---|
| *(in Euros)* | (Unaudited) | |
| Value Added Tax (VAT) | € 1,072,002 | € 820,780 |
| Research and development tax credit | 800,000 | 600,000 |
| Advances payments to suppliers | 35,401 | 58,009 |
| Other current assets | 180,709 | 21,987 |
| Other prepaids | 648,996 | 18,247 |
| Total | € 2,737,108 | € 1,519,023 |

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 2022 and 2021 is 22%. Reduced rates are provided for specifically listed supplies of goods and services. It is carried forward indefinitely and does not expire. During the six months ended June 30, 2022, the Company received a reimbursement of approximately €821,000 related to preceding periods of VAT tax credit. Based on the historical timing and amounts of VAT tax credit reimbursement received by the Company, at June 30, 2022, the VAT tax credit residual balance after the mentioned reimbursement, amounted to approximately €1.1 million and was recorded as a current asset, since it is expected to be collected from the tax agency within 12 months.

Tax credits on research and development represent a special tax relief offered to Italian companies operating in the research and development sector and can be used to offset most taxes payable. The Company has a total research and development tax credit available to be used of approximately €4.2 million at June 30, 2022, 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 June 30, 2024. This estimate is consistent with the Company's most updated cash budget utilization projections approved by the Board of Directors in July 2022. According to the budget approved, the Company's available cash as of June 30, 2022, is deemed more than sufficient to cover the operating activities through at least the first half of 2024, without additional financing or other management plans.

During the six months ended June 30, 2022, the Company utilized approximately €306,000 to offset certain social contributions and taxes payable, while during the six months ended June 30, 2021, the Company utilized approximately €204,000. In addition, the recorded benefit for the six months ended June 30, 2022, and June 30, 2021, was approximately €706,000 and €204,000, respectively, to offset research and development expenses. The Company reclassified to other non-current assets a portion of the receivable, which is expected to be realized beyond 12 months. (See Note 8. Other non-current assets.)

Other current assets mainly relate to a tax credit recognized by the Italian Revenue Agency for approximately €180,000 that is expected to be collected in less than 12 months.

At June 30, 2022, Other prepaid expenses mainly relate to: i) the directors and officers ("D&O") insurance policy paid in January 2022 of approximately €582,000; ii) the prepayment of Nasdaq registration fees for one year (from January 1, 2022 for €20,000); and, iii) prepaid expenses of €30,000 recorded to adjust the manufacturing expenses accrued during the six months ended June 30, 2022, for the actual statement of work confirmed by the manufacturer. Other prepaid expenses as of June 30, 2021, were comprised of miscellaneous minor prepaid expenses.

**7. Property and equipment, net**

Property and equipment consist of the following:

| | At June 30, 2022 | At December 31, 2021 |
|---|---|---|
| *(in Euros)* | (Unaudited) | |
| Computer | € 20,353 | € 24,869 |
| Auto | 49,320 | - |
| Furniture and fixtures | 10,440 | 5,010 |
| Total property and equipment | 80,113 | 29,879 |
| Less: accumulated depreciation | (14,185) | (6,789) |
| Property and equipment, net | € 65,928 | € 23,090 |

Property and equipment consist of computers, an auto, and furniture and fixtures of our office space in Milan, Italy. There were no disposals, nor 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, 2022.

Depreciation expense for the six months ending June 30, 2022, and June 30, 2021, were €2,813 and €2,086, respectively.

**8. Other non-current assets**

Other non-current assets consist as follows:

| *(in Euros)* | At June 30, 2022 (Unaudited) | At December 31, 2021 |
|---|---|---|
| Value Added Tax (VAT) | € - | € 641,215 |
| Research and development tax credit | 800,000 | 600,000 |
| Total | € 800,000 | € 1,241,215 |

VAT tax credit at June 30, 2022 is recorded in other current assets. (See Note 6. Prepaid expenses and other current assets.)

The research and development tax credit increased due to the increase in the utilization rate. (See Note 6. Prepaid expenses and other current assets.)

Other non-current assets - related party includes a security deposit of €3,350 paid to OSR - San Raffaele Hospital as security guarantee for the office lease contract. (See Note 13. Commitments and contingencies.)

**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, 2022 and December 31, 2021 was €55,192 and €30,618, respectively.

**10. Stockholders' equity**

The Company was an S.r.l., which is an Italian limited liability company similar to a limited liability company in the United States. The Articles of Incorporation, Shareholders' Agreement and the By-laws of the Company provided for different quotas, which represented the Company's corporate capital, rather than shares of stock as ownership corporate capital. As an S.r.l., the Company's ownership was called "corporate capital" and "quotas" rather than shares, stock, or units.

The Company's capital was divided between the five quotas as summarized below at December 31, 2020:

| **Quota** | **At December 31, 2020** | **Ownership %** |
|---|---|---|
| A | € 10,458 | 28% |
| B | 6,886 | 19% |
| C | 8,645 | 23% |
| D | 4,034 | 11% |
| E | 7,033 | 19% |
| **Total** | **€ 37,056** | **100%** |

The Company had five (5) quotas:

- Quota A. Quota A was reserved for certain founders. One of the founders had the right to appoint three (3) board members out of five (5), appoint the Chair from these three (3) persons and appoint one (1) member of the Board of Statutory Auditors. One other founder had the right to appoint two (2) board members out of five (5), appoint two (2) statutory auditors and appoint the Chair of the statutory auditors from the two (2) appointees. Quota A had voting rights.

- Quota B. Quota B had no voting rights, the same profit-sharing rights as Quota A and was priced at a nominal amount of €1.00. The Company had historically utilized Quota B for its share-based compensation program offered to board members, employees, and consultants. Quota B was also held by certain co-founders. The Company's stock options were exercisable into Quota B for past and present board members, employees, and consultants.

- Quota C. Quota C had the right to appoint one (1) member of the Board of Statutory Auditors; specifically, the one (1) that a founder had the right to appoint. Investors received Quota C in the Company's first funding round (2014/2015) where approximately €10 million was raised.

- Quota D. Investors received Quota D in the Company's second funding round (2017) where approximately €7 million was raised.

- Quota E. Investors received Quota E in the Company's third funding round (through December 31, 2019) where approximately €14.8 million was raised approximately (€15.1 million gross, net of approximately €0.3 million of financing fees). Investors received Quota E in the Company's second tranche of the third funding round (through December 31, 2020) where approximately €1.4 million was raised (approximately €1.5 million gross, net of approximately €0.1 million of financing fees).

- Quotas A, C, D & E. During a divestiture proceeding (meaning Quotas representing 100% of the corporate capital of the Company) or a dissolution of the Company, Quotas C, D & E all had the same rights with respect to the proceeds of a divestiture, i.e., all three (3) quotas shared the divestiture consideration equally (on a pari passu basis) up to the amount of their investment. If there was any consideration remaining after payment to quotas C, D & E, then quota A was entitled to the amount remaining up to the amount of their investment. If proceeds of a divestiture were less than or equal to €50 million, then any proceeds remaining after payment of quotas A, C, D & E, were to be shared equally among quotas A, C, D & E; however, if proceeds of a divestiture were greater than €50 million, then any proceeds remaining after payment of quotas A, C, D & E, were to be distributed to each quota separately according to a detailed formula specified in the Company's By-Laws, including quota B. Similar to a divestiture, net profits, if any, were to be distributed in the same manner to quotas A, B, C, D & E, after deducting not less than five (5) percent for a legal reserve (up to where this reserve equals one-fifth of the quota capital). A, C, D, E had equal voting rights and the Company By-laws specify protective provisions for each class of quota for A, C, D & E.

