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

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12 (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report_____

For the transition period from _____ to _____

Commission file number: 001-41115

Genenta Science S.p.A.

(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Italy
(Jurisdiction of incorporation or organization)

Via dell'Annunciata No. 31
Milan, Italy
(Address of principal executive offices)
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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
American depositary shares (each American depositary share representing one ordinary share)	**GNTA**	**The Nasdaq Stock Market LLC (The Nasdaq Capital Market)**
Ordinary shares, no par value*		**The Nasdaq Stock Market LLC (The Nasdaq Capital Market)**

* Not for trading, but only in connection with the listing of American depositary shares on The Nasdaq Capital Market.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the Issuer's classes of capital or common stock as of the close of the period covered by the annual report.

The registrant had 23,432,183 ordinary shares outstanding as of December 31, 2025.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Note — Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒ International Financial Reporting Standards as issued by the International Accounting Standards Board ☐ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. ☐ Yes ☐ No

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CERTAIN INFORMATION

As used in this Annual Report on Form 20-F (this "Annual Report"), unless otherwise indicated or the context otherwise requires, references to

- "we," "Genenta," "us," "our," "the Company," or "our company" are to Genenta Science S.p.A., including its subsidiaries;
- "ordinary shares" are to our ordinary shares, no par value;
- "ADSs" or "American Depositary Shares" are to our American depositary shares, each representing one ordinary share;
- "Nasdaq" are to the Nasdaq Capital Market;
- "Italy" are to the Republic of Italy, "E.U." are to the European Union, and "U.S." are to the United States of America;
- "$," "USD," "dollars," "USD$" or "U.S. dollars" are to the legal currency of the U.S.; and
- "€," "EURO," or "Euros" are to the legal currency of the E.U.

Solely for the convenience of the reader, this Annual Report contains translations of certain U.S. dollar amounts into Euros at specified rates. Except as otherwise stated in this Annual Report, all foreign currency transactions are translated into Euros through a specific application embedded in our accounting system, which is powered by the official exchange rates provided by HSBC (Hongkong and Shanghai Banking Corporation) in the City of London, United Kingdom. Specifically, the Consolidated Balance Sheet balances resulting from our financial statement as of December 31, 2025, are translated at the spot exchange rate as of December 31, 2025, that is $1.00 per €0.8518, while the Consolidated Statements of Operations and Comprehensive Loss balances are translated at the weighted average exchange rate of non-Euro currency transactions during the reporting period. No representation is made that such U.S. dollar amounts referred to in this Annual Report could have been or could be converted into Euros at such rates or any other rates. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding.

The audited consolidated financial statements and notes thereto as of and for fiscal 2025, 2024, and 2023 included elsewhere in this Annual Report have been prepared in accordance with U.S. generally accepted accounting principles ("US GAAP"). Our fiscal semi-annual year-end is June 30th, and our fiscal year-end is December 31st.

FORWARD-LOOKING STATEMENTS

This Annual Report contains many statements that are "forward-looking" and uses forward-looking terminology such as "anticipate," "believe," "could," "estimate," "expect," "future," "intend," "may," "ought to," "plan," "possible," "potentially," "predicts," "project," "should," "will," "would," negatives of such terms or other similar statements. You should not place undue reliance on any forward-looking statement due to its inherent risk and uncertainties, both general and specific. Although we believe the assumptions on which the forward-looking statements are based are reasonable and within the bounds of our knowledge of our business and operations as of the date of this Annual Report, any or all of those assumptions could prove to be inaccurate. As a result, the forward-looking statements based on those assumptions could also be incorrect. The forward-looking statements in this Annual Report include, without limitation, statements relating to:

- our goals and strategies;
- our future business development, results of operations and financial condition;
- our ability to protect our intellectual property rights;
- projected revenues, profits, earnings and other estimated financial information;
- our ability to maintain strong relationships with our customers and suppliers;
- our planned use of proceeds; and
- governmental policies regarding our industry.

The forward-looking statements included in this Annual Report are subject to known and unknown risks, uncertainties and assumptions about our business and business environment. These statements reflect our current views with respect to future events and are not a guarantee of future performance. Actual results of our operations may differ materially from information contained in the forward-looking statements as a result of risk factors, some of which are described under the headings "Risk Factors", "Operating and Financial Review and Prospects," "Information on our Company" and elsewhere in this Annual Report.

These risks and uncertainties are not exhaustive. Other sections of this Annual Report include additional factors which could adversely impact our business and financial performance. The forward-looking statements contained in this Annual Report speak only as of the date of this Annual Report or, if obtained from third-party studies or reports, the date of the corresponding study or report, and are expressly qualified in their entirety by the cautionary statements in this Annual Report. Since we operate in an emerging and evolving environment and new risk factors and uncertainties emerge from time to time, you should not rely upon forward-looking statements as predictions of future events. Except as otherwise required by the securities laws of the U.S., the E.U. and Italy, we undertake no obligation to update or revise any forward-looking statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management

Not required.

B. Advisers

Not required.

C. Auditors

Not required.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

A. Offer Statistics

Not applicable.

B. Method and Expect

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. Capitalization and Indebtedness

Not required.

C. Reasons for the Offer and Use of Proceeds

Not required.

D. Risk Factors

You should carefully consider all of the information in this report, including various changing regulatory, competitive, economic, political, and social risks and conditions described below, before making an investment in our ordinary shares. One or more of a combination of these risks could materially impact our business, results of operations, and financial condition. In any such case, the market price of our ADSs or ordinary shares could decline, and you may lose all or part of your investment.

Summary of Risk Factors

Risks relating to our business include issues arising from the following matters and related adverse developments:

- We have a limited operating history and have incurred significant losses since our inception. We have never generated revenue and will require significant additional funds, which may not be available on acceptable terms or at all. As a result, you could lose your entire investment.

- We are attempting to evolve into a next-generation strategic industrial consolidator in response to evolving market dynamics and strategic opportunities. We have never attempted a strategic transformation of this type. Although we intend to evolve into a next-generation strategic industrial consolidator organized around key synergistic pillars – Biotechnology, Defense, Aerospace, and National Security, and focused on acquiring privately held businesses operating in national-security regulated sectors contemplated by the "Golden Power" legislation, there can be no assurance that this effort will be successful. As a result, our efforts could have a material adverse impact on your investment.

- Our lentiviral-based gene therapy product candidates are based on a novel technology that is in preliminary stages of evaluation, which makes it difficult to predict the time and cost of product candidate development or the likelihood of receiving required regulatory approvals. Our rights to the intellectual property underlying our novel technology derive solely from our license agreement with San Raffaele Hospital ("OSR") and any failure to comply with the terms of such license agreement could have a material adverse effect on our intellectual property position and our ability to seek approval for and ultimately commercialize such product candidates.

- Even if we do receive regulatory approvals for our product candidates, they may face commercialization issues from significantly larger oncology competitors, unfavorable pricing regulations or lack of acceptance by doctors, hospitals, patients and insurers. Our product candidates and the process for administering them may also cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval.

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

- We are seeking a partner or strategic relationship in order to advance Temferon, but there can be no assurance that we will be successful in establishing a strategic partnership or collaboration. If we are not able to develop an alliance or strategic partnership or other collaboration, we may not be able to further advance Temferon's clinical development, which would inhibit our ability to generate value from the Temferon asset. Such strategic partnership and collaboration arrangements are also complex and time-consuming to negotiate, document, and implement and they may require substantial resources to maintain. Any strategic partnerships or collaborations we enter into may not be successful and we may not realize the benefits from such arrangements.

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

- Our Chief Executive Officer, directors, and shareholders who own more than 5% of our outstanding ordinary shares currently own approximately 25% of our ordinary shares and approximately 58% of the voting power due to the Company's loyalty share program and will therefore be able to exert significant control over matters submitted to our shareholders for approval.

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

- As a company organized under the laws of Italy and whose shares are represented by ADSs, the rights of investors in the Company differ in several material respects from the rights of holders of shares of common stock of a U.S. domestic company and may not provide investors the same protections.

Risks Related to Our Financial Position and Capital Requirements

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

As of December 31, 2025, our cash and cash equivalents and marketable securities were approximately €28.1 million. If we continue to use cash at our historical rates of use, we will need significant additional financing, which we may seek through a combination of private and public equity offerings, debt financing and collaboration, in-licensing arrangements, joint ventures, strategic alliances or partnerships. For example, on May 12, 2023, we filed with the Securities and Exchange Commission (the "SEC") a shelf registration statement, which was declared effective by the SEC on May 24, 2023 and permits us to sell from time to time additional ordinary shares, ordinary shares represented by ADSs or rights exercisable for ordinary shares or ADSs in one or more offerings in amounts, at prices and on the terms that we will determine at the time of offering for aggregate gross sales proceeds of up to $100.0 million. As of December 31, 2025, approximately $86.0 million of securities remained available under this registration statement. Further, we have entered into an ATM sales agreement, as amended (the "Sales Agreement"), with Virtu Americas LLC and Rodman & Renshaw LLC (the "Sales Agents") pursuant to which we may, but are not obligated to, offer and sell, from time to time, ADSs with an aggregate offering price up to $29,696,999 through the Sales Agents, subject to the terms and conditions described in the Sales Agreement and SEC rules and regulations (our "ATM offering"). As of December 31, 2025, approximately $26.4 million of capacity remained available under this ATM offering. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any such offerings may include liquidation or other preferences that may adversely affect the then existing shareholders' rights. Debt financing, if available, would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, licensing arrangements, joint ventures, strategic alliances, or partnerships with third parties, we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable, or if we have specific strategic considerations.

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

- the scope, progress, results and costs of drug discovery, laboratory testing, pre- and non-clinical development and clinical trials for our product candidates, including Temferon;
- the cost, timing, and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of future acquisition activities, as we evolve into a next-generation strategic industrial consolidator, including the cost related to acquiring and supporting businesses operating in national-security regulated sectors contemplated by the "Golden Power" legislation;
- the cost of preparing, filing and prosecuting patent and trademark applications, maintaining and enforcing our intellectual property rights and defending our intellectual property-related claims;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and,
- the administrative and compliance costs of transitioning to an industrial consolidator.

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

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

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier trials may not be predictive of future trial results. If clinical studies of our product candidates are prolonged or delayed, we may be unable to obtain the required regulatory approvals and, therefore, be unable to commercialize our product candidates on a timely basis or at all.

We have a limited history of conducting large-scale or pivotal clinical studies, and no history commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability. Our operations to date have been limited to financing and staffing our company, developing our technology, and developing Temferon for glioblastoma multiforme. We have not yet demonstrated an ability to successfully complete a large-scale or pivotal clinical study, obtain marketing approval, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

If clinical studies for our product candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay or restrict our receipt of any product revenue. There have been significant developments in the highly dynamic field of immuno-oncology such as the earlier availability of product candidates or earlier approval of drugs for the same indications as our product candidates, which may lead us to adapt or alter our clinical programs. At this stage, we cannot assure you of the safety or tolerability of Temferon as a monotherapy, or of its ability to demonstrate efficacy in humans. The commencement of planned clinical studies could be substantially delayed or prevented by several factors, including:

- discussions with the Italian Medicines Agency (Agenzia italiana del farmaco, or "AIFA"), FDA, EMA, or other regulatory agencies regarding the scope or design of our clinical studies;
- the limited number of, and competition for, suitable sites to conduct our clinical studies, many of which may already be engaged in other clinical study programs, including some that may be for the same indication as our product candidates;
- approval of drugs for the same indications as our product candidates;
- any delay or failure to obtain regulatory approval or agreement to commence a clinical study in any of the countries where enrollment is planned;
- inability to obtain sufficient funds required for a clinical study;
- clinical holds on, or other regulatory objections to, a new or ongoing clinical study;
- delay or failure in the testing, validation, manufacture and delivery of sufficient supplies of product candidate for our clinical studies;
- delay or failure to reach agreement on acceptable clinical study agreement terms with prospective sites or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; and
- delay or failure to obtain institutional review board ("IRB") or ethics committee approval to conduct a clinical study at a prospective site.

The completion of our clinical studies could in the future be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment, due to factors including, but not limited to, the availability of other drugs to treat potential patients, the unwillingness of patients to participate in low-dose groups of dose-ranging studies and lack of recruitment by clinical study sites;
- delays relating to adding new clinical study sites;
- failure of patients to complete the clinical study or return for post-treatment follow-up;
- failure of our collaborators to provide us with products necessary for us to conduct our combination studies;
- safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;
- the AIFA, FDA, EMA, or other regulatory authorities requiring us to suspend or terminate a clinical study, or requiring us to submit additional data or imposing other requirements before permitting us to continue a clinical study;
- lack of efficacy during clinical studies;
- errors in trial design or conduct;
- termination of our clinical studies by one or more clinical study sites;
- inability or unwillingness of patients or clinical investigators to follow our clinical study protocols, including clinical investigators' failure to comply with our clinical study protocols without our notice;
- inability to monitor patients adequately during or after treatment by us and/or our CROs; and
- the need to repeat or terminate clinical studies as a result of inconclusive or negative results or unforeseen complications in testing.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical study protocols or submit new clinical study protocols to reflect these changes with the appropriate regulatory authorities. In addition, changes in the competitive environment have occurred and may continue to occur. Amendments may require us to renegotiate terms with CROs or resubmit clinical study protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical study.