  During the six months ended June 30, 2021, two events occurred which together had a significant impact on the Company's equity:

  On April 1, 2021, the Board of Directors resolved to grant to employees and non-employees stock options and accelerate the vesting of other stock options on €715 quota B and €172 quota B were repurchased at nominal value, cancelled, and allocated to the option plan as available for grant by Drs. Naldini and Gentner, leaving a net equity increase of €543 quota B. All quota B ownership has limited rights and carries a par value of €1 per quota. The Corporate Capital amount was € 37,771 (€37,056 corporate capital at December 31, 2020 + €715 exercise of Quota B options before the conversion).

  On May 20, 2021, at a special quotaholders' meeting, the quotaholders resolved to convert the Company from an S.r.l. to an S.p.A., which conversion became effective on June 18, 2021. As consequence of the conversion, the Corporate Capital has been converted to ordinary shares with no par value and it was increased to €50,000 to satisfy the minimum capital requirement to qualify as an S.p.A. This increase was an adjustment from Additional Paid-in Capital to Common stock, no par value.

  As a result of the Company conversion, the Corporate Capital was reclassified as ordinary shares, no par value, combining the minimum capital amount of €50,000 with the Additional Paid-In Capital for a total of €37,139,431. The outstanding quota of €50,000 before the conversion were all converted into 15 million shares of ordinary shares, no par value, after the conversion at the same conversion rate of approximately 300 quota percentage of ownership. All preferences related to the quota classes were terminated and all shareholders now hold ordinary shares, no par value. All shares outstanding after the conversion are held in ledger form. The Company adopted a new Article of Association, appointed two new directors (including Mr. Squinto as Chairman) and re-appointed the existing members of the Board of Directors it and the existing Board of Statutory Auditors.

During the six months ended June 30, 2022, no significant events occurred; however, the Company granted a nonqualified fully vested stock option on April 26, 2022, to its chairman at a price based on a sub-plan called "2021-2025 Chairman Sub-Plan. The expense was recorded in the statement of operations and comprehensive loss for the six months ended June 30, 2022, in the amount of €240,043. (See Note 2. Summary of significant accounting policies & Note 11. Share-based compensation.)

**11. Share-based compensation**

The Company granted options on its corporate capital to certain directors, officers, employees, and consultants, as an incentive and as additional compensation prior to the Company's conversion to an S.p.A. All options converted into Quota B when vested and exercised. All options had an exercise price of €1.00 per quota. Options generally vested over a one-to-three-year period and have been exercised when vested.

In April 2021, €172 of quota B shares were repurchased, cancelled, and allocated to the option plan as available for grant. The Board of Directors approved new option grants on €169 of quota B and accelerated the vesting of options on €546 quota B and all options were exercised. The total of €715 quota B were issued and exercised in April 2021 with no options remaining outstanding at that time.

In May 2021, in context of the corporate conversion from a limited liability company (società a responsabilità limitata, or S.r.l.) to a joint stock company (società per azioni, or an S.p.A.), the quotaholders approved a capital increase to allow for issuance of up to 2.7 million ordinary shares, or 10% of the total outstanding ordinary shares of the Company after the IPO, in the service of a four-year employees' share option plan, "Equity Incentive Plan 2021–2025," (the "Plan") that was adopted by the board of directors. The Plan is administered by the Board of Directors in consultation with the Compensation, Nomination and Governance Committee.

At June 18, 2021, the date of the Company's conversion to an S.p.A., all stock options were granted, fully vested, exercised and converted into ordinary shares with no par value. At June 30, 2021, there were no outstanding stock options.

On April 26, 2022, 147,783 NSOs were granted to Dr. Squinto, Chairman of the Company at that time, and were fully vested and priced based on a sub-plan called "2021-2025 Chairman Sub-Plan" attached to the Plan. Total recognized expense was €240,043.

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding, vested and expected to vest as of December 31, 2020 | 546 | € 1.00 | 1.0 | € 584,132 |
| Exercisable as of December 31, 2020 | - | - | - | - |
| Granted | 169 | 1.00 | - | 183,831 |
| Vested and exercised | 715 | 1.00 | - | 777,920 |
| Outstanding, vested and expected to vest as of June 30, 2021 | - | - | - | - |
| **Exercisable as of June 30, 2021** | **€ -** | **-** | **-** | **€ -** |
| | | | | |
| Outstanding, vested and expected to vest as of January 1, 2022 | - | - | - | - |
| Granted and immediately vested | 147,783 | 6.38 | 2.00 | - |
| Vested and exercised | | | | |
| Cancelled or forfeited | - | - | - | - |
| Outstanding, vested and expected to vest as of June 30, 2022 | 147,783 | 6.38 | 1.82 | 29,878 |
| **Exercisable as of June 30, 2022** | **€ 147,783** | **€ 6.38** | **1.82** | **€ 29,878** |

The Company's share-based compensation expense for the period ended June 30, 2022 and June 30, 2021 is represented by the following table:

| | Six Months Ended June 30, | |
|---|---|---|
| | **2022** | **2021** |
| Research & development expense | € - | € 82,669 |
| Research & development expense - related party | - | 179,480 |
| General & administrative expense | 240,043 | 234,955 |
| Total | € 240,043 | € 497,104 |
| Unrecognized expense | € - | € - |

For the periods ended June 30, 2022, and June 30, 2021, the Company recorded €240,043 and €497,104, respectively, as the fair value of the stock options granted. There was no amount of unrecognized expense at June 30, 2022 and June 30, 2021, since the options vested immediately and all expense was recognized during the period. The weighted average fair value of the options granted during the six months ended June 30, 2022 and June 30, 2021 was € 1.62 per share and €1,088 per quota B respectively.

*Six months ended June 30, 2022, NSOs Chairman Sub Plan - Valuation*

At the Board of Directors meeting on April 26, 2022, the Company granted options on 147,783 shares to its Chairman, Dr. Squinto. The terms and conditions of this grant are as follows:

- Term: Two (2) years, i.e., expiring on April 26, 2024;
- Price: €6.38 per share, as outlined in the Sub-Plan; and,
- Vesting: Immediately vested per the Sub-Plan.

The Company calculated the stock compensation expense for the options granted to Dr. Squinto by utilizing the Black Scholes method with the following inputs:

- Current stock price ("$S_t$") of $5.41 is the closing share price on the option grant date.
- Strike price ("K") of $6.81 was calculated by converting the Sub-Plan exercise price of €6.38 to $6.81 using the day exchange rate of 1.0674.
- Risk Free Interest Rate ("r") based on the expected term of 18 months, the Company used the 1.5-year treasury rate of 2.27% as the risk- free interest rate to align with the estimated exercise period.
- Expected Term ("t") An estimated expected term of eighteen (18) months was used.
- Volatility ("σ") a volatility of 82.0% was used

Using the assumptions described above, the estimated fair value of options granted to Dr. Squinto on April 26, 2022 was approximately €1.62 per share.

Therefore, the expense for the fully vested shares was €240,043 ($256,222) and was recorded in the six months ended June 30, 2022.

*Six months ended June 30, 2021 - Quota B Valuations*

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

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

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

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

The weighted average fair value of the options granted during 2021 was €1,088.

*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, 2022, and June 30, 2021, respectively, there was a weighted average of €18,216,858 and €14,772,610 shares of the Company's ordinary shares, no par value.

**12. Related parties**

The Company's research and development expenses are a combination of third-party expenses, and related party expenses, as detailed below:

| | Six Months Ended June 30, 2022 | | |
|---|---|---|---|
| | Third Parties | Related Parties | Total |
| *(in Euros)* | | (Unaudited) | |
| Consultants & other third parties | € 298,265 | € 40,000 | € 338,265 |
| Materials & supplies | 837,098 | - | 837,098 |
| Compensation (including share-based) | 162,167 | 215,761 | 377,928 |
| Travel & entertainment | 65,938 | - | 65,938 |
| Other | 21,350 | - | 21,350 |
| Total | € 1,384,818 | € 255,761 | € 1,640,579 |

| | Six Months Ended June 30, 2021 | | |
|---|---|---|---|
| | Third Parties | Related Parties | Total |
| *(in Euros)* | | (Unaudited) | |
| Consultants & other third parties | € 525,978 | € 1,541,526 | € 2,067,504 |
| Materials & supplies | 717,905 | - | 717,905 |
| Compensation (including share-based) | 221,900 | 179,480 | 401,380 |
| Travel & entertainment | 10,445 | - | 10,445 |
| Other | 2,000 | - | 2,000 |
| Total | € 1,478,228 | € 1,721,006 | € 3,199,234 |

Research and development expenses mainly refer to LVV (Lentiviral Vector for Gene therapy) production activities and to preclinical and clinical activities mainly at the San Raffaele Hospital in Milan. Specifically, the related party research and development expenses refer to the costs of preclinical and clinical activities charged by San Raffaele Hospital.

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 30,2022 | | |
|---|---|---|---|
| | Third Parties | Related Parties | Total |
| *(In Euros)* | | (Unaudited) | |
| Compensation (including share-based) | € 522,012 | € 421,558 | € 943,570 |
| Accounting, legal & other professional | 376,642 | - | 376,642 |
| Facility & insurance related | 3,873 | 7,457 | 11,330 |
| Consultants & other third parties | 384,243 | - | 384,243 |
| Other | 794,248 | 3,525 | 797,773 |
| Total | € 2,081,018 | € 432,540 | € 2,513,558 |

| | Six Months Ended June 30,2021 | | |
|---|---|---|---|
| | Third Parties | Related Parties | Total |
| *(In Euros)* | | (Unaudited) | |
| Compensation (including share-based) | € 258,514 | € 150,000 | € 408,514 |
| Accounting, legal & other professional | 181,354 | - | 181,354 |
| Facility & insurance related | 1,712 | 7,197 | 8,909 |
| Consultants & other third parties | 127,988 | - | 127,988 |
| Other | 115,471 | - | 115,471 |
| Total | € 685,039 | € 157,197 | € 842,236 |

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

| | At June 30, 2022 | At December 31, 2021 |
|---|---|---|
| *(in Euros)* | (Unaudited) | |
| San Raffaele Hospital | € 265,616 | € 25,047 |
| Carlo Russo | 8,208 | - |
| Richard Slansky | 3,830 | - |
| Total | € 277,654 | € 25,047 |

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

| | At June 30 2022 | At December 31 2021 |
|---|---|---|
| *(in Euros)* | (Unaudited) | |
| San Raffaele Hospital (OSR) | € 172,359 | € 19,201 |
| Executive bonus | - | 25,000 |
| XDG Biomed | - | 34,438 |
| Financial consultant | - | 53,502 |
| Total | € 172,359 | € 132,141 |

The increase in San Raffaele Hospital (OSR) account payables balance and accrued expenses compared to December 31, 2021, was due to a delay in the invoicing process by OSR.

The Company has identified the following related parties:

- Pierluigi Paracchi (director and co-founder of the Company);
- Luigi Naldini (co-founder of the Company and executive scientific board chairman);
- Bernard Rudolph Gentner (co-founders of the Company and member of scientific advisory board);
- Carlo Russo (Chief Medical Officer, operating by his Company XDG Biomed LLC); and,
- Richard Slansky (Chief Financial Officer);
- Spafid S.pA. (shareholder ownership > 5%)
- 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, President and Chairman of the Company prior to the conversion, is the current Chief Executive Officer, Vice-Chairman, as well as co-founder. His annual compensation, until December 16, 2021, amounted to €250,000 per year plus an annual performance bonus of €50,000, which was earned in the period July-June of each year payable after Board of Director's approval. On December 17, 2021, his arrangement with the Company was changed and he became employed by the Company as chief executive officer (aka general manager in Italy), with an annual gross salary of €420,000 plus a 20% annual bonus subject to Board of Director's approval. Mr. Paracchi also has use of a company car, for which the Company entered an operating leasing agreement in February 2022.

In April 2022, Mr. Paracchi received a bonus of €50,000 (gross amount), of which €23,000 related to the activity performed in the second half of 2021 and €37,000 related to the activity performed in the first few months of 2022.

For the six months ended June 30, 2022, the Company expensed €248,242 and €150,000, respectively, for Mr. Paracchi's compensation.

For the six months ended June 30, 2022, the Company accrued approximately €14,000 for the retirement benefit obligation of Mr. Paracchi, as it is provided by the new employment agreement he has as an executive.

**Luigi Naldini/Bernard Rudolph Gentner**

Drs. Naldini and Gentner are co-founders of Genenta and part of the SAB – Scientific Advisory Board, with Dr. Naldini as Chairman, and Dr. Gentner as a member. Dr. Naldini has an advisory agreement approved by the Board of Directors and performs the pre-clinical studies for the Company. In particular, the pre-clinical experiments are in solid tumor indications. The agreement with Dr. Naldini, signed in 2019, in place during the six months ended June 30, 2022, provided for an annual fee of €50,000, and the Company expensed and paid €25,000 as of June 30, 2022, and June 30, 2021, respectively.

Dr. Gentner, like Dr. Naldini, oversees pre-clinical research related to the Company's platform technology. In addition, he analyzes clinical biological data. The last agreement with Dr. Gentner, which is still in force, was signed in 2017. His annual fee is €30,000. For the six months ended June 30, 2022, and June 30, 2021, the Company expensed and paid €15,000, respectively.

**XDG Biomed LLC/Carlo Russo**

XDG Biomed is the LLC of Dr. Carlo Russo. Dr. Russo has a single contract signed by XDG and the Company that was approved by the Board of Directors and was subject to multiple amendments. In particular, Dr. Russo, via XDG, served as the Company's Chief Medical Officer and Head of Development pre-IPO. Dr. Russo is responsible for the clinical development of Temferon™, the Company's gene therapy platform. The recurring fee for Dr. Russo's services until the IPO date (i.e., December 15, 2021) was €300,000 per year, plus a performance bonus of €50,000 for the period July-June of each year and payable after Board of Directors approval. From the IPO date, Dr. Russo has been employed by the US Subsidiary with the same title, role and responsibilities under a new employment agreement. The annual gross salary of Dr. Russo as an employee of the Company amounts to $500,000 per year, plus a 30% annual bonus subject to Board of Director approval.

For the six months ended June 30, 2022, and June 30, 2021, the Company expensed €215,761 and €175,000, respectively, related to Dr. Russo as an employee and XDG Biomed LCC as an advisor, respectively.

In April 2021, Dr. Russo was awarded a stock option grant, which was immediately vested and exercised, with a value accrued in the Consolidated Statement of Operations and Comprehensive Loss of €179,480.

At December 31, 2021, €25,000 was accrued as a bonus for the six months ended June 30, 2021, based on the agreement in place with XDG Biomed LLC, but subsequently during the six months ended June 30, 2022, the bonus was not approved by the Board of Directors; and therefore, reversed in the Company's Consolidated Statement of Operations and Comprehensive Loss.