Our clinical studies may be suspended or terminated at any time by the AIFA, FDA, EMA, other regulatory authorities, the IRBs or ethics committees overseeing the clinical study at issue, any of our clinical study sites, or us, due to a number of factors, including:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- safety issues or any determination that a clinical study presents unacceptable health risks;
- lack of adequate funding to continue the clinical study due to unforeseen costs or other business decisions;
- upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates; and
- availability of a new effective treatment for the respective disease or condition that would be considered to be standard of care by regulatory bodies.

Our research, development and clinical costs will increase if we experience delays in clinical studies or marketing approvals or if we are required to conduct additional clinical studies or other testing of our product candidates. We may be required to obtain additional funding to conduct and complete such clinical studies. We cannot assure you that our clinical studies will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which may harm our business and results of operations. Any failure or significant delay in completing clinical studies for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

Although we are transitioning to become an industrial consolidator, we are currently a clinical-stage biopharmaceutical company with limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

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

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

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and have incurred losses each year since our inception. Our losses for the years ended December 31, 2025, 2024, and 2023 were approximately €6.5 million, €8.9 million, and €11.6 million, respectively. As of December 31, 2025, we had an accumulated deficit of approximately €62.6 million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development activities, including pre- and non-clinical development of our gene therapy product candidates, namely our leading product candidate Temferon, and from general and administrative costs associated with our operations.

We expect that it will be several years, if ever, before we have any product approved for commercial sale. We have funded our operations to date primarily through proceeds from our registered direct offering in October 2025, our mandatory convertible bond financing in March 2025, our ATM offering, and our initial public offering of ADSs and ordinary shares in December 2021 (the "IPO") and, prior to our IPO, the private placement of ordinary shares to our founding shareholders. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we:

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

- develop and obtain regulatory approval for registration studies for our current product candidate, Temferon, and any additional product candidates that we may pursue in the future;

- seek regulatory and marketing approvals for our product candidates that successfully complete clinical studies, including obtaining orphan drug designation;

- establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;

- industrialize our lentivirus *ex-vivo* gene therapy approach into a robust, scalable and, if approved, commercially viable process;
- maintain, protect, and expand our intellectual property portfolio;
- hire and retain qualified technical personnel, such as clinical, quality control, commercial and scientific personnel;
- expand our infrastructure and facilities to support our operations, including adding equipment and physical infrastructure to support our research and development; and
- incur additional legal, accounting, and other expenses associated with operating as a public company.

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

Our ability to generate revenue from product sales or acquire majority ownership in revenue generating companies under the "Golden Power" legislation, so that we could consolidate their revenue is uncertain. Our ability to achieve profitability also depends on our ability, along or with partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates, and/or maintain and grow the profitability of our acquisition companies. We do not anticipate generating revenues from product sales for the next several years, if ever, and our ability to do so depends heavily on our success in many areas, including but not limited to:

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

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

We do anticipate that the companies we acquire will be profitable, and our involvement with those companies will enhance their ability to grow and magnify their profitability; however, there can be no assurance that even if the acquired companies are profitable at the time of the acquisition, that they will remain profitable.

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

Risks Related to Product Development, Regulatory Approval, and Commercialization

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

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

- obtaining regulatory approval for our product candidates, as the AIFA, FDA, EMA, and other regulatory authorities have limited experience with lentivirus *ex-vivo* gene transfer therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient's hemapoietic stem progenitor cells ("HSPCs") *ex vivo* and infusing the engineered HSPCs back into the patient;

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

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

- regulatory requirements governing gene and cell therapy products are evolving in response to new clinical data. To date, several cell therapy products that involve the genetic modification of patient cells have been approved in the United States and/or the European Union, including two lentivirus *ex-vivo* gene transfer products;
- genetically modified products could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells in the event of improper insertion of a gene sequence into a patient's chromosome, or due to other unknown causes;
- although our viral vectors are not able to replicate, there is a risk with the use of lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases; and,
- the FDA recommends a 15-year follow-up observation period for patients who receive treatment using gene therapies and guidance promulgated by the EMA requires a similar follow-up observation period for patients who receive cell therapeutic products, which has to be sufficient to observe the subjects for risks that may be due to the characteristics of the product, the nature and extent of the exposure, and the anticipated time of occurrence of delayed adverse reactions and could be as long as life-time, and we may need to adopt an observation period for our product candidates.

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

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

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

There have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia with the use of gammaretrovirus vector and patient deaths in other clinical trials. There have been recent case reports of suspected unexpected serious adverse reactions ("SUSARs") involving an ex-vivo transduced lentivirus vector ("LVV") gene therapy product, Bluebird Bio, Inc.'s ("Bluebird Bio") elivaldogene autotemcel ("Lenti-D"), involving two SUSARs for cases of acute myeloid leukemia ("AML"), and one case involving myelodysplastic syndrome.

In July 2021, the EMA safety committee (Pharmacovigilance Risk Assessment Committee – PRAC) announced that there is no evidence the LVV used in both Lenti-D and the E.U.-approved gene therapy Zynteglo spurred the AML cases.

Bluebird Bio announced on August 9, 2021 that the SUSAR involving myelodysplastic syndrome occurred in one patient treated with Lenti-D over a year previously, that this SUSAR "is likely mediated by Lenti-D lentiviral vector (LVV) insertion," and that "[e]vidence currently available suggests that specific design features of Lenti-D LVV likely contributed to this event." As a result of this SUSAR, the FDA placed a clinical hold on Bluebird Bio's Lenti-D phase 3 trial for cerebral adrenoleukodystrophy. Post-approval, on November 24, 2024, the FDA announced that the FDA is investigating the known risk of hematologic malignancies with serious outcomes, including those such as hospitalization, the requirement for allogeneic hematopoietic stem cell transplantation, and death, and is evaluating the need for further regulatory action.

Gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. Possible adverse side effects that may occur with treatment with gene therapy products include an immunologic reaction early after administration that could substantially limit the effectiveness of the treatment or represent safety risks for patients. Another safety concern for gene therapies using viral vectors has been the possibility of insertional mutagenesis by the vectors, leading to malignant transformation of transduced cells. While our lentivirus *ex-vivo* gene transfer therapy approach is designed to avoid immunogenicity after administration, there can be no assurance that patients would not create antibodies that may impair treatment. Our approach involves the use of integrating vectors which have the potential for genomic disruption and therefore could interfere with other genes with adverse clinical effects. If any of our gene therapy product candidates demonstrates adverse side effects, we may decide or be required to halt or delay clinical development of such product candidates.

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

To date, Temferon has only been administered to a small number of glioblastoma multiforme (GBM) patients in our Phase 1/2a clinical trial. Only one serious adverse reaction has been attributed to Temferon (abnormal liver enzyme) that occurred early in a patient who subsequently survived more than three years. Adverse events that have occurred in this clinical trial have been attributed either to the autologous stem cell transplant procedures (which include conditioning chemotherapy), concomitant medications or disease progression. The majority of these adverse events resolved. Three patients with GBM died within 122 days of Temferon administration due to complications resulting from conditioning chemotherapy and possibly concomitant steroid use.

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

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

- regulatory authorities may suspend or withdraw approvals of such a product candidate;
- regulatory authorities may require additional warnings or limitations of use in product labeling;

- we may be required to change the way a product candidate is distributed, dispensed, or administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

We may not have sufficient capital to progress Temferon to a full Phase 2 trial.

We are at an early stage of development for our gene therapy platform. Temferon was authorized by AIFA for evaluation in Phase 1/2a clinical trials in Italy, where we evaluated Temferon in newly diagnosed unmethylated MGMT gene promoter glioblastoma tumor patients (the "TEM-GBM Study"). The enrollment of the Phase 1/2A of the TEM-GBM study has been completed. Although the preliminary results of the trial were encouraging, we were not able to make a clinical claim of efficacy based on the number of patients enrolled. Significant additional capital would be needed to advance Temferon. We have engaged DC Advisory to assist us in seeking a partner or strategic relationship in order to advance Temferon, but there can be no assurance that we will be successful in establishing a strategic partnership or collaboration. If we are not able to develop an alliance or strategic partnership or other collaboration or financing mechanism, we may not be able to further pursue clinical development, which would inhibit our ability to generate value from the Temferon asset. Such strategic partnership and collaboration arrangements are also complex and time-consuming to negotiate, document, and implement and they may require substantial resources to maintain. Any strategic partnerships or collaborations we enter into may not be successful and we may not realize the benefits from such arrangements.

We may not always be successful in our efforts to fund and design appropriate clinical trials for Temferon indications.

We began a Phase 1 clinical trial in metastatic renal cell carcinoma ("mRCC") patients (the "TEM-GU Study") in late 2024. To date, for reasons beyond our control, we have not been able to enroll sufficient patients in the trial. Following a strategic review in January 2026 and an evaluation of the impact of the delayed and, later, refused financing by the TEM-GU Study lead investor, we discontinued the GU development program, and no active clinical development activities are currently being conducted under the TEM-GU Study. Our ability to continue the clinical development of Temferon may depend on our ability to raise capital for the studies or develop a strategic partnership arrangement.

We may not be able to conduct clinical trials outside of Italy.

We have conducted all of our clinical trials in Italy. To commence a clinical trial in the United States, we would be required to obtain FDA acceptance of an investigational new drug application ("IND") for each product candidate. At present, we do not have active plans to initiate clinical trials outside of Italy. Regulatory authorities such as the FDA or EMA may require additional preclinical, manufacturing, or clinical data before allowing further development, and there can be no assurance that prior data generated in Italy would be deemed sufficient to support future regulatory submissions.

The development of gene therapy product candidates remains subject to substantial regulatory, clinical, and operational uncertainties. We have not previously submitted a biologics license application ("BLA") to the FDA or the equivalent application to the EMA. Any future development of Temferon, or other product candidates would require significant time, financial resources, and regulatory engagement, and there can be no assurance that such efforts would result in marketing approval. Failure to secure sufficient capital, regulatory alignment, or strategic partnerships could prevent or delay any future clinical development or commercialization of Temferon or other platform-based candidates.

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

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

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

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

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by AIFA, the FDA, EMA or other regulatory authorities;
- unforeseen safety issues or lack of effectiveness; and,
- lack of adequate funding to continue the clinical trial.

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

In addition, if we make changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions, this will increase the costs and could delay our clinical development plan, or marketing approval for our product candidates. Any modification of our product candidates will likely require updates to our clinical trial applications and INDs with the relevant regulatory authorities, which may result in delay, suspension, or termination of ongoing or future clinical trials pending our submission and the agencies' review of such updates. Clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

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

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

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

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

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

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

In addition, we may not be able to identify, recruit and enroll a sufficient number of patients due to the existence of efficacious alternative treatments, the size of the patient population and process for identifying subjects, the design of the trial protocol, the exclusion/inclusion criteria that we are currently targeting may limit the pool of patients that may be enrolled in our ongoing or planned clinical trials. Additional challenges include the proximity and availability of clinical trial sites for prospective subjects, and the patient referral practices of physicians, and the ability to obtain and maintain subject consent. Furthermore, there is a risk of high screening failure rates due to patient ineligibility and a significant number of withdrawals from consideration for the trial caused by the rapid deterioration of patients' clinical conditions, along with the risk that enrolled subjects will drop out before completion of the trial.

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

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

The results of clinical trials conducted at clinical sites outside the U.S. may not be sufficient to the FDA and the results of clinical trials conducted at clinical sites in the U.S. may not be sufficient to international regulatory authorities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have received orphan drug designation for Temferon for the treatment of GBM, and we may seek orphan drug designation for additional indications and for other product candidates. We may be unable to maintain orphan drug designation for our product candidates and, even if so, we may not be able to realize the benefits of such designation, including potential marketing exclusivity of our product candidates, if approved.

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

Temferon has been granted orphan drug designation in the U.S. and E.U. for the treatment of GBM. If we request orphan drug designation from the FDA for Temferon for additional indications, if we request the international equivalent from the applicable regulatory authorities for Temferon or if we request orphan drug designation or the international equivalent for any of our other product candidates, there can be no assurances that the FDA or international regulatory authorities will grant any of our product candidates such designation. This designation of a product candidate as an orphan product does not mean that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates prior to our product candidates receiving exclusive marketing approval.

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

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

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply enough orphan medicinal product.

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

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

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

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

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

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

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

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

- issue an untitled letter or warning letter that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the products or require the withdrawal of the product from the market;
- refuse to permit the import or export of the products; or
- refuse to allow us to enter supply contracts, including government contracts.