**Richard Slansky**

Mr. Richard Slansky is the Chief Financial Officer of the Company. He was engaged in late 2020 by the Company to assist with financial, accounting and audit support under an advisory agreement until the end of October 2021. On November 1, 2021, he joined the Company full time and has been employed as Chief Financial Officer.

During the six months ended June 30, 2021, by the advisory agreement, Mr. Slansky invoiced Genenta for €42,224.

In April 2021, Mr. Slansky was awarded a stock option grant, which was immediately vested and exercised, with value accrued in the Company's Consolidated Statement of Operations and Comprehensive Loss of €54,388.

At December 31, 2021, a bonus was accrued, after the success of the IPO, in the amount of $50,000 and paid in early 2022.

Under the new employment agreement, which started on November 1, 2021, Mr. Slansky is entitled to receive a gross annual compensation of $300,000 per year, plus a 30% annual bonus subject to Board of Director approval.

During the six months ended June 30, 2022, the Company recorded a total cost for Mr. Slansky amounting to €173,317.

**Spafid SpA**

Spafid is a Genenta shareholder with an ownership greater than 5%. Spafid is also a service provider to Genenta. The engagement started on May 20, 2021, and relates to several services concerning corporate governance activities as shareholders book and shareholders meeting management, shares dematerialization and centralization, etc.

For the six months ended June 30, 2022, Spafid invoiced the Company €3,525, which was recorded in the Company's Consolidated Statements of Operations and Comprehensive Loss as a general & administrative expense. No expenses were incurred in the six months ended June 30, 2021.

**OSR – San Raffaele Hospital**

OSR - San Raffaele Hospital is a co-founder of the Company and a shareholder with an ownership greater than 5%, 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 in an OSR facility.

*License Agreement*

The Company has a License Agreement with OSR entered in December 2014, for the exclusive use of different patents. In particular, OSR granted the Company an exclusive, world-wide, royalty bearing license under certain technology to conduct research and develop, make, use, import and sell licensed products. The License Agreement covers patents and patent applications, as well as proprietary technologies. The Company's rights to use these patents and patent applications and to utilize the inventions claimed in these licensed patents are subject to the continuation of, and the Company's compliance with, the terms of the license agreement.

Based on the preclinical studies conducted by OSR, in particular by its SR-TIGET Institute (San Raffaele Telethon Institute for Gene Therapy), on a specific gene therapy strategy with respect to lympho-hematopoietic indication and/or solid cancer indication, the Company decided to develop a new therapy to treat cancer through a cell and gene therapy strategy. The "Field of Use" as defined in the License Agreement is:

a) Lympho-Hematopoietic Indication[1]; and,

b) Solid Cancer Indication.

The agreement provided for an upfront fee of €250,000 (which was paid in 2015), future option fees are as follows:

- option fee on the first indication = €1.0 million (subsequently reduced to €0.5 million);
- option fee on the second indication = €0.5 million;
- option fee on the third indication = €0.3 million; and,
- option fee on any additional indications = no license fee.

[1] The Company later amended the License Agreement focusing on GBM options. The TEM-MM option fee has never been exercised and instead the related research was abandoned in early 2021.

In addition, the Company is obligated make payments on milestones depending on the Field of Use (as defined in the agreement) and pay royalties of 4% of net sales of each Licensed Product (as defined in the License Agreement).

In connection to the License Agreement, the Company engaged OSR to provide certain research activities regarding the Licensed Products in the Field of Use, based on a mutually agreed study plan and utilizing the extensive resources at OSR. (See Note 13. Commitments and contingencies.) In consideration of the research activities provided by OSR, the Company agreed to pay scientific collaboration research fees in advance. In December 2014, the Company and OSR signed a Scientific Collaboration Agreement and subsequently modified the Agreement with Research Addenda 1, 2 and 3 in 2016, 2017 and 2018, respectively. During the six months ended June 30, 2022 and June 30, 2021, there were no costs incurred for the above activities.

The protocol TEM-GBM_001 received approval by national Competent Authorities in September 2018 and recruited the first patient in April 2019.

*License Agreement Amendment #2*

In February 2019, the Company and OSR entered into Amendment #2 of the License Agreement to conduct a clinical trial according to the protocol TEM-GBM_001 and EudraCT 2018-001404-11 entitled: "A phase I/IIa dose escalation study evaluating the safety and efficacy of autologous CD34+ enriched hematopoietic progenitor cells genetically modified with a lentiviral vector encoding for the human interferon-α2 in patients with GBM who have an unmethylated O-6-methylguanine-DNA methyltransferase gene promoter." In Amendment #2, the Company and OSR also revised the license fee requirement for the first Solid Cancer indication (GBM). In relation to the GBM trial, the Company and OSR agreed that the Company would be obligated to pay OSR the €1.0 million Option Fee only in the event that the Company was able to dose its tenth patient. Under this Amendment, the Company is also obligated to pay for the costs of the study-related procedures performed on the patients recruited in the trial, according to periodic study reports delivered by OSR. The first GBM patient was recruited in April 2019 and related clinical activity costs were recorded by the Company. During the six months ended June 30, 2022 and June 30, 2021, the comparable costs incurred and expensed for the GBM program were approximately €0.3 million and €0.8 million, respectively.

Under Amendment #2, the Company is obligated to cover the costs of the study-related procedures performed on the patients recruited in the Trial, according to periodic study reports delivered by OSR.

*License Agreement Amendment #3*

In December 2020, the Company and OSR entered into Amendment #3 of the License Agreement: The initial €1.0 million payment in the event of the tenth patient dosed in the GBM trial was reduced to €0.5 million, in exchange for the Company's agreement to exercise a second option for an additional Solid Cancer indication (possibly Liver Cancer) and an agreement to execute a Sponsored Research Agreement in February 2021. Note: If the Company was not able to obtain approval from the competent authorities to initiate a human clinical trial on or before September 30, 2021, the Company had the right, at no additional costs, to convert this second solid cancer option to an "Alternate Indication," i.e., an indication other than liver cancer. This right was updated in License Agreement Amendment #4 (see below).

In summary, the Amendment #3 formalized the new arrangement as follows:

- exercise of option fee on the first solid cancer indication = €0.5 million (accrued in 2019, since it was considered probable, and paid in December 2020); plus,

- commitment to enter into a Sponsored Research Agreement by February 2021; and,

- exercise of option fee on the second indication = €0.5 million (accrued at December 31, 2020 and was paid on June 30, 2021).

At June 30, 2022, no milestones were achieved related to any indication, as provided by License Agreement and subsequent amendments; therefore, no such payments were due to OSR. The Company paid €1.25 million to OSR, since inception under the License Agreement. No events have occurred or have been achieved (and none are considered probable) to trigger any contingent payments under the License Agreement during the six months ended June 30, 2022. For information relating to the contingency payments or future milestones for these indications, please refer to Note 13 - Commitments and Contingencies.

OSR may terminate the Company's rights as to certain fields of use for the Company's failure to develop (a) with respect to a solid cancer indication, upon third anniversary of the date the Company exercised such option, if the Company has not filed an IND with respect to such optioned solid cancer indication specifically, as to GBM, the Company is required to file an IND regarding Temferon for GBM prior to February 2022, or (b) with respect to a lympho-hematopoietic indication, on the earlier of (i) the fifth anniversary of the initiation (first patient dosed) of the first human clinical trial for a licensed product in any lympho hematopoietic indication or solid cancer indication if a patient has not been dosed with a licensed product in a Phase 3 clinical trial, or (ii) September 1, 2025.

*License Agreement Amendment #4*

On September 28, 2021, the fourth amendment to the License Agreement was signed with the aim to extend the deadline for the definition of the second Solid Cancer Indication. If the Company is not able to obtain approval of the Regulatory Authorities to initiate a human clinical trial in any country with respect to solid liver cancer on or before September 30, 2022, then the Company shall have the right, at no additional cost, to convert the option exercise for the second Solid Cancer Indication to an indication (the "Alternate Indication") other than solid liver cancer, upon written notice to OSR, such notice is to be delivered to OSR within September 30, 2022. Under the amendment, the Company will be entitled to exercise the Option set forth above with respect to any other Solid Cancer Indication for the remainder of the Option Period that will expire on December 23, 2022, and shall not be subject to further extensions.

At June 30, 2022, the cumulative total amount of expenses for the OSR clinical trial activity from inception amounted to approximately €9.0 million and it includes the cost for the exercise of the first and the second Solid Cancer indication Option fee of €1.0 million.

*License Agreement Amendment #5*

On January 22, 2022, the fifth amendment to the License Agreement was signed with the aim to clarify certain terms. It has been stated that solely with respect to GBM, "IND" means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations. IND shall include any comparable filing(s) outside the United States of America for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application, or CTA, in the European Union).

In addition, with respect to Licensed Products for GBM, Genenta commits to carry out a Phase III Clinical Trial also in US.

With respect to GBM, Genenta shall pay to OSR an additional Milestone Payment equal to €350,000 upon the first patient being dosed in a Phase III Clinical Trial in US with respect to a Licensed Product for GBM.

Moreover with regards to termination rights, if Genenta has not filed an IND with respect to such Solid Cancer Indication within three (3) years from the date of the exercise of the option (or, in relation to GBM, has not dosed the first patient with a Licensed Product for GBM in a Phase III Clinical Trial started in the US within 72 months from the first patient being dosed in the first human clinical trial of such applicable Licensed Product for GBM), the termination rights shall be limited to such Licensed Product in the Terminated Solid Cancer Indication. Any further activity on such Licensed Product in the Terminated Solid Cancer Indication shall be immediately discontinued by Genenta.

As of June 30, 2022, no milestones were achieved related to any indication, as provided by the License Agreement; therefore, no payments were due to OSR, nor other contingencies exist

*Research Funding Agreement*

In March 2019, the Company and OSR entered a Research Funding Agreement to conduct a clinical trial according to the multiple myeloma protocol, TEM-MM-101 and EudraCT 2018-001741-14, entitled "A Phase I/II dose escalation study evaluating safety and activity of autologous CD34+ enriched hematopoietic progenitor cells genetically modified with a lentiviral vector encoding for the human interferon-α2 in multiple myeloma patients with early relapse after intensive front-line therapy." This agreement required OSR to perform certain clinical procedures and exploratory analyses on the study population, as per the protocol approved by the relevant competent authorities. The Company was required to fund the costs of the study-related procedures performed on patients recruited in the Trial, according to periodic study reports delivered by OSR. TEM-MM-101 received approval by national Competent Authorities in November 2018 and the first TEM-MM-101 trial patient was enrolled in August 2019.

The Company discontinued the multiple myeloma program in early 2021 due to the relatively small number of eligible patients, and the highly competitive MM landscape. (See Note 13.)

*Sponsor Research Agreement (SRA)*

As stated above, in exchange for a reduction in the first Solid Cancer indication option fee from €1.0 million to €0.5 million, the Company agreed to enter into a Sponsored Research Agreement (SRA). The Company and OSR executed the agreement in February 2021. Under the SRA, sponsored research activities will be conducted for between €0.5 million and €1.0 million (minimum commitment €0.5 million). The activities relate to:

- Research 1: Additional preclinical mouse model studies directed to identify Temferon effectors cells (transduced Tie2-expressing cells) and to test Temferon in combination with CAR-T in a GBM mouse model; and,

- Research 2: Additional exploratory analyses, including single cell sequencing, to be conducted on samples collected from patients belonging to TEM-GBM_001 clinical trial aimed to deepen Temferon mechanism of action and get a broader insight on its biological activity in humans.

For the six months ended June 30, 2022, and June 30, 2021, the Company paid and expensed €375,000 and €500,000, respectively, related to the SRA. The last tranche of activities is expected to be completed and invoiced before the end of 2022.

*Amendment #01 to the Agreement of March 2, 2019*

On April 27, 2022 OSR and Genenta signed this Amendment #01 as an amendment to the Agreement for Clinical Trials called: "*Phase I/IIa clinical trial to assess the safety and efficacy of increasing doses of autologous CD34+ hematopoietic stem cells genetically modified with a lentiviral vector encoding for the human interferon-alpha2 gene in patients with Glioblastoma Multiforme with unmethylated MGMT gene promoter*" ("Clinical Trial") relating to protocol number TEMGBM_001; EudraCT 2018-001404-11. The Agreement will have to be updated to allocate to the TEM-GBM study the fee for the personnel shares not yet accrued and originally allocated to the TEM-MM study. Specifically, the different items and their amounts are:

- TEM-MM unspent budget to be reallocated to the TEM-GBM study:

- Investigator €105,000

- Data Manager €92,500

- Total €197,500

During the six months ended June 30, 2022, the Company recorded expenses of €105,551 in the Consolidated Statement of Operations and Comprehensive Loss.

*Operating leases*

The Company entered into a non-cancelable lease agreement for office space in January 2020. (See Note 13. Commitments and contingencies.)

**13. Commitments and contingencies**

The Company exercises considerable judgment in determining the exposure to risks and recognizing provisions or providing disclosure for contingent liabilities related to pending litigations or other outstanding claims and liabilities. Judgment is necessary in assessing the likelihood that a pending claim will succeed, or a liability will arise and to quantify the possible range of the final settlement. Provisions are recorded for liabilities when losses are considered probable and can be reasonably estimated. Because of the inherent uncertainties in making such judgments, actual losses may be different from the originally estimated provision. Estimates are subject to change as new information becomes available, primarily with the support of internal specialists or outside consultants, such as actuaries or legal counsel. Adjustments to provisions may significantly affect future operating results.

The following table summarizes the Company obligations by contractual maturity on June 30, 2022:

| | Payments by Period | | | | |
|---|---|---|---|---|---|
| *(in Euros)* | Total | Less than a year | 1 to 3 years | 4 to 5 years | More than 5 years |
| OSR operating leases and office rent | € 33,500 | € 13,400 | € 20,100 | € - | € - |
| AGC manufacturing | 83,200 | 8,050 | 58,150 | 17,000 | - |
| Insurances on operating leases | 25,653 | 6,996 | 18,657 | - | - |
| Total | € 142,353 | € 28,446 | € 96,907 | € 17,000 | € - |

The commitments with OSR relate to the office rent agreement while the commitments with AGC Biologics ("AGC") relate to biologic stability studies on plasmid batches. Insurances on operating leases are related to the non-lease insurance component of BMW car leasing 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.

*CMOs and CROs 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*

The License Agreement in place with OSR provides for milestone payments and royalties. The OSR agreements are non-cancelable, except in the case of breach of contract, and includes total potential milestone payments of up to €10 million related to the lympho-hematopoietic indication of each Licensed Product, and up to €53 million related to each Solid Cancer indication (as defined in the agreement); however, starting with the fifth Solid Cancer indication, the first two related milestone payments totaling €7.0 million, are reduced to €3.5 million. The milestones relate to certain events such as, dosing of the first patient with a licensed product in Phase II and III of the trial, MAA (marketing authorization application) and NDA (new-drug application) approval of the licensed product, the first commercial sale of the product in the US and major European countries, and annual sales for the licensed product exceeding a certain amount in different territories.