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

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

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

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

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

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

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

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

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

- the strength of sales, marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement and the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors;
- the strength of sales, marketing and distribution support;
- the willingness of patients to pay for drugs out of pocket in the absence of third-party coverage; and,
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidate, Temferon, is being studied for GBM patients with unmethylated methylguanine methyltransferase ("MGMT") status, as determined by a laboratory test. If approved for use only in uMGMT-GBM patients, use of such a laboratory test would be required for each patient before treatment with Temferon. There are several currently marketed, CE-marked tests for uMGMT status in the E.U., one or more of which may be used in our clinical trials and which we would expect to be used in clinical practice upon approval of Temferon. If a regulatory authority were, however, to deem that no currently-available tests are appropriate for use with Temferon, or if appropriate tests were to become commercially unavailable, we might be required to develop and obtain regulatory approval for our own version of such a companion diagnostic test, or work with another entity to develop such a test, in which case we could experience significant delays in obtaining regulatory approval or interruptions in our ability to market Temferon.

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

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

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

Before we can begin to commercially manufacture our viral vector or product candidates in our own facility, or the facility of a CMO, we must obtain regulatory approval from AIFA and eventually the FDA, EMA, or other regulatory authorities for our manufacturing processes and for the facility in which manufacturing is performed. A manufacturing authorization must also be obtained from the appropriate regulatory authorities. In addition, we must pass a pre-approval inspection of our or our CMOs manufacturing facility by AIFA, the FDA, EMA, or other relevant regulatory authorities before any of our gene therapy product candidates can obtain marketing approval. To obtain approval, we will need to ensure that all of our processes, quality systems, methods, equipment policies and procedures are compliant with GMP, and perform extensive audits of vendors, contract laboratories, CMOs and suppliers. If any of our vendors, contract laboratories, CMOs or suppliers is found to be out of compliance with GMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The GMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with GMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we will be subject to possible regulatory action and may not be permitted to sell any products that we may develop.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Any collaborations, licensing arrangements, joint ventures, strategic alliances, or partnerships that we may enter in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

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

Additionally, we may not be able to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, the ownership or control of intellectual property developed during the collaboration or the scope of our or our collaborators' other rights or obligations related to development or commercialization activities. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be averse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators or our future products. Disagreements between us and our collaborators can lead to delays in the development process or commercializing the applicable product candidate or product, may result in litigation or arbitration, which would increase our expenses and divert the attention of our management, and may result in termination or dissolution of the transaction or arrangement and, in such event, we may not continue to have rights to the product candidate or products relating to such transaction or arrangement or may need to purchase such rights at a premium. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

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

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

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

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

Risks Related to Intellectual Property

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

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

The ARLA imposes upon us various diligence, payment and other obligations, including the following:

- our obligation to pay OSR various milestone payments upon the achievement of certain milestone events, such as the initiation of different phases of clinical trials of a licensed product, MAA approval by a major market country, MAA approval in the U.S., the first commercial sale of a licensed product in the U.S. and certain E.U. countries, and achievement of certain net sales levels;
- our obligation to pay OSR royalties based on net sales of each licensed product;
- our obligation to pay OSR a royalty of our net sublicensing income for each licensed product; and
- our obligation to pay costs associated with the preparation, prosecution and maintenance of the licensed patent rights.

Although we own a patent application relating to methods of treating solid cancers with Temferon in combination with a checkpoint inhibitor and a patent application relating to methods of treating renal cell carcinoma with Temferon in combination with a checkpoint inhibitor (together, the "Genenta Applications"),we are heavily reliant upon the ARLA to licensed patents that are important or necessary to the development of our technology and product candidates, including the patents relating to Temferon. Our license is exclusive only to specific fields of use, namely: the field(s) of Interferon ("IFN") gene therapy by lentiviral based-HSPC gene transfer with respect to (a) any Solid Cancer Indication (as defined in the ARLA) (including GBM and solid liver cancer) and/or (b) any Lympho-Hematopoietic Indication (as defined in the ARLA) for which we have the right to exercise an option to be included as part of the field of use, as provided in the ARLA; and (2) certain specified gene therapy products developed during the license term for use in the aforementioned field(s). Although we have exclusive option rights to license additional fields of use, or indications, upon the payment of additional fees to OSR, there is no guarantee that we will be in a position to do so within the time period specified to exercise such right.

We do not control the preparation, prosecution, and maintenance of the licensed patent rights under the ARLA, or the enforcement of the licensed patent rights and know-how rights against infringement by third parties. Thus, the licensed patent rights were not drafted by our attorneys or us, and we do not control or have any input into the prosecution of these patent rights. We cannot be certain that drafting or prosecution of the licensed patent rights has been conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. OSR maintains control of the preparation, prosecution, and maintenance of the licensed patent rights, and controls enforcement of the licensed patent rights and know-how rights.

Pursuant to the ARLA, OSR may terminate the agreement in the event we breach certain of our obligations or fail to make certain payments and upon our liquidation. In addition, OSR may terminate our rights as to certain fields of use for our failure to achieve certain development milestones for specified licensed products within certain time periods. In addition, OSR may terminate the agreement in the event that commercialization of a licensed product is not started within 24 months from the grant of both (i) the MAA approval and (ii) the pricing approval of such licensed product, provided that such termination will relate solely to such licensed product and to such country or region to which both such MAA approval and pricing approval were granted. If the ARLA is terminated, we may not be able to develop, manufacture, market or sell the product candidates covered by the agreement and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under the ARLA.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, the patent applications we have filed and the patents and patent applications licensed to us may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that the U.S. patents involved are eligible for certain (and time-limited) patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO, and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to such patents, or may grant more limited extensions than requested. For example, depending upon the timing, duration, and specifics of any FDA marketing approval of any product candidates we may develop, one or more of the U.S. patents licensed to us may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five (5) years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable period or the scope of patent protection afforded could be less than requested. If we are unable to obtain patent term extension or term of any such extension is less than requested, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, under Italian law, in case of inventions developed by our employees, which were developed while performing their employment activities, but outside the performance of their contractual duties, the rights to the inventions belong to us but we are required to compensate the employees for the rights to their respective inventions. Regarding independent consultants, Italian law provides that, save for the case in which the inventive activity of the same has been set forth as the subject of the consulting agreement and compensated for this purpose, the rights to economically exploit the original contributions and inventions realized in the execution of the consulting agreement will belong to consultant.

To date, neither the employment agreements nor the consultancy agreements provide any specific compensation related to the inventive activity. Therefore, employees and independent consultants may ask for fair compensation due to such inventions and, regarding independent consultants, the failure to pay fair compensation could prevent us from obtaining rights to their inventions, and this could have a material adverse effect on our operations and ability to effectively compete.

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks Related to Our Business Operations

As a company currently with substantial operations outside of the U.S., our business is subject to global economic conditions, macro events, political, regulatory, pandemic, and other risks associated with international operations and macro-economic trends.

As a company with substantial operations in Italy, our business is subject to risks associated with conducting business outside the U.S. Many of our suppliers and clinical trial relationships are located outside the U.S. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity, and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, inflation, fluctuating interest rates, increased tariffs and uncertainty about economic stability. Fluctuating interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect investor confidence. Similarly, regional geopolitical conflicts and trade disputes have created extreme volatility in the global capital markets and are expected to have further global economic consequences, including disruptions of the global supply chain and energy markets.

Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate because of political unrest or war, it may make any debt or equity financing more costly or more dilutive or more difficult to obtain in a timely manner or on favorable terms, if at all. Accordingly, our future results could be harmed by a variety of factors, including:

- economic downturns, recessions, inflation, fluctuating interest rates, supply chain shortages, rising fuel prices, tariffs or political instability in particular non-U.S. economies and markets could negatively impact our budget projections, clinical trial cost estimates, and potential clinical timeline;
- instability in the domestic and international banking systems where the Company has accounts;
- differing and changing regulatory requirements for product approvals in the U.S. and Italy;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights that could impact our ability to develop and/or license our technology;
- difficulties in compliance with different, complex, and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations that could affect our need to hire subject matter experts or retain third-party experts;
- changes in non-U.S. regulations and customs, tariffs, and trade barriers;
- foreign exchange risks and currency controls due to maintaining our cash and cash equivalents both in U.S. dollars and Euros;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of options granted under our share incentive plans;

- workforce uncertainty in countries where labor unrest is more common than in the U.S.;

- litigation or administrative actions resulting from claims against us by current or former employees or by employees of third-party contractors or consultants, individually or as part of class actions, including: (i) claims of wrongful terminations and payment of the related damages, (ii) discrimination, (iii) misclassification, (iv) claims for salary differences or for a different classification according to national collective bargaining agreement, (v) claims for the payment of social security charges or severance benefits, (vi) claims from suppliers' employees or external consultants such as, by way of example, claims for reclassification as employees, rather than independent contractors, or, as indicated above, requests for payment of salary / social security charges, (vii) any sanctions due to the above-mentioned obligations, (viii) or other violations of labor law or other alleged conduct;

- difficulties associated with staffing and managing international operations, including differing labor relations;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods, and fires.

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

Our key people include our Chief Executive Officer, Pierluigi Paracchi, who co-founded our Company in 2014 along with Prof. Luigi Naldini, and Bernhard Gentner. Our other key people include Dr. Francesco Galimi, our acting Chief Medical Officer & Head of Development, Richard Slansky, our Chief Financial Officer, Barbara Regonini, our Finance Director, Stefania Mazzoleni, our Director of Clinical Development, Marco Casucci, our Director of Regulatory Affairs, and Gianfranco De Nigris, our Vice President of Business Development. Our future growth and success depend on our ability to recruit, retain, manage, and motivate our employees and key consultants. The loss of the services of our Chief Executive Officer or any of our key personnel or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Although we expect to enter into employment agreements with management, these agreements will likely be terminable at will with notice.

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

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

We currently rely on a single third-party manufacturing facility for the production of our lentiviral vectors, and our historical operations have been dependent on the availability of such capacity. However, this arrangement is subject to ongoing litigation and strategic reassessment.

In particular, our manufacturing relationship is governed by contractual arrangements that provide for capacity reservation and fixed payments, which may be due irrespective of actual production volumes. There are litigations to acknowledge if the contract is valid and binding, but at the moment, any reduction, delay or suspension in our clinical development activities may expose us to high costs for unused manufacturing capacity.

The outcome of the above-mentioned dispute is uncertain and may result in material financial liabilities, diversion of management attention, and increased legal costs.

More broadly, disruptions to our manufacturing strategy - whether due to operational issues, contractual disputes, or strategic changes in our business focus - could delay or impair our ability to advance our clinical programs, or may require us to identify alternative manufacturing solutions, which could be time-consuming and costly.

Furthermore, any transition to alternative manufacturing arrangements would require significant time, capital investment and regulatory approvals, and may not be achievable on acceptable terms or within required timelines.

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

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

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

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

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a U.S. federal healthcare program, such as the Medicare and Medicaid programs;

- U.S. federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

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

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

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

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

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

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

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

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

On July 4, 2025, President Trump signed into law the One Big Beautiful Bill Act ("OBBBA"), which, among other things, contains a number of provisions designed to reduce the number of Americans insured under Medicaid and health exchange plans established under the PPACA. In addition, the OBBBA makes changes to the PPACA insurance marketplaces, including, among other measures, greater limitations on enrollment periods, which will result in an additional Americans being uninsured. These significant decreases in the numbers of insured Americans will reduce the ability of patients, especially those of modest means, to afford medications, which could reduce the demand for our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may become involved in litigation that may materially adversely affect us.

From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including intellectual property, commercial, product liability, employment, class action, whistleblower and other litigation and claims, and governmental and other regulatory investigations and proceedings.

For instance, in September 2025, the Company filed a civil action before the Court of Milan against AGC Biologics S.p.A., seeking a declaratory judgment of nullity and/or termination, with retroactive effect, of the Master Service Agreement and related amendments. In addition, on January 27, 2026, the Company initiated legal proceedings before the Court of Milan against Fondazione Enea Tech e Biomedical, with which the Company entered into a €20 million convertible bond loan agreement in March 2025. The proceedings seek, among other things, a declaration that the convertible bond loan agreement is null and void and the recovery of damages. Legal proceedings can be time-consuming, divert management's attention and resources from the operation of our business, and cause us to incur significant expenses or liability or require us to change our business practices. Because of the potential risks, expenses, and uncertainties of litigation, from time to time, we may settle disputes, even where we believe that we have meritorious claims or defenses. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business. Adverse outcomes in such proceedings or claims could result in significant liabilities, monetary damages, fines, or injunctive relief, which may materially impact our financial condition, results of operations, or cash flows. Additionally, the uncertainty surrounding litigation and the potential for adverse publicity related to such matters could harm our reputation, affecting customer confidence and investor perception.

We may engage in strategic acquisitions or transactions, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

In response to evolving market dynamics and strategic considerations, we are pursuing a strategic transformation to expand our business beyond its current clinical-stage biotechnology focus on Temferon, while continuing to operate as a biotechnology company. As part of this transformation, we intend to focus on acquiring and integrating majority-owned operating companies in national-security-regulated sectors subject to the Italian "Golden Power" legislation, however, our ability to do so successfully cannot be ensured.

For instance, on January 24, 2026, we entered into an Investment Agreement with A.T.C. S.r.l. ("A.T.C."), a private Italian manufacturer of high-precision tactical rifles, special-forces weapon systems, and competition-grade sporting firearms. Pursuant to the Investment Agreement, we acquired an initial 19.5% equity ownership in A.T.C. for €1.275 million, with the opportunity to acquire up to 51% equity ownership over multiple closings for a total of €5.1 million, subject to A.T.C. meeting certain turnover and "EBITDA" performance milestones and maintaining the licenses required under Italian law to conduct its business activity. "EBITDA" is defined as net loss adjusted to exclude interest income, income tax expense, and depreciation and amortization.

Our acquisitions and strategic investments will involve securities of privately held companies. Investments in private companies are inherently riskier than investments in public companies because less information is available, operating and financial results may be more volatile, and these counterparties may require additional capital to fund operations or growth. Adverse developments at any such company could require us to record losses or impairments or could otherwise reduce or eliminate the value of our investment.

There will be no established, liquid trading market for the privately issued securities we acquire, and any private secondary markets for such securities are limited, irregular, and subject to legal and contractual transfer restrictions. As a result, we may be unable to sell all or part of a position when desired or at attractive prices, and the value we ultimately realize may be significantly below the amount at which we carry the investment. Because these securities lack quoted market prices, our valuations necessarily involve judgment and are based on limited, unobservable inputs and information that may change over time. Realizing value is typically dependent on uncertain liquidity events, such as a sale of the company, which may take longer than expected or may never occur. In addition, certain of the securities we receive in connection with acquisitions or strategic investments, such as preferred stock, warrants, or convertible instruments, may be subordinated to senior classes of capital or otherwise subject to complex rights and preferences, which can further impair recoveries in a downside scenario and increase the risk that we are unable to monetize our position on acceptable terms.

Acquisitions involve a number of risks, including diversion of management's attention, ability to finance the acquisition on attractive terms, failure to retain key personnel or valuable customers, legal liabilities, the need to amortize acquired intangible assets, and intellectual property ownership and infringement risks, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows. Any additional future acquisitions may also result in the incurrence of indebtedness or the issuance of additional equity securities.

We could also experience financial or other setbacks if transactions encounter unanticipated problems, including problems related to governmental approval, execution, integration or underperformance relative to prior expectations. Acquisitions may not result in long-term benefits to us, and we cannot guarantee that we will be able to fully recover the costs of such acquisitions or that we will be successful in further developing the acquired business in the manner we anticipated. We may encounter difficult or unforeseen expenditures in integrating an acquisition, particularly if we cannot retain the key personnel of the acquired company. In addition, if we fail to successfully integrate such acquisitions, or the assets, technologies, or personnel associated with such acquisitions, into our company, the business and results of operations of the combined company would be adversely affected.

We may also experience unanticipated difficulties identifying suitable or attractive acquisition candidates that are available for purchase at reasonable prices and that meet our objectives. The identification of suitable acquisition candidates can be difficult, time-consuming, and costly, and we may not consummate acquisitions successfully that we target in the future. Even if we are able to identify such candidates, we may be unable to consummate an acquisition on suitable terms or in the face of competition from other bidders. We also cannot predict the number, timing, or size of any future acquisitions or the effect that any such transactions might have on our operating results.

Risks Related to Ownership of Our Securities

We cannot guarantee that we will be able to satisfy the continued listing standards of Nasdaq going forward.

Our American Depository Shares ("ADS") are listed on the Nasdaq. However, we cannot ensure that we will be able to satisfy the continued listing standards of the Nasdaq going forward. If we cannot satisfy the continued listing standards going forward, the Nasdaq Stock Market may commence delisting procedures against us, which could result in our ADS being removed from listing on the Nasdaq, or requiring us to take other action to remain listed, e.g., obtaining shareholder approval for a reverse stock split, etc. If any of our ADSs were to be delisted, the liquidity of our ADSs could be adversely affected and the market price of our ADSs could decrease. Delisting could also adversely affect the ability of the holder of our ADSs to trade or obtain quotations on our ADSs because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our ADSs. Investors may also not be able to resell their ADSs at or above the price they paid for such securities or at all.

The trading price of the ADSs is likely to be highly volatile.

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

- adverse results or delays in pre- and non-clinical studies or clinical trials;
- reports of adverse events in other gene therapy products or clinical studies of such products;
- inability to obtain additional funding;
- inability to obtain the approvals necessary to commence clinical trials;
- unsatisfactory results of clinical trials;
- announcements of regulatory approval or the failure to obtain it, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by our competitors or us;
- adverse actions taken by regulatory authorities with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to the treatment of cancer tumors, or any other indication that we may seek to develop;
- any adverse changes to our relationship with manufacturers or suppliers;

- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the biotechnology and pharmaceutical industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of, or involvement in, litigation;
- any major changes in our board of directors or management;
- our ability to recruit and retain qualified regulatory, research, and development personnel;
- legislation in the U.S. relating to the sale or pricing of biotechnology or gene therapy products;
- the depth of the trading market in the ADSs;
- economic downturns, recessions, inflation, fluctuating interest rates, supply chain shortages, rising fuel prices, tariffs or political instability in global, U.S., or particular foreign economies and markets;
- instability in the global or U.S. banking systems or the banking systems of foreign countries;
- business interruptions resulting from a local or worldwide pandemic, geopolitical actions, including war and terrorism, or natural disasters;
- the granting or exercise of employee stock options or other equity awards;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or shareholder litigation;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- our inability to negotiate favorable terms of any "Golden Rule" legislation acquisitions; and/or,
- any adverse developments in our ability to close any national-security regulated sector transactions.

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

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

The Bank of New York (formerly the Bank of New York Mellon), the depositary for the ADSs (the "Depositary"), has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses and subject to the terms of the deposit agreement. You will receive these distributions in proportion to the number of ordinary shares the ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, the Depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended (the "Securities Act"), but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend made in respect of deposited ordinary shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the Depositary may determine not to distribute such property and hold it as "deposited securities" or may distribute the net cash proceeds from the sale of the dividends. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights, or anything else to holders of ADSs. In addition, the Depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the Depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

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

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

Further, as described in more detail below, our loyalty share program is available only to holders who own their ordinary shares in registered form, and is not available to ADS holders. See "Risks Related to Italian Law and Our Operations in Italy—Our loyalty share program could have a negative effect on the liquidity of our ADSs and may make it more difficult for investors to acquire a controlling interest, change the management or the strategy of our company or exercise influence over us, which may adversely affect the market price of the ADSs. Further, our loyalty share program is available only to holders who own their ordinary shares in registered form, and the ability of ADS holders to influence corporate decisions may therefore be limited."

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

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

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

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

Our Chief Executive Officer, directors, and shareholders who own more than 5% of our outstanding ordinary shares currently own approximately 25% of our ordinary shares and have an approximately 58% voting interest through our loyalty share program. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

Our Chief Executive Officer and directors, and shareholders who own more than 5% of our outstanding ordinary shares beneficially own approximately 25% of our ordinary shares and have an approximately 58% voting interest through our loyalty share program. This significant concentration of share ownership and voting power may adversely affect the trading price for the ADSs because investors often perceive disadvantages in owning securities in companies with controlling shareholders. As a result, these shareholders, if they acted together, could significantly influence, or even unilaterally approve matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders. Also, the concentration of our beneficial ownership may have the effect of delaying, deterring, or preventing a change in our control, or may discourage bids for our shares at a premium over the market price of the shares. The significant concentration of share ownership may adversely affect the trading price of our ADSs due to investors' perception that conflicts of interest may exist or arise.

There is a substantial risk that we are or will become classified as a passive foreign investment company. If we are or become classified as a passive foreign investment company, our U.S. shareholders may suffer adverse tax consequences as a result.

In general, we will be treated as a passive foreign investment company (a "PFIC") for U.S. federal income tax purposes in any taxable year in which either:

(1) at least 75% of our gross income is "passive income," or (2) on average, at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents, and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes interest income earned by reason of the temporary investment of funds, including those raised in a public offering, and the excess of certain foreign currency gains over certain foregoing currency losses.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition, and value of our assets. Our status may also depend, in part, on how quickly we utilize cash proceeds received from previous offerings of our ADSs or ordinary shares in our business. Based on preliminary analysis, we believe that we were likely classified as a PFIC in 2025, and we may be classified as a PFIC for 2026 and future years.

If we are a PFIC in any taxable year during which a U.S. taxpayer holds the ADSs, such U.S. taxpayer would be subject to certain adverse U.S. federal income tax rules. In particular, if the U.S. taxpayer did not make an election to treat us as a "qualified electing fund" ("QEF") or make a "mark-to- market" election, then "excess distributions" to the U.S. taxpayer, and any gain realized on the sale or other disposition of the ADSs by the U.S. taxpayer: (1) would be allocated ratably over the U.S. taxpayer's holding period for the ADSs; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, U.S. taxpayers who have held the ADSs during a period when we were a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. taxpayers who made a timely QEF or mark-to-market election. Currently, we do not expect to provide U.S. shareholders with the information necessary for a U.S. shareholder to make a QEF election. Prospective investors should assume that a QEF election will not be available. U.S. taxpayers who hold the ADSs are strongly urged to consult their tax advisors about the PFIC rules, including tax return filing requirements and the eligibility, manner, and consequences to them of making a QEF or mark-to-market election with respect to the ADSs in the event that we are a PFIC. See "Item 10. Additional Information—E. Taxation—U.S. Federal Income Tax Consequences—Passive Foreign Investment Companies" for additional information.

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

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

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

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

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

As a U.S. public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Nasdaq listing requirements and other applicable securities rules and regulations. The Exchange Act requires that we file periodic reports with respect to our business and financial condition and maintain effective disclosure controls and procedures and internal control over financial reporting. In addition, subsequent rules implemented by the SEC and the Nasdaq Stock Market may also impose various additional requirements on public companies. As a result, we have incurred and will continue to incur legal, accounting, and other expenses that we did not incur as a nonpublic company, particularly after we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act ("JOBS Act"). Further, the need to establish the corporate infrastructure demanded of a public company may divert management's attention from implementing our development plans. We have made changes to our corporate governance standards, disclosure controls and financial reporting and accounting systems to meet our reporting obligations. The measures we take, however, may not be sufficient to satisfy our obligations as a public company, which could subject us to delisting of our securities, fines, sanctions, and other regulatory action and potentially civil litigation.

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

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

- the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;

- Section 107 of the JOBS Act, which provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This means that an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay the adoption of new or revised accounting standards. As a result of this election, our consolidated financial statements may not be comparable to companies that comply with the public company effective date; and

- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We intend to take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the date of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, as defined in the rule under the Exchange Act, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

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

As a foreign private issuer, the Company is permitted to follow certain corporate governance practices of its home country, Italy, in lieu of certain requirements of the Nasdaq Stock Market pursuant to Nasdaq Rule 5615(a)(3).

The corporate governance rules of the Nasdaq Stock Market generally require listed companies to have, among other things, a board of directors composed of a majority of independent directors (Nasdaq Rule 5605(b)(1)) and a compensation committee composed entirely of independent directors (Nasdaq Rule 5605(d)).

Italian corporate law does not require companies such as ours to have a board of directors composed of a majority of independent directors, nor does it require the establishment of a compensation committee composed exclusively of independent directors. Instead, under Italian law, oversight of directors' remuneration and related matters is exercised by the board of directors, with additional oversight provided by the statutory board of auditors (collegio sindacale), the members of which are subject to mandatory independence requirements.

In reliance on our status as a foreign private issuer, we are not required to meet, and we do not follow, Nasdaq Rules 5605(b)(1) and 5605(d), and instead follow Italian corporate governance practices.

As a result of these governance practices, our board of directors' approach to governance and oversight may differ from that of a board composed of a majority of independent directors and committees comprised solely of independent directors. Consequently, the oversight of our management and business may be more limited than it would be if we were subject to all of the Nasdaq Stock Market's corporate governance standards, and the ability of our independent directors to influence our business policies and affairs may be reduced.

Decisions regarding executive compensation are made by our board of directors, with oversight by the statutory board of auditors, in accordance with Italian law. For more information, see "Item 6. Directors, Senior Management and Employees - C. Board Practices - Differences between Italian Laws and Nasdaq Requirements."

The Company believes that its governance structure, including the presence of a Board of Statutory Auditors with statutory independence requirements under Italian law, provides appropriate oversight and protection for shareholders.

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

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

Risks Related to Italian Law and Our Operations in Italy

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

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

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

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

The ability of shareholders to bring actions or enforce judgments against us or our directors and executive officers may be limited. Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of Italy and our registered office and domicile is in Milan, Italy. Moreover, a majority of our directors and executive officers are not residents of the U.S., and all or a substantial portion of our assets are located outside the U.S. As a result, it may not be possible for investors to effect service of process within the U.S. upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the U.S.