*Glioblastoma multiforme (GBM)*

As discussed in Note 12, in December 2020, the Company had one indication ongoing, GBM. The Company's contingent liability for this first solid cancer indication potentially payable to OSR was €53 million, as explained above.

*Liver cancer (LC)*

In relation to the option exercised by the Company for the second solid cancer indication, the Company and OSR agreed that the payment due in relation to the "First patient dosed with a Licensed Product in Phase I/II Clinical Trial," as stated in the agreement, was reduced to €0.5 million rather than €1.0 million. The reduction applied to the first license fee payment only. All the additional contingent payments, other than the last contingent payment of €5.0 million, remained a contingent liability of the Company and potentially payable to OSR. Therefore, for the second solid cancer indication (liver cancer), the total potential commitment of possible contingent payments could amount to €47.5 million.

The agreements also include a €7.8 million commitment related to the development and manufacturing of licensed products, of which the Company had incurred €0.8 million and €0.7 million of expenses during the first six months ended June 30, 2022 and June 30, 2021, respectively. The cumulative expense to date is €6.2 million.

*AGC Biologics (formerly MolMed)*

The AGC agreement is non-cancelable, except in the case of breach of contract, and includes a potential milestone of €0.3 million if a phase 3 study is approved by the relevant authority, as well as potential royalty fees between 0.5% and 1.0% depending on the volume of annual net sales of the first commercial and named patient sale of the product. In the AGC Agreement, the Company entrusts AGC with certain development activities that will allow the Company to carry out activities related to its clinical research and manufacturing. The AGC agreement also includes a technology transfer fee of €0.5 million related to the transfer of the manufacturing know-how and €1.0 million related to the marketability approval by regulatory authorities. The agreement is a "pay-as-you-go" type arrangement with all services expensed in the period the services were performed. In February 2020, the Company entered into Amendment 4 to the Framework Service Agreement with AGC Biologics related to production and testing of the Company's GBM trials, for a total amount of €360,000. In March 2020, the Company entered into Amendment 5 to the Framework Service Agreement with AGC Biologics related to production and testing of the Company's GBM trials, for a total amount of €259,000. In March 2020, the Company entered into Amendment 6 to the Framework Service Agreement with ACG Biologics related to production and testing of the Company's GBM trials, for a total amount of €41,000. In August 2020, the Company entered into Amendment 7 to the Framework Service Agreement with ACG Biologics related to production and testing of the Company's GBM trials for a total amount of €259,000, which provides the Company with an option to accelerate GBM production as stated in Amendment 5 at a 20% cost increase. In October 2020, the Company entered into Amendment 8 to the Framework Service Agreement with ACG Biologics related to production and testing of the Company's GBM trials, for a total amount of €17,000. In October 2021 the Company entered into Side Letter to the Framework Service Agreement with ACG Biologics to perform the manufacture of one (1) additional *GMP* batch of 24L INFa LV vector (TIA-126 LV) in 2021 (the "LVV Batch") in connection with the Study TEM-GBM001, Genenta is in the process of completing, for a total amount of €311,280. In December 2021 the Company entered into Side Letter to the Framework Service Agreement with ACG Biologics to perform the manufacture of one (1) additional *GMP* batch of 24L INFa LV vector (TIA-126 LV) in 2022 (the "LVV Batch") in connection with the Study TEM-GBM001, Genenta is in the process of completing, for a total amount of €311,280. In March 2022 the Company entered into Side Letter to the Framework Service Agreement with ACG Biologics to perform the manufacture of one (1) additional GMP batch of 24L INFa LV vector (TIA-126 LV) in 2022 for use in connection with the Study for €272,800.

In early 2020, the Company and AGC amended the Master Service Agreement for the fourth time to regulate some new production activities for which the total estimated budget amounts to €0.3 million. At June 30, 2022, the Company is committed to pay a total of €32,200 relating to various stability timepoints, which will be realized and come due at different times.

In September 2021, the Company extended the stability studies on the plasmid batch pIFNa 16024 (p906) up to nine (9) years and at June 30, 2021, the Company was committed to pay a total of €51,000 relating to various stability timepoints which will be realized in the future. At June 30 ,2022, the total commitment of the Company for stability endpoints to be realized in the future amounts to €83,200.

*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 to €13,400, at June 30, 2022, outstanding minimum payments amount to €6,700 until January 1, 2023.

*Capital lease*

On February 11, 2022, the Company entered into a four (4) year car lease. This lease has been recognized as a capital lease. For the six months ended June 30, 2022, the Company recorded in the Consolidated Statement of Operations and Comprehensive amortization expenses of €4,583.

On June 30, 2022, the Company recorded €44,737 property and equipment, net and €12,330 and €32,407 for Lease Current and Non-Current liabilities, respectively.

The car underling 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 car lease agreement. Therefore, it is accounted for in insurance expense in the Consolidated Statement of Operations and Comprehensive Loss when occurred. For the six months ended June 30, 2022, the Company recorded insurance costs of €2,332. On June 30, 2022, the outstanding payments for insurance expense related to the car under lease amounted to €25,653.

*Legal proceedings*

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of ASC 450, Contingencies. The Company was notified by Theravectys of the possible infringement by the Company of Theravectys' exclusive license to patents no. EP 1071804, EP 1224314, and EP 1222300 granted from the owner of the patents Institut Pasteur. Each of these patents is now expired, having each reached the end of it its patent term on April 23, 2019 for EP 1071804 and October 10, 2020 for EP 1224314, and EP 1222300. The Company considered the situation and determined that the likelihood of a material adverse effect on its business is remote. To date, the Company has not engaged in any such discussions with Theravectys nor has the Company received any further communication from Theravectys. The Company expenses, as incurred, the costs related to its legal proceedings, if any.

*Coronavirus Pandemic*

On March 11, 2020, the World Health Organization declared the outbreak of the coronavirus (COVID-19) pandemic. Significant uncertainties may arise with respect to potential shutdowns of operations or government orders to cease activities due to emergency declarations, inability to operate, or employee shortages, claims for business interruption insurance, etc. Although the Company has experienced minimal disruption to date and still has staff working remotely from home, the Company may find it difficult to enroll patients in its clinical trials, which could delay or prevent the Company from proceeding with the clinical trials of its product candidates; therefore, the coronavirus pandemic may still have a significant impact on the future results of the Company.

**14. Subsequent events.**

*Board Resignations*

On July 7, 2022, and July 8, 2022, Dr. Daniela Bellomo and Dr. Luca Guidotti, respectively, resigned from the Board. Dr. Bellomo's and Dr. Guidotti's resignations did not result from any disagreements with management or the Board.

*Stock Option Grant*

Nonqualified stock options on 392,740 shares were granted on July 21, 2022, to certain employees and directors of the Company. For these July 21, 2022, grants, the Company adopted a 30-day value weighted average pricing ("VWAP") adjusted by Black Scholes method of stock option pricing, rounded to the nearest penny, to determine the exercise price of the options. The cost or expense of the stock option(s) to the Company is also based on the Black Scholes method.

*OSR Letter Agreement*

On September 29, 2022, the Company entered into a letter agreement with OSR to extend each of the alternative indication notice period (as defined by the Amendment 4 to the License Agreement) and the competing product period (as defined in the Amendment 3 to the License Agreement) to December 23, 2022.