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

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

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

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

Under Italian law, we may issue debt securities in an amount not to exceed twice the sum of our capital, our legal reserve and any other disposable reserves appearing on our latest Italian GAAP balance sheet approved by our shareholders, unless the debt securities are listed on regulated markets or provide the holder of such securities the right to purchase or convert the same into our shares, in which case such restrictions do not apply. The legal reserve is a reserve to which we allocate 5% of our Italian GAAP net income each year until it equals at least 20% of our capital. One of the other reserves that we maintain on our balance sheet is a "share premium reserve," meaning amounts paid for our ordinary shares in excess of the amount of such ordinary shares that is allocated to the capital. At December 31, 2025, the sum of our capital, legal reserves and other reserves on our unaudited Italian GAAP financial statements was approximately €31.6 million before the Italian GAAP net loss of approximately €9.0 million for the period. If, in the future, we issue debt securities that are not listed on regulated markets or do not provide the holder of the securities the right to purchase or convert the same into our shares, until such debt securities are repaid in full, we may not voluntarily reduce our capital or allocate our reserves (such as by declaring dividends) if it results in the aggregate of the capital and reserves being less than half of the outstanding amount of the debt. In such a case, if our equity is reduced by losses or otherwise such that the amount of the outstanding debt securities is more than twice the amount of our equity, some legal scholars believe that the ratio must be restored through a recapitalization of our company. If our equity is reduced, we could recapitalize by issuing new shares or having our shareholders contribute additional capital to us, although there can be no assurance that we would be able to find purchasers of new shares or that any of our current shareholders would be willing to contribute additional capital.

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

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

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

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

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

Purchasers of our ordinary shares and ADSs may be exposed to increased transaction costs because of the Italian financial transaction tax or the proposed European financial transaction tax.

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

The Italian financial transaction tax (the "IFTT") applies with respect to trades entailing the transfer of (i) shares or equity-like financial instruments issued by companies resident in Italy, such as the ordinary shares; and (ii) securities representing the shares and financial instruments under (i) above (including depositary receipts such as the ADSs), regardless of the residence of the issuer. The IFTT may also apply to the transfer of ordinary shares and ADSs by a U.S. resident. The IFTT does not apply to companies having an average market capitalization lower than €500 million in the month of November of the year preceding the year in which the trade takes place. In order to benefit from this exemption, companies whose securities are listed on a foreign regulated market, such as the Company, need to be included on a list published annually by the Italian Ministry of Economy and Finance. The Company is in the process with the relevant procedures to be included in such list. For so long as the Company is not included in such list, investors in the ordinary shares and ADSs may be exposed to increased transaction costs. See "Item 10. Additional Information—E. Taxation."

It may be difficult for investors outside of Italy to enforce civil liabilities against us.

We are incorporated under the laws of Italy and our registered office and domicile is in Milan, Italy. A majority of our directors and executive officers are not residents of the U.S., and all or a substantial portion of our assets are located outside the U.S. As a result, it may not be possible for investors to effect service of process within the U.S. upon us or upon such persons.

Judgments of U.S. courts may not be directly enforceable outside of the U.S. and the enforcement of judgments of U.S. courts outside of the U.S. may be subject to limitations. Investors may also have difficulties pursuing an original action brought in a court in a jurisdiction outside the U.S. for liabilities under the securities laws of the U.S.

Our loyalty share program could have a negative effect on the liquidity of our ADSs and may make it more difficult for investors to acquire a controlling interest, change the management or the strategy of our Company or exercise influence over us, which may adversely affect the market price of the ADSs. Further, our loyalty share program is available only to holders who own their ordinary shares in registered form, and the ability of ADS holders to influence corporate decisions may therefore be limited.

At our shareholders' meeting held on May 2, 2024, our shareholders approved a loyalty share program through an amendment to our bylaws. The loyalty share program gives shareholders the opportunity to request to be included on a special list maintained by us and thereby receive increased votes for each ordinary share held in registered form after certain continuous periods of ownership of such ordinary shares. For more information regarding our loyalty share program, see "Item 10. Additional Information. B. Memorandum and Articles of Association."

Under our loyalty share program, shareholders who hold a significant quantity of ordinary shares in registered form for the continuous periods prescribed in our bylaws and who request and are included on the special list could be in a position to exercise a significant percentage of votes at meetings of shareholders and have substantial influence over our Company. A qualifying shareholder is entitled to a double vote (i.e., two votes for each ordinary share) for each ordinary share in registered form held by the same shareholder for a continuous period of not less than 24 months. An additional vote is also granted for each additional continuous 12-month period the same shareholder holds such ordinary share, for up to a total of ten votes per ordinary share. Continuous ownership prior to the registration date in the special list is taken into account. Furthermore, only shareholders who own their shares in registered form are entitled to take advantage of the loyalty share program and ADS holders are not entitled to additional voting rights. As a result, a relatively large proportion of our voting power may be concentrated in a relatively small number of registered shareholders who may have significant influence over us, and the ability of ADS holders to influence corporate decisions may therefore be limited. As a result, the loyalty share program may discourage change of control transactions that otherwise could involve payment of a premium over prevailing market prices for our ADSs or otherwise adversely impact the liquidity and market price of the ADSs.

Risks Related to the Mandatory Convertible Bond

Upon an event of default, we may not be able to make any redemption payments under the Mandatory Convertible Bond.

On March 12, 2025, the Company and Enea, a private law foundation subject to the supervision of the Ministry of Enterprises and Made in Italy, entered into a Subscription Agreement (the "Subscription Agreement") providing for the subscription of a mandatory convertible bond loan denominated "MANDATORY CONVERTIBLE LOAN GENENTA 2025-2028" (the "Mandatory Convertible Bond") by Enea, with an aggregate nominal value of up to €20 million and consisting of up to a total of 2,000 bonds (the "Convertible Bonds"), each with a nominal value of €10,000 (the "Nominal Value"), to be issued in two tranches by the Company at an issue price per unit equal to €10,000 for 100% of the Nominal Value. Upon the occurrence of certain events of default, Enea may demand the early redemption of the Convertible Bonds for a cash amount equal to 100% of the total amount thereof. We may not have sufficient assets to repay Enea and a default would also likely significantly diminish the market price of our ADSs.

Conversion of the Convertible Bonds may dilute the ownership interest of existing shareholders or may otherwise depress the price of our ADSs.

The Convertible Bonds will automatically convert into ordinary shares of the Company (the "Conversion Shares") on the earlier of (i) the occurrence of either (x) a Change of Control, which is defined as an acquisition by a person or group of persons not currently controlling the Company of more than 50% of the Company's issued share capital with voting rights or a takeover bid and/or exchange offer launched on all of the Company's outstanding ordinary shares and American depositary shares ("ADSs") or (y) the completion of an Investment Round, which is defined as any further investment transactions in the Company's share capital through the issuance of shares, convertible bonds, warrants or similar instruments for a total aggregate amount of €50,000,000 (the "Early Conversion Date" and, together with the Maturity Date, each a "Conversion Date") and (ii) three years after the First Tranche Issue Date (the "Maturity Date"). The conversion of the Convertible Bonds into Conversion Shares will dilute the ownership interests of existing shareholders to the extent we deliver shares upon conversion of the Convertible Bonds. Any sales in the public market of the Conversion Shares could adversely affect prevailing market prices of our ADSs. In addition, the existence of the Convertible Bonds may encourage short selling by market participants because the conversion of the Convertible Bonds could be used to satisfy short positions, or the anticipated conversion of the Convertible Bonds into Conversion Shares could depress the price of our ADSs.

In addition, the Convertible Bonds consist of two tranches: an initial tranche in the amount of €7,500,000 (the "First Tranche") issued on March 19, 2025 (the "First Tranche Issue Date") and a subsequent tranche in the amount of €12,500,000 (the "Second Tranche") to be issued by September 19, 2026 (the "Second Tranche Issue Date" and, together with the First Tranche Issue Date, each an "Issue Date"). The issuance of the Second Tranche on the Second Tranche Issue Date is subject to a number of conditions precedent, including but not limited to the completion of investment transactions in the Company's share capital through the issuance of shares, convertible bonds, warrants or similar instruments for a total aggregate amount of €32,500,000. If such investment transactions occur, and if the additional conditions precedent to the issuance of the Second Tranche are met, such investment transactions and the conversion of the Second Tranche into Conversion Shares may further dilute the ownership interest of existing shareholders or otherwise depress the price of our ADSs.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Corporate History and Operating Segment Evolution

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

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

Our leadership team has a proven track record as biotech executives. Their expertise spans from finance and venture capital to medical affairs, from scientific research to clinical drug product development and clinical trial management. For example, members of our management team have been involved in the successful development of Ethical Oncology Science, which was acquired in 2013 for over $400 million. Our management team members have played important roles both large pharma companies such Amgen, GNF/Novartis and biotech startups, such as Adicet Bio, Onyx Pharmaceuticals, Biological Dynamics, GenMark Diagnostics (now part of Roche) and C-N Biosciences (now part of Merck). We believe this multi-disciplinary competence provides a unique blend for the development of innovative gene and cell therapy products and constitutes a fertile ground for alliances with industrial partners that could help us bring new therapies to patients.

Strategic Transformation and Expansion into Defense, Aerospace, and National Security Sectors

In response to evolving market dynamics and strategic considerations, we announced on January 27, 2026, our intention to pursue a strategic transformation to expand our business beyond its current clinical-stage biotechnology focus on Temferon, while continuing to operate as a biotechnology company. As part of this transformation, we intend to broaden our operating activities by acting as a biotechnology, defense, aerospace, and national security industrial consolidator. Our strategy is focused on acquiring and integrating majority-owned operating companies in national-security-regulated sectors subject to the Italian "Golden Power" legislation.

We expect to target businesses with established operating profitability, generally generating up to approximately €5 million in EBITDA. Our strategy contemplates acquiring controlling ownership interests in such businesses at private-market valuations and integrating them within the Company's corporate structure, with the objective of enhancing operational efficiency, governance, and financial transparency.

Change to Corporate Name and Nasdaq Ticker Symbol

In connection with the extension of our corporate purpose, we announced on January 27, 2026, our intention to adopt the new corporate name, "Saentra Forge S.p.A." and a new Nasdaq ticker symbol, "SAEN." The adoption of the new corporate name and ticker symbol was originally anticipated to be approved by our shareholders at an Extraordinary Shareholders' Meeting scheduled to be held on March 25, 2026 (first call), and, if necessary, on March 26, 2026 (second call).

On March 23, 2026, we issued a notice of revocation announcing that our Board of Directors had resolved to revoke the call of the Extraordinary Shareholders' Meeting. Following further evaluation, we concluded that our current corporate name, "Genenta," continues to maintain significant recognition and association with our business. Accordingly, we decided to retain our current corporate name at this time. We may reconsider a corporate name change in the future.

Registered Office

Our registered office changed on January 27, 2026, and it is currently in Via dell'Annunciata 31, 20121 Milan, Italy, and our telephone number is +39.02.29.00.10.55.

B. Business Overview

Overview

We are embarking on a strategic transformation to evolve into a next-generation strategic industrial consolidator focused on acquiring privately held businesses operating in national-security regulated sectors contemplated by the "Golden Power" legislation; however, we are currently a clinical-stage biotechnology company engaged in the development of hematopoietic stem cell gene therapies for the treatment of solid tumors. We have developed a novel biologic platform that involves the *ex-vivo* gene transfer of a therapeutic candidate into autologous hematopoietic stem/progenitor cells ("HSPCs") to deliver immunomodulatory molecules directly to the tumor by infiltrating monocytes/macrophages (Tie2 Expressing Monocytes or "TEMs"). Our technology is designed to turn TEMs, which normally have an affinity for and travel to tumors, into a "Trojan Horse" to counteract cancer progression and prevent tumor relapse. Because our technology is not target-dependent, we believe it can be used for treatment across a broad variety of cancers.

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

- *Trojan Horse Mechanism of Action ("MoA"):* We use and modify TEMs, a subpopulation of tumor-associated myeloid cells, known to be involved in tumor growth and in the inhibition of immune system response, to allow the immune system to recognize the tumor and to deliver to the cancer site a chosen therapeutic.

- *Select Regulation of Transgene Expression:* Our selected control of the chosen therapeutic gene expression is designed to avoid off-target and systemic toxicity.

- *Potential Long-Term Effect:* Through the use of hematopoietic stem cells, our therapeutic candidate is designed as a "*living therapy*" intended to break the cancer-induced immune tolerance and to establish a competent immune surveillance throughout the life of the patient.

- *Agnostic Response*: In contrast to antigen-restricted CAR-T cells, our platform is not restricted to a pre-selected tumor antigen, nor any one tumor type. As such, it may be applied to a broad range of solid tumors and cancer subtypes, which would overcome one of the central unresolved challenges of immune-oncology cancer therapies.

Our lead product candidate, Temferon, was developed using our proprietary platform and carries the interferon-alpha ("IFN-α") payload. IFN-α is a well-known therapeutic that was previously administered intravenously for treatment of various cancers, but it is currently rarely used because of its systemic toxicity. The Temferon-modified TEMs express the transgene payload, IFN-α, in the tumor microenvironment, thereby reprogramming the Tumor Micro Environment ("TME"), which disrupts tumor induced immune-tolerance in blocks. Consequently, the immune system has been observed to recognize the tumor, respond, and inhibit tumor growth. Because Temferon is designed to deliver the IFN-α payload directly into the tumor, we believe it will demonstrate clinical activity without the side effect profile of systemic delivery of IFN-α. In preclinical mouse cancer models treated with Temferon, both direct (anti-angiogenic, pro-apoptotic) and indirect (immune response) effects were observed.

We are currently developing Temferon for the treatment of glioblastoma multiforme ("GBM") in patients who have an unmethylated MGMT gene promoter ("uMGMT-GBM"). GBM is the most common malignant primary brain tumor, accounting for more than half of all central nervous system cancers. Patients suffering from GBM have limited, non-curative treatment options. Although these treatments may improve survival, the prognosis for GBM patients remains poor, with a median overall survival ("mOS") of approximately 13 to 15 months and only 5.5% of patients estimated to be alive five (5) years after diagnosis. With no curative treatments available and such poor prognosis for patients, there remains a large, unmet medical need. We chose uMGMT-GBM among our first targets for clinical development after considering the medical need, the active role that TEMs have in GBM pathology, and the high number of newly diagnosed uMGMT-GBM patients potentially interested in participating in our study. As a result, we believe uMGMT-GBM offers a good profile for our initial proof of concept trial in humans. The preliminary results in uMGMT-GBM patients indicate that Temferon has been generally well tolerated, with no dose limiting toxicities observed to date.

A Phase 1 study of Temferon in metastatic Renal Cell Carcinoma ("mRCC") had been initiated to evaluate the safety and preliminary biological activity of the product candidate in this indication. However, following the strategic review completed in January 2026, we discontinued the GU development program and we are no longer pursuing active clinical development in mRCC. mRCC is the most common form of kidney cancer, accounting for approximately 74,000 new cases annually in the U.S. Despite treatment with curative intent, approximately one-third of patients experience metastatic disease recurrence, and approximately 30% of patients present with metastatic disease at diagnosis. Metastatic RCC remains a highly lethal condition, with a five-year overall survival rate of approximately 14%.

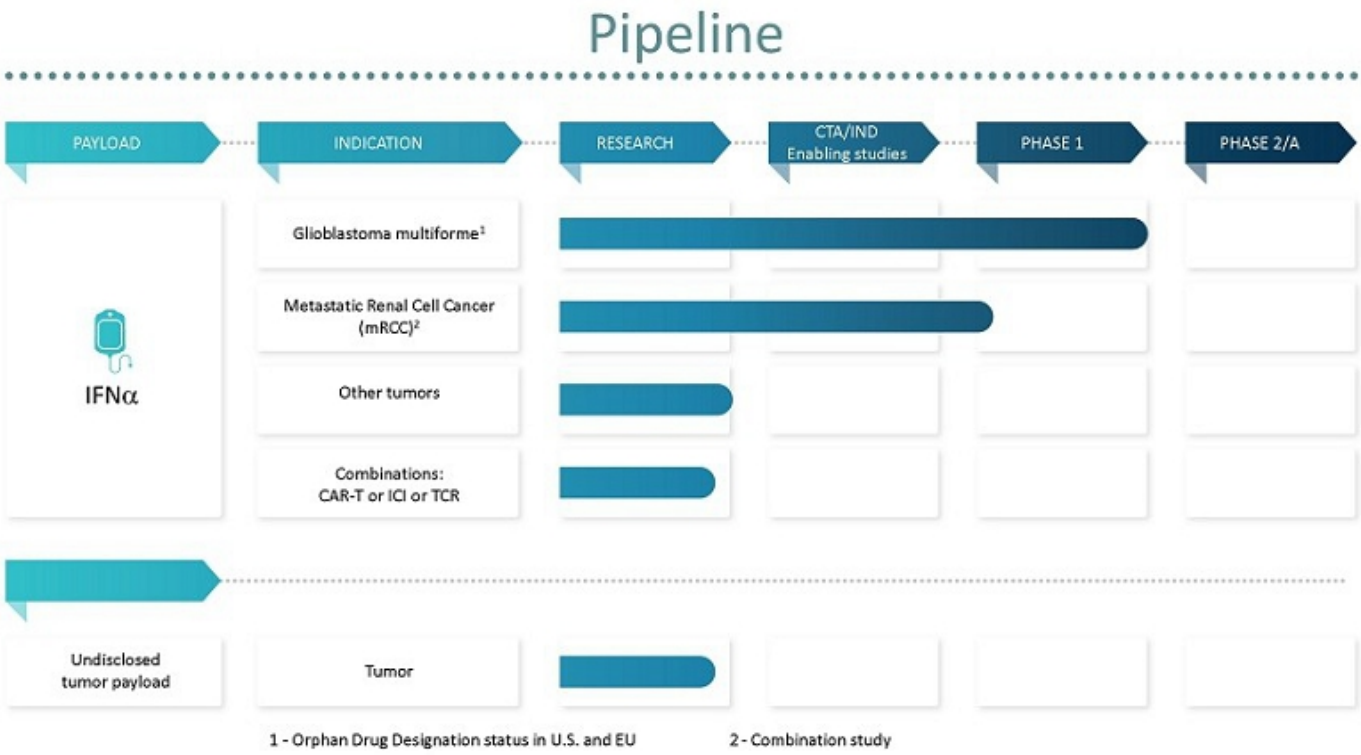
In addition to the prior Temferon clinical programs in uMGMT-GBM and mRCC, the Company holds exclusive option rights to license: (i) Temferon for additional indications; and, (ii) other drug candidates currently at the preclinical stage of development, whether as standalone treatments or in combination therapies. In light of the strategic transformation initiated in January 2026, the Company is not currently allocating resources to expand such development programs, and any future advancement would be subject to strategic and capital allocation review.

Research and Development Pipeline

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

To date, certain of these rights have not been exercised and, unless and until exercised in accordance with the agreement, the related intellectual property is not included within our licensed technology. See "—Intellectual Property Rights—Collaboration/Licensing" for a description of our license agreements with OSR.

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



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

Strategy

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

Advance the development of our leading clinical-stage product candidate, Temferon

We previously conducted a Phase 1/2a clinical trial in Italy to evaluate the safety and tolerability of Temferon.
The Phase 1 portion of the TEM-GBM Phase 1/2a study, which administered escalating doses of Temferon to glioblastoma patients with an unmethylated MGMT promoter following radiotherapy, has been completed. Preliminary observations from the dose-escalation phase indicated that Temferon was generally well tolerated. Exploratory analyses suggested potential biological activity, including modulation of the tumor microenvironment and survival outcomes that warrant further investigation. However, such findings were derived from a limited patient population and are not sufficient to establish clinical efficacy. We are not currently advancing to a Phase 2 study in GBM and no additional enrollment activities are ongoing.

The Phase 1 study in metastatic renal cell carcinoma ("TEM-GU study") was initiated to explore the safety and potential biological activity of Temferon in a second solid tumor indication. At the end of January 2026, we discontinued the GU development program as part of our broader strategic transformation, and no further clinical development activities are being pursued under this protocol.

Any future clinical development of Temferon would require additional capital, regulatory engagement, and strategic reassessment.

Extend our product pipeline across multiple indications

If we are successful in our efforts to seek a strategic partner with the assistance of DC Advisory, we intend to expand our product pipeline by:

- *Identifying additional indications suitable for Temferon.* We have selected Refractory Advanced Genitourinary Malignancies, including metastatic Renal Cell Carcinoma ("mRCC"), as the second solid tumor indication for Temferon. We believe that results from ongoing clinical studies in GBM and mRCC will inform and guide future therapeutic strategies in these and other indications.

- *Using our platform with different transgene payloads*. Our platform technology is designed to enable us to use different transgene payloads to potentially achieve therapeutic outcomes in selected cancer indications.

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

- *Exploring combination therapies*. We will seek to enter into collaborations with other companies to explore combination studies of our therapeutics with other cancer therapies, such as ICI, CAR-T cell therapies and TCR therapies. We believe our product, through its MoA, has the potential to enhance the durability and efficacy of the existing therapies, including restoring responsiveness in cases where these treatments were previously administered but lost effectiveness over time, thereby overcoming immune tolerance to the tumor and extend the durability of the response.

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

Develop and maintain efficient manufacturing processes to support anticipated growth

To meet our drug product supply needs for conducting larger trials, we intend to optimize our manufacturing processes for both lentiviral vector (LVV) and drug product (DP) production with a focus on meeting regulatory requirements for Marketing Authorization Application (MAA). This includes implementing scalable processes to enable cost-efficient production at a significantly reduced cost and exploring the potential for decentralized manufacturing approaches to further enhance flexibility, accessibility, and efficiency in delivering our product to patients. Currently, Temferon, is manufactured by the European Cell and Gene Therapy unit of AGC Biologics, a leading global contract development and manufacturing organization ("CDMO"), which is headquartered in Italy and specializes in the manufacturing of viral vectors and genetically engineered cells. AGC Biologics' facility is certified by AIFA.

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

Since cell and gene-based therapies are relatively new approaches in oncology, we intend to implement programs to improve patient and physician education regarding the availability of gene therapy-based products for those cancers with a high unmet medical need. We have established a network of leading U.S. Key Opinion Leaders ("KOLs"), which include: Antonio Chiocca, MD, Professor Neurosurgeon-in-Chief and Chairman, Department of Neurosurgery at Brigham and Women's Hospital in Boston, MA; Frederick Lang, MD, Professor and Chairman of the Department of Neurosurgery at MD Anderson in Houston, TX; and David A. Reardon, MD, Department of Medical Oncology at Dana-Farber Cancer Institute in Boston, MA; Timothy F. Cloughesy, MD, Professor of Clinical Neurology Director of Neuro-Oncology Program at University of California Los Angeles (UCLA); Richard Everson, MD, Assistant Professor, Department of Neurosurgery at UCLA; Donald B. Kohn, MD, Distinguished Professor Depts. of MIMG, Pediatrics and MMP at UCLA; Robert Prins, PhD, Associate Professor Neurosurgery at UCLA; and Patrick Wen, MD, Professor of Neurology, Harvard Medical School, Director of the Center For Neuro-Oncology at Dana-Farber Brigham Hospital.

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

We may choose to partner with pharmaceutical companies whose core competencies and oncology strategies are in line with ours. These partnerships could include the provision of market-approved therapies for combination testing with Temferon, enabling us to explore synergistic effects and expand potential therapeutic indications. Additionally, we are open to establishing clinical development collaborations with other biotech companies that have complementary products in development. Such partnerships would allow us to leverage combined expertise, accelerate clinical progress, and create innovative treatment options for patients with high unmet medical needs.

Our Platform

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

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

Our platform technology employs the following key components:

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

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

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

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

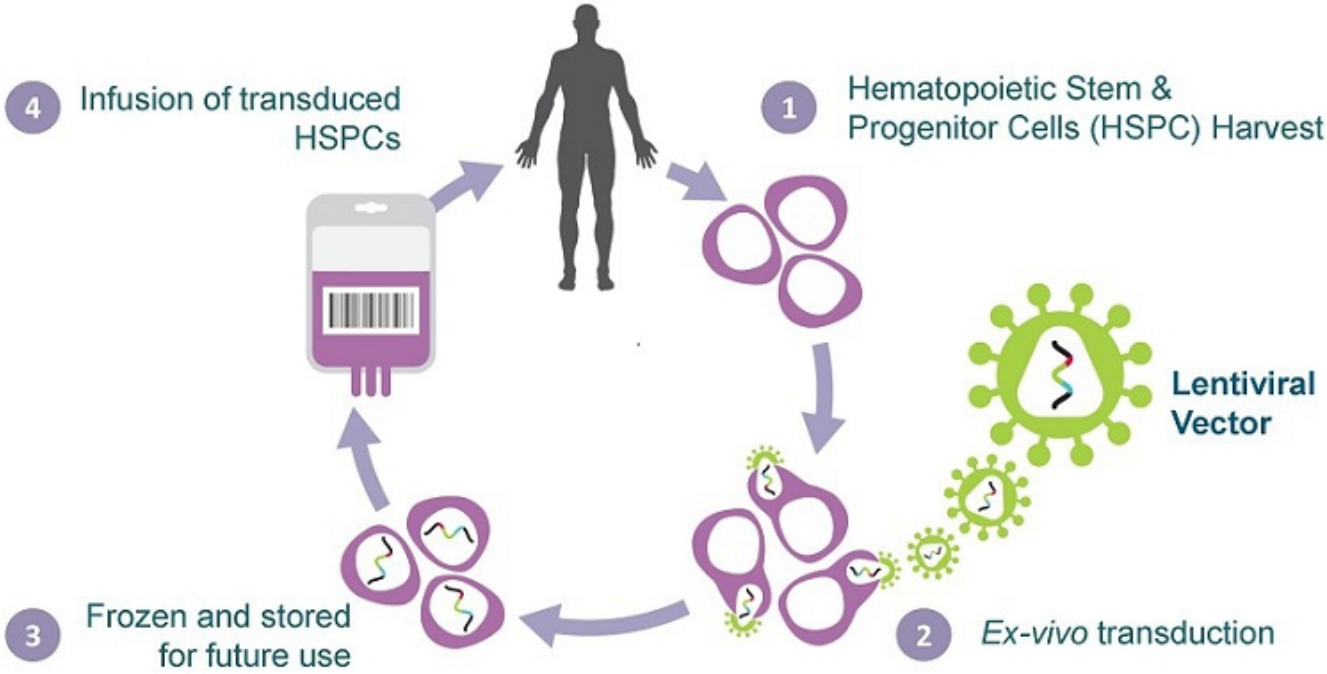


Illustration of our ex-vivo approach (steps 1-2-3) and treatment process (step 4)

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

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

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

b) Ex-vivo LVV based Transduction

After collection, a functional copy of the therapeutic gene is inserted into the patient's own HSPCs using a non-replicating LVV. This is an *ex-vivo* process called transduction. We believe that LVVs are the first choice for *ex-vivo* gene therapy in humans because they can (i) carry large transgenes that will allow us to expand the therapeutic options to a multitude of payloads without "size" limits and (ii) efficiently transduce non-proliferating or slowly proliferating cells, such as hematopoietic stem and progenitor cells. Most importantly, there is already an abundance of safety data generated using these vectors to develop investigational products currently under clinical testing, including CARs, TCRs, as well as commercial products such as Kymriah® (CD-19 CAR-T, Novartis Pharma) and Zynteglo® (β-Thal, Bluebird Bio). With more than 100 clinical trials either completed or in progress using LVVs worldwide, this delivery method accounts for more than a third of *ex-vivo* modified gene therapy clinical trials.