**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, 2021, filed with the Securities and Exchange Commission on May 2, 2022. References to "we," "Genenta," "us," "our," "the Company," or "our company" herein are to Genenta Science S.p.A., including its subsidiaries.*

*In May 2021, we converted from a limited liability company (società a responsabilità limitata, or S.r.l.) to a joint stock company (società per azioni, or an S.p.A.) (the "Corporate Conversion"). This change in incorporation did not affect the financial information herein presented, except for the transformation of our quotas into ordinary shares. As such, our historical financial statements are not required to be retrospectively adjusted.*

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

Since our inception in 2014, we have devoted substantially all of our resources to organizing and staffing our Company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights, conducting discovery, research and development activities for our programs and planning for eventual commercialization. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations with proceeds from the sales of equity securities, which through June 30, 2022, aggregated gross cash proceeds of approximately €67.0 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, 2022, and June 30, 2021 were approximately €2.1 million and approximately €4.0 million, respectively. As of June 30, 2022, and December 31, 2021, we had an accumulated deficit of approximately €29.1 million and €27.0 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 securities, including the net proceeds from our IPO and follow-on offerings. We also plan to pursue additional funding from outside sources, including but not limited to our entry into or expansion of new borrowing arrangements; research and development incentive payments, government grants, pharmaceutical companies and other corporate sources; and our entry into potential future collaboration agreements with pharmaceutical companies or other third parties for one or more of our programs. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and eventual commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

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

As of June 30, 2022, we had cash and cash equivalents of approximately €34.7 million. We believe that our existing cash and cash equivalents as of June 30, 2022, will enable us to fund our operating expenses and capital expenditure requirements for substantially more than 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.

**COVID-19 Update**

As of the date of the filing of the Form 6-K, the global healthcare community continues to respond to the coronavirus (COVID-19) pandemic, including the recent emergence of the delta and other variants. In February 2020, the COVID-19 pandemic commenced in Italy. Regulatory guidance was issued in March and updated in April 2020 relating to the management of clinical trials during the pandemic. As the global healthcare community continues to respond to the COVID-19 pandemic, many hospitals, including our clinical sites, temporarily paused elective medical procedures, including dosing of new patients in clinical trials of our investigational gene therapies. While dosing of new patients and data collection from enrolled patients has resumed at clinical sites, the extent to which clinical activities continue to be delayed or interrupted will depend on future developments that are highly uncertain. We have not experienced significant interruptions related to COVID-19. We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates. We continue to closely monitor this rapidly evolving situation and the potential impact on us.

**Components of Operating Results**

***Revenue***

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products in the near future until we obtain regulatory approval of, and commercialize, our product candidates.

***Operating Expenses***

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

***Research and Development Expenses***

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

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2022 | 2021 |
| *(in Euros)* | (Unaudited) | |
| Direct research and development expenses by program: | | |
| TEM-GBM | € 618,871 | € 1,692,458 |
| TEM -LT | 672 | |
| TEM-MM | 14,200 | 18,609 |
| TEM-HC | (942) | 667 |
| | | |
| Unallocated costs: | | |
| Personnel (including share-based compensation) | 377,928 | 401,380 |
| Consultants and other third parties | 144,772 | 760,831 |
| Materials & supplies | 397,790 | 312,844 |
| Travel Expenses | 65,938 | 10,445 |
| Other | 21,350 | 2,000 |
| Total research and development expenses | € 1,640,579 | € 3,199,234 |

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

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

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

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

***General and Administrative Expenses***

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

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

***Other Income (Expense)***

Other income (expense) consists primarily of interest income/(expense), foreign exchange income/(loss) and, for the six months ended June 30, 2022, a tax credit to be reimbursed to the Company by the Italian Revenue Agency.

***Income taxes***

We are subject to taxation in Italy and in the state of Delaware. Taxes are recorded on an accrual basis. They therefore represent the allowances for taxes paid or to be paid for the year, calculated according to the current enacted rates and applicable laws. Due to the tax loss position reported, no income taxes were due for the six months ended June 30, 2022, and June 30, 2021.

As of each reporting date, we consider existing evidence, both positive and negative, that could impact our view regarding to future realization of deferred tax assets. We believe that it is more likely than not that the benefit for deferred tax assets will not be realized. In recognition of this uncertainty, a full valuation allowance was applied to the deferred tax assets. Future realization depends on our future earnings, if any, the timing and amount of which are uncertain as of June 30, 2022. In the future, should management conclude that it is more likely than not that the deferred tax assets are partially or fully realizable, the valuation allowance would be reduced to the extent of such expected realization and the amount would be recognized as a deferred income tax benefit in our statements of operations.

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

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

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

The 2020 Italian Budget Law established that: (i) the tax credit due is up to 12% of the research and development costs incurred (up to a maximum of € 3.0 million); (ii) the actual support of eligible expenditure and its correspondence with the accounting documents must result from a specific certification issued by the person responsible for the legal audit; (iii) the tax credit due can only be used as compensation in three equal annual installments. The 2021 Italian Budget Law established that: (i) the tax credit due is up to 20% of the costs incurred (up to a maximum of € 4.0 million); (ii) the tax credit can be used for 2021 and 2022 fiscal years; (iii) it is necessary to have, besides the audit report, a technical report.

**Results of Operations**

***Comparison of the Six Months Ended June 30, 2022 to the Six Months Ended June 2021***

The following table summarizes our results of operations for the six months ended June 30, 2022 and June 30, 2021:

| | Six Months Ended June 30, | |
|---|---|---|
| | **2022** | **2021** |
| | (Unaudited) | |
| Operating expenses | | |
| Research and development | € 1,640,579 | € 3,199,234 |
| General and administrative | 2,513,558 | 842,236 |
| Total operating expenses | 4,154,137 | 4,041,470 |
| | | |
| Loss from operations | (4,154,137) | (4,041,470) |
| | | |
| Other income (expense) | | |
| Other income | 215,486 | 2,679 |
| Unrealized exchange rate gain | 1,826,330 | (9,111) |
| Total other income (expense) | 2,041,816 | (6,432) |
| | | |
| Loss before income taxes | (2,112,321) | (4,047,902) |
| Income taxes benefit (expenses) | - | - |
| Net loss | (2,112,321) | (4,047,902) |
| | | |
| Net loss and comprehensive loss | € (2,112,321) | € (4,047,902) |
| | | |
| Loss per share: | | |
| Loss | € (2,112,321) | € (4,047,902) |
| Loss per share - basic | € (0.12) | € (0.27) |
| Weighted average number of shares outstanding - basic | 18,216,858 | 14,772,610 |

*Research and Development Expenses*

Research and development expenses were approximately €1.6 million for the six months ended June 30, 2022, as compared to approximately €3.2 million for the six months ended June 30, 2021. The decrease of approximately €1.5 million was primarily due to the lower number of patients in trial, the different mix of therapy treatments to which patients in the trial were subjected, and the greater compensation effect of the tax credit recognized by the Italian Revenue Agency for research and development expenses accrued.

During the six months ended June 30, 2022, we utilized approximately €0.3 million to offset certain social contributions and taxes payable, while during the six months ended June 30, 2021, we utilized approximately €0.2 million. The benefit recorded for the six months ended June 30, 2022, and June 30, 2021, to offset research and development expenses was approximately €0.7 million and €0.2 million, respectively. We reclassified to other non-current assets a portion of the receivable, which was expected to be realized beyond 12 months. The increase in the benefit recorded for the six months ended June 30, 2022, was due to the increase in the utilization rate of research and development credit, as a consequence of the increase in our structure compared to the previous period. This estimate was deemed reasonable and prudent based on the actual research and development tax credit utilization rate.

*General and Administrative Expenses*

General and administrative expenses were approximately €2.5 million for the six months ended June 30, 2022, as compared to approximately €0.8 million for the six months ended June 30, 2021. The increase of approximately €1.7 million of general and administrative expenses was primarily due to the increase in size of our internal structure to manage the increase in operating activities mainly related to compliance, administration, and corporate governance, as a result of our initial public offering (IPO) that took place in December 2021.

More specifically, the increase from the six months ended June 30, 2021 to the six months ended June 30, 2022 of €0.5 million in compensation expense (including share-based compensation), was due to new administrative staff hired at the end of the first half of 2021, an increase in board compensation in May 2021, a new employment agreement for the CEO and the CFO of the Company starting on December 15, 2021 and November 1, 2021, respectively, and a stock option granted to the former Chairman of the board of directors (the "Board"), Dr. Squinto, for €0.2 million on April 26, 2022.

We incurred an increase of approximately €0.2 million in accounting, legal and professional expenses that occurred in the six months ended June 30, 2022, compared to the six months ended June 30, 2021, mainly due to the costs related to our public company compliance.

We incurred an increase of approximately €0.3 million in advisory expenses in the six months ended June 30, 2022, compared to the six months ended June 30, 2021, mainly due to an advisory agreement with Roth Capital LLC entered into in January 2022 after the Company's IPO.

Finally, we incurred an increase of approximately €0.6 million in directors' and officers' liability insurance costs, and €0.1 million in miscellaneous other expenses in the six months ended June 30, 2022, compared to the six months ended June 30, 2021. The other administrative expense increases were mainly due to business travels, meetings and catering costs related to business development activities.

*Other Income*

Other income was approximately €0.21 million for the six months ended June 30, 2022, as compared to €2,679 for the six months ended June 30, 2021. The increase was due to approximately €0.2 million in tax reimbursement to be collected from the Italian Revenue Agency.

*Foreign Exchange Gains*

Our foreign exchange gain was approximately €1.8 million for the six months ended June 30, 2022, due to cash held in USD, as compared to a loss of €9,111 for the six months ended June 30, 2021. The increase was due to the strengthening dollar and weakening Euro in the six months ended June 30, 2022.

*Net loss*

Our net loss was approximately €2.1 million for the six months ended June 30, 2022, as compared to approximately €4.0 million for the six months ended June 30, 2021. The decrease of approximately €1.9 million was primarily due to the fluctuation in the foreign exchange rate and a decrease in our overall research and development spending, combined with the increased general and administrative expenses described 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 IPO, of our shares as an S.p.A. We received gross cash proceeds of approximately €33.6 million from sales of quotas (pre-IPO) and approximately €32.7 million of gross proceeds from the IPO. As of June 30, 2022, the Company had approximately €34.7 million in cash and cash equivalents.

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

| | Six Months Ended June 30, (Unaudited) | |
|---|---|---|
| *(in Euros)* | **2022** | **2021** |
| Net cash used in operating activities | € (2,566,193) | € (4,690,869) |
| Net cash used in investing activities | (2,813) | (3,727) |
| Net cash provided by (used in) financing activities | - | (216,741) |
| **Net increase (Net decrease) in cash and cash equivalents** | € (2,569,006) | € (4,911,337) |
| Cash and cash equivalents at beginning of year | 37,240,162 | 15,465,243 |
| **Cash and cash equivalents at end of year** | € 34,671,156 | € 10,553,906 |

***Operating Activities***

During the six months ended June 30, 2022, and June 30, 2021, operating activities used approximately €2.6 million and €4.7 million, respectively, of cash and cash equivalents, resulting mainly from our loss of approximately €2.1 million. The net change in our operating assets and liabilities was primarily due to the decrease in payment from related party research and clinical activities. 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.

***Financing Activities***

During the six months ended June 30, 2022, cash flow from financing activities was €0, while during the six months ended June 30, 2021, cash flow from financing activities was €(216,741) consisting mainly in prepaid offering costs and cash proceeds from the exercise of options on our class B quota. During the six months ended June 30, 2021, €172 class B quota was repurchased from Drs. Naldini and Gentner at nominal value, cancelled, and allocated to the option plan as available for grant.

***Current Outlook***

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

As of June 30, 2022, our cash and cash equivalents were approximately €34.7 million. Our primary cash obligations relate to payments to Ospedale San Raffaele (OSR) pursuant to the license agreement and other providers of clinical trial related services.

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

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

- the length of the COVID-19 pandemic and its impact on our planned clinical trials, operations and financial condition;
- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- any cost that we may incur under in- and out-licensing arrangements relating to our product candidate that we may enter into in the future;

- the costs and timing of obtaining regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of, and timing for, amending current manufacturing agreements for production of sufficient clinical and commercial quantities of our product candidates, or entering into new agreements with existing or new contract manufacturing organizations (CMOs);
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally; and
- the costs of acquiring or undertaking the development and commercialization efforts for additional, future therapeutic applications of our product candidates and the magnitude of our general and administrative expenses.

Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through our existing cash, cash equivalents and short-term deposits.

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 upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the 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 in order to understand the judgements and estimates used in the financial statements and to fully understand and evaluate our financial condition and results of operations.

***Accrued Research and Development Expenses***

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

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

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

***Share-based compensation***

To reward the efforts of employees, directors, and certain consultants to promote our growth, the Board has historically approved, during its existence, various share-based awards.

During the six months ended June 30, 2021, the Board granted fully vested options on €169 quota B. In addition, the Board accelerated the vesting of other stock options on €546 quota B that were previously granted. This amounted to a total of €715 quota B that were exercised prior to the Corporate Conversion. All options were awarded with an exercise price of €1 per quota and, when exercised, were first converted to quota B of Genenta Science S.r.l. and then to ordinary shares giving effect to our Corporate Conversion to Genenta Science S.p.A. All options were granted and there were no outstanding options as of June 30, 2021.

On May 20, 2021, the Board approved the general terms (e.g., regulation) of our 2021 – 2025 Equity Incentive Plan. Under Italian law, there is no need to obtain the approval of the specific terms of our equity incentive plans from our shareholders. The number of stock options available are determined by the Company's shareholders by vote at an annual or special meeting of shareholders. Currently, the Company has options on 1,821,685 shares (i.e., 10% of the number of shares outstanding, which are currently 18,216,858 shares outstanding); however, at the quotaholders' meeting held on May 20, 2021, the quotaholders approved a paid share capital increase to service the Plan, up to a maximum amount of €27,000,000, through the issue of a maximum of 2,700,000 new ordinary shares (and in any case within the limit of 10% of the number of shares in circulation at the time of issue). Therefore, as the Company raises additional capital and the number of issued and outstanding shares grows, the Board has authority to issue shares in the range from 1,821,685 to 2,700,000, i.e., the Company does not have to obtain further authorization from shareholders to increase the number of shares available for equity grants until the outstanding shares exceed 27,000,000.

Nonqualified stock options were granted on April 26, 2022 by the Board (i.e., the administrator of our 2021 – 2025 Equity Incentive Plan ) to Dr. Stephen Squinto, the Company's Chairman of the Board at the time. Options granted on April 26, 2022 were priced based on a sub-plan called "2021-2025 Chairman Sub-Plan" attached to the Plan. The cost or expense of the stock option(s) to the Company is also based on the Black Scholes method.

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

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

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

**Off-Balance Sheet Arrangements**

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

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

**Quantitative and Qualitative Disclosure About Market Risk**

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

***Foreign Currency Exchange Risk***

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

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

**Other Events**

In July 2022, Dr. Daniela Bellomo and Dr. Luca Guidotti resigned from the Board. Dr. Bellomo’s and Dr. Guidotti’s resignations did not result from any disagreements with management or the Board.