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

Differences exist between LVVs used for *ex-vivo* transduction that could, in theory, lead to differences in the long-term safety profile of products, particularly in terms of genotoxic potential. Use of strong promoters in conditions where a high pre-existing risk for hematologic malignancies exists, such as sickle cell disease ("SCD"), could in the long-term (i.e. 5 years or more) contribute to the development of leukemia. There have been several significant adverse side effects in gene therapy treatments involving an ex-vivo transduced lentivirus vector ("LVV") gene therapy product, Bluebird Bio's elivaldogene autotemcel ("Lenti-D"), involving two SUSARs for cases of acute myeloid leukemia ("AML"), and one case involving myelodysplastic syndrome.

In February 2021, Bluebird Bio temporarily suspended its gene therapy clinical trials for SCD (HGB-206 and HGB-210) and the marketing of Zynteglo® due to a suspected unexpected serious adverse reaction ("SUSAR") of acute myeloid leukemia (AML) in a SCD patient who received the product more than five years ago. In July 2021, the European Medicines Agency's ("EMA") safety committee (Pharmacovigilance Risk Assessment Committee – "PRAC") announced that there is no evidence the LVV used in both Lenti-D and the E.U.-approved gene therapy Zynteglo spurred the AML cases.

Bluebird Bio announced on August 9, 2021, that the SUSAR involving myelodysplastic syndrome occurred in one patient treated with Lenti-D over a year earlier. Bluebird Bio stated that this SUSAR "was likely mediated by Lenti-D lentiviral vector (LVV) insertion," and that "specific design features of Lenti-D LVV likely contributed to this event." As a result of this SUSAR, the FDA has placed a clinical hold on Bluebird Bio's Lenti-D phase 3 trial for cerebral adrenoleukodystrophy.

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

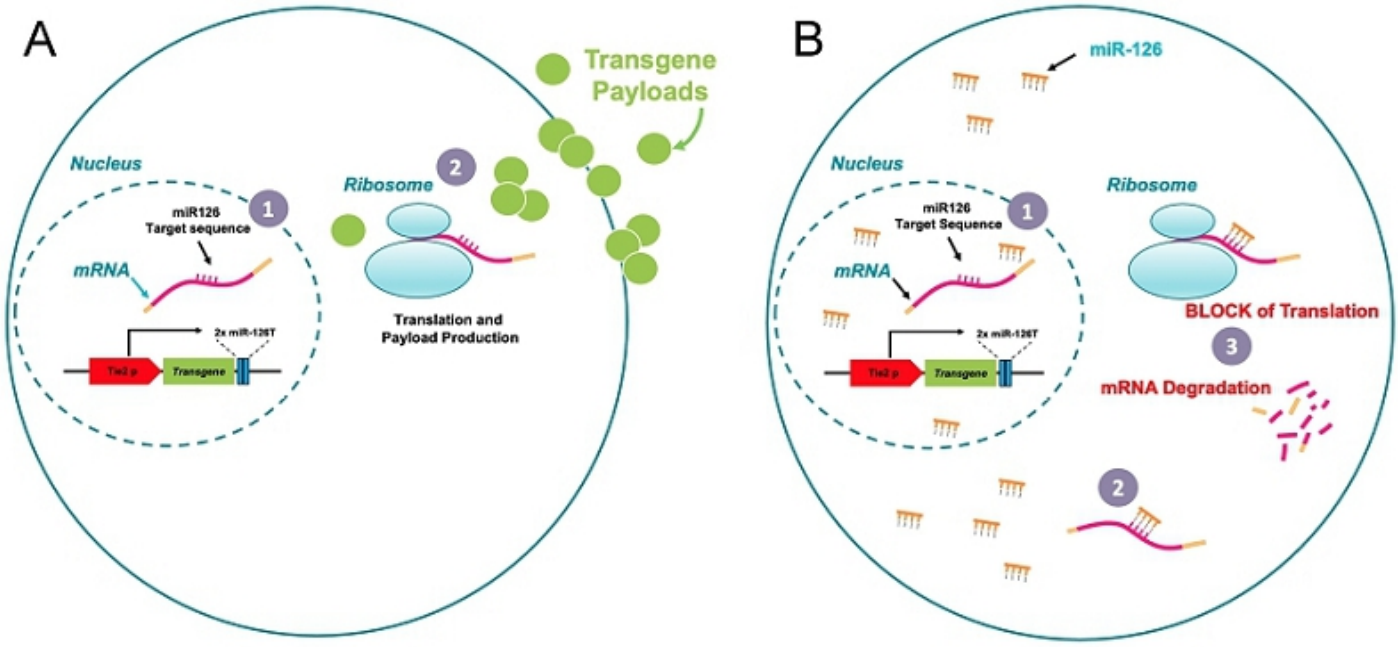
c) Tumor-Targeted Payload Delivery

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

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

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

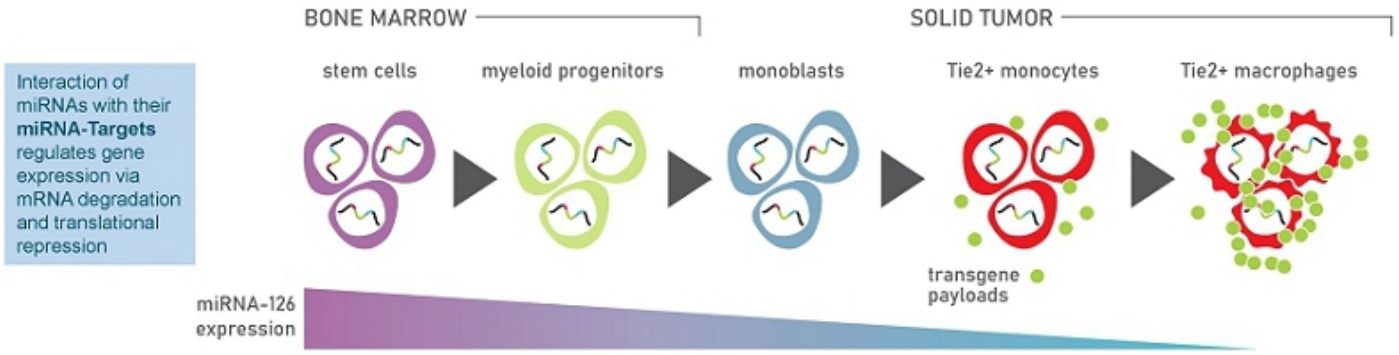
(ii) ***miRNA-126 target sequences***. The miRNA-126 target sequence serves as a post-transcriptional regulation layer that allows the expression of the transgene payload only in cells where miRNA-126 is not expressed. In our case, because miRNA-126 is highly expressed in HSPCs but down-regulated in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



Post-transcriptional control mechanism of transgene expression

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

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



De Palma et al., Cancer Cell, 2008; *Gentner et al.*, Sci Transl Med, 2010; *Escobar et al.*, Sci Transl Med, 2014; *Catarinella et al.*, EMBO Mol Med, 2016; *Escobar et al.*, Nat Commun, 2018

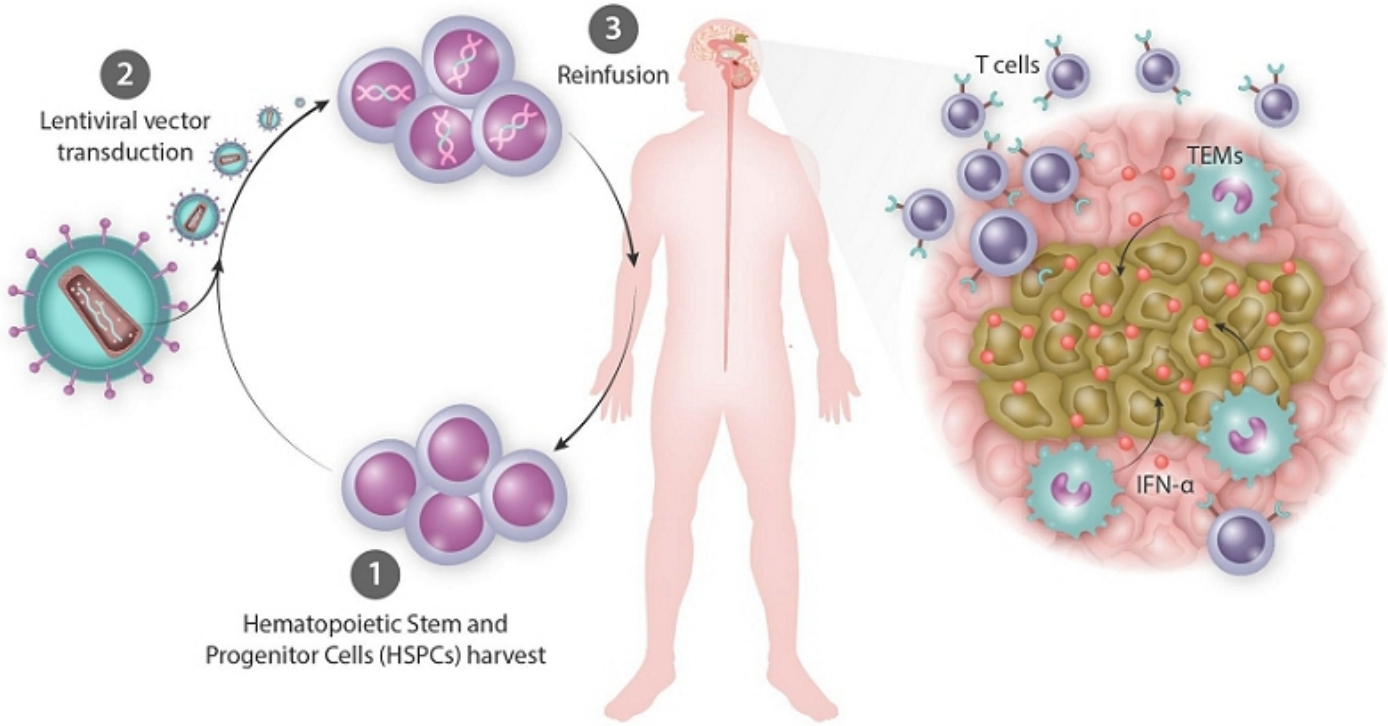
Transgene payload expression as the result of the transcriptional (promoter) and post-transcriptional regulation (miRNA-126 target sequence) imposed by our expression cassette.

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

Our Leading Product Candidate: Temferon

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

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



Overview of Temferon manufacturing process and mechanism of action.

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

Temferon for uMGMT-GBM

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

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

- ***Immunosuppressive tumor microenvironment.*** GBM is characterized by an immunosuppressive microenvironment that is mediated by tumor-associated myeloid cells (including TEMs) that prevent the immune system from recognizing and rejecting the tumor. Our treatment approach is designed to exploit TEMS to deliver IFN-α to the tumor so that the immune system recognizes the tumor and halts tumor cell proliferation and recurrence.

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

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

- ***Market Opportunity.*** Based on currently available treatments, the global market size for all GBM is projected to grow to over $6 billion by 2032. We believe a novel therapeutic, which demonstrates improvement over existing therapies, would greatly increase the market size.

We are discussing other studies using Temferon in solid tumor indications, for which we are considering patients with unmet medical needs suffering from solid tumors that recruit TEMs in order to grow.

Disease Overview

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

Disease Overview (Background Information)

Renal cell carcinoma ("RCC") accounts for over 80% of primary renal malignancies, with clear cell RCC representing the most common subtype. Combination immunotherapy and targeted regimens currently represent the standard of care in first-line treatment, with several additional therapies approved in later-line settings. [The above scientific and market overview is provided for contextual purposes only and does not reflect an ongoing development program by us as of the date of this filing.]

Clinical Development of Temferon in advanced genitourinary malignancies

TEM-GU Phase 1/2a Clinical Trial (Discontinued Program)

The TEM-GU study was originally designed as an open-label, single-center, Phase 1/2a therapeutic exploratory clinical trial intended to evaluate the safety, tolerability, biological activity, and preliminary efficacy of Temferon in patients with metastatic renal cell carcinoma ("mRCC").

The study protocol contemplated the evaluation of Temferon in combination with either immune checkpoint inhibitors ("ICI") or tyrosine kinase inhibitors ("TKI") in patients who had experienced disease progression after standard treatments. The clinical activities were planned to be conducted at the Genitourinary Oncology Unit of San Raffaele Hospital in Milan, Italy, with hematological follow-up and administration procedures coordinated within the same hospital's specialized hematology and bone marrow transplant unit.

However, following the strategic review completed in January 2026 and the related decision to discontinue the genitourinary ("GU") development program, we are no longer actively pursuing clinical development under the TEM-GU protocol. No new patient enrollment is ongoing or planned, and no material research and development expenditures are currently allocated to this indication.

Additional Pipeline Platform Development

Our Temferon platform was originally designed to be adaptable to multiple oncology indications through genetic modification of hematopoietic progenitor cells and targeted expression of therapeutic payloads.
In light of the strategic transformation announced in January 2026 and the progressive wind-down of internal research and development activities, we are not currently allocating resources to new pre-clinical platform expansion programs or to the development of next-generation constructs. Any future reactivation of platform development activities would be subject to strategic review and capital allocation decisions.

Combination Treatment

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

In preclinical studies conducted in the laboratories of our founders, Prof. Luigi Naldini and Dr. Bernhard Gentner, Temferon was evaluated in combination with CAR T, TCR-edited T cells directed against tumor-associated antigens and immune checkpoint blockers. The results showed promising additive-to-synergistic anti-tumor activity in leukemia experimental models (Escobar et al., Nature Communication 2018), glioblastoma models, and multiple myeloma mouse models. Specifically, a CD19 CAR-T approach in a leukemia mouse model had a detectable, but not significant, effect on the tumor burden. However, when used in combination with Temferon, the combination treatment resulted in a significant inhibition of the hematological malignancy, with a significant fraction of CAR-T/Temferon treated mice surviving to the latest timepoint of analysis. Similarly, the combination of IFN gene therapy to α-CTLA4, an immune check point blocker, or adoptive T cell therapy, significantly improved the survival of the mice (Escobar et al., Nature Communication 2018). Further, in a multiple myeloma mouse model, Temferon was administered in combination with human TCR-edited T cells directed against NY-ESO1 and anti-myeloma drugs. The combination approach showed promising additive-to-synergistic effects without exacerbating hematologic or systemic toxicities. These results lead us to believe that IFN gene therapy might also boost the efficacy of other immunotherapies.

Switchable Platform

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

An inducible version of the IFN-α payload has been generated by fusing the protein with a destabilizing domain (DD), which targets the protein to proteasomal degradation, unless a small molecule ligand binding to the DD and stabilizing it, is administered. The optimized fusion construct is delivered by the TEM platform and the exogenous administration of the ligand switches on its secretion within the tumor. The results from experiments performed in the laboratory of Prof. Naldini with a glioblastoma mouse model showed similar anti-tumor activity of the inducible and wild-type IFN payload. Moreover, the inducible construct allows switching of IFN release upon tumor clearance (Birocchi et al., Sci Transl Med 2022). We plan to use our second-generation platform carrying an IFN-α payload in combination with CAR T cells to target glioblastoma-associated antigens or immune checkpoint blockers in an experimental tumor model in mice.

Other Payloads

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

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

Moreover, experiments conducted with our second-generation inducible platform expressing IL-12 support the hypothesis that our proprietary transcriptional and microRNA regulated expression of the payload may prevent or limit toxicity. Indeed, IL-12 is a potent cytokine that must be kept within a therapeutic dose range to prevent toxicity. Targeted delivery and anti-tumor activity of the new inducible payload are being investigated (Mucci et al., EMBO Mol Med 2021). The laboratory of Prof. Naldini plans to test the combination of TEM-mediated gene-based delivery of inducible Il-12 or additional inducible payloads with CAR-T, TCR and ICI in experimental murine tumor models.

Competition

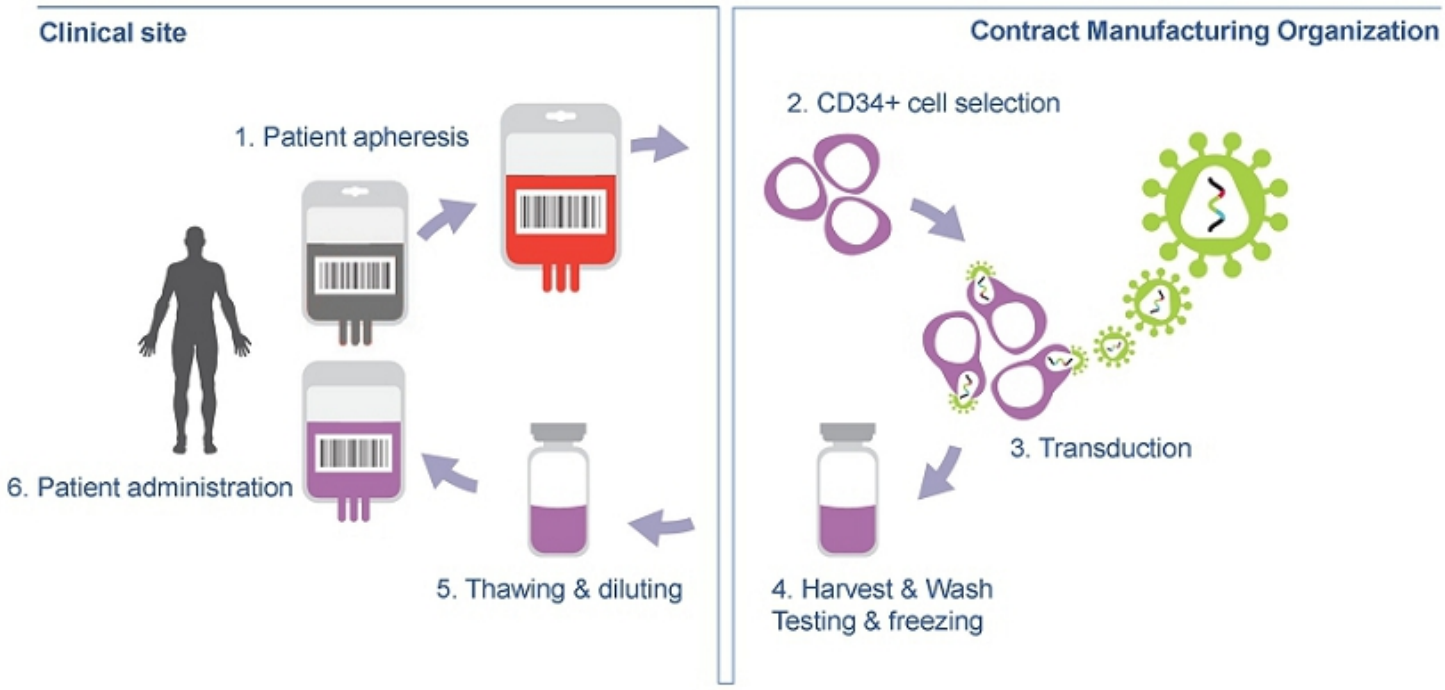
Biotechnology and pharmaceutical industries put significant resources in developing novel and proprietary therapies for the treatment of cancer. For the cell therapy field in particular, this results in rapidly advancing and changing technologies, intense competition and a strong emphasis on intellectual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

Manufacturing

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

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

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



Overview of Temferon Manufacturing Process

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

AGC Biologics Capabilities

Our agreements with AGC establish agreed-upon timelines for purchase order submissions and manufacturing date changes/cancellation. The agreements also set milestones both during the clinical phase and any future commercial phase of our product candidates and for technology transfer if required, as well as customary termination provisions, allowing for termination by a party upon the other party's uncured material breach or upon the other party's insolvency. On January 9, 2025, we announced the introduction of an exclusive GMP suite at AGC Biologics' facility in Italy, dedicated to the production of Temferon batches. The agreement with AGC Biologics related to the exclusive GMP suite has since been terminated, and the parties are currently involved in a legal dispute.

First and Second Amendment to Development and Master Services Agreement

On September 19, 2024, we entered into an amendment to the Master Services Agreement with AGC Biologics to extend the term of the Master Services Agreement to June 30, 2025 (the "First Amendment"). The First Amendment was considered effective retroactively from March 5, 2024, the day on which the Master Service Agreement expired, to cover the preceding period during which the same Master Service Agreement continued to be operating. Additionally, on October 14, 2024, we entered into an Agreement for the Conduct of Clinical Trials on Medical Products with OSR) to conduct an open-label 1/2 clinical trial in Renal Cell Cancer.

Effective December 24, 2024, we and AGC Biologics entered into the Second Amendment (the "Second Amendment") to the Development and Master Services Agreement, effective as of March 6, 2019 and as amended as of March 5, 2024 (the "MSA"), pursuant to which AGC Biologics manufactures our LVV) and certain drug products for our ongoing clinical programs in Italy.

In conjunction with entry into the Second Amendment, we also entered into work statement No. 1 to manufacture, test and release certain of our cell therapy products.

The Second Amendment provides that AGC Biologics will reserve an exclusive GMP suite (the "EGS") for our exclusive benefit in connection with manufacturing services for cell therapy and commit a specified number of full-time equivalent employees to us. In addition, AGC Biologics will make the EGS available for a specified number of weeks per a recurring 12-month period commencing in the first quarter of 2025. In the event this specified number of weeks is not reached, AGC will issue certain credit notes to us equal to the lost volume of activity. Further, if AGC is unable to offer EGC availability for this specified number of weeks over a 12-month period, AGC Biologics will issue certain credit notes to us as a penalty based on formulas specified in the Second Amendment.

The Second Amendment also provides that AGC Biologics will charge us monthly fees during the ramp-up phase, which begins on such specified date in the first quarter of 2025 and is estimated to end in the third quarter of 2025, and annual fees, payable quarterly, once the ramp-up phase is completed, as specified in the work statement.

On July 1, 2025, AGC and we signed the Second Amendment to their original MSA dated 2019, effective on June 30, 2025, to further extend the term of the original MSA, until September 30, 2025, including the possibility of further extension upon mutual written agreement.

On August 1, 2025, we issued a formal written notice of termination of Work Statement No. 01 dated December 24, 2024, pursuant to Section 4.1 of the MSA dated December 2024. This notice commences the twelve-month prior notice period ending on July 31, 2026 (the "Termination Date"), during which AGC will continue to issue quarterly invoices in accordance with the MSA, and the Company will remain responsible for all payment obligations relating to the Exclusive GMP Suite (EGS) and the EGS Team, as specified in Section 3 of Schedule 1A of the Second Amendment to the MSA, until the Termination Date.

On August 27, 2025, the Company received formal notification from AGC, referencing Work Statement 1 dated December 24, 2024, confirming that the Ramp-up phase - which began on February 1, 2025 - has been successfully completed. AGC stated that both contractual conditions have been met: the Authorization from AIFA to use the Exclusive Suite was received on July 3, 2025, and the training of the personnel assigned to the Dedicated Team has been finalized. Consequently, the Routine Phase is set to commence on September 1, 2025.

On September 24, 2025, we filed a civil action before the Court of Milan against AGC Biologics S.p.A., seeking a declaratory judgment of nullity and/or invalidity, with retroactive effect, of the Master Service Agreement and related amendments executed on December 24, 2024. The claim is based on the failure of an essential underlying assumption - the availability of a minimum number of patients required to initiate and sustain clinical production activities. As a result, we believe that the manufacturing agreement with AGC is no longer operative; however, we proposed to continue working with AGC based on the availability of production slots, as in the previous agreement.

The proceedings are ongoing, the first hearing was on March 11, 2026, and the next hearing is scheduled for June 3, 2026. Please refer to Note 19 - Subsequent events.

Government Regulation

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

Approval and Regulation of Drugs in the United States

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

In the U.S., all cell therapy product candidates are regulated by the FDA as biologics. Biologics require the submission of a BLA and approval by the FDA before being marketed in the U.S. Manufacturers of biologics may also be subject to state and local regulation.

The steps required before a biologic may be marketed in the U.S. generally include:

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

- satisfactory completion of an FDA Advisory Committee review, if applicable;
- potential FDA audit of the preclinical study and clinical trial sites that generated the data in support of the BLA in accordance with any applicable expedited programs or designations;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies);
- FDA review and approval, or licensure, of the BLA to permit commercial marketing of the product for particular indications for use in the U.S.;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the biologic is produced to assess compliance with current Good Manufacturing Practices ("cGMP") and to assure that the facilities, methods, and controls are adequate; and
- FDA review and approval of the BLA.

Preclinical Studies and the IND Process

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

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

Clinical Trials

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

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

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

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

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

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

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

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

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

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

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

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

Biologics License Applications

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

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

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

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

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

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

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

Regulation of Companion Diagnostics

For drugs and therapeutic biologics where the use of a specific diagnostic test is essential for the safe and effective use of the therapeutic product, such as when the use of a product is limited to a specific patient subpopulation that can be identified by using the test, regulatory authorities may require, as a condition of approval, that a relevant "companion diagnostic" test also be approved or cleared for the appropriate indication. This general policy approach may be inapplicable in cases where the drug or therapeutic biologic is intended to treat a serious or life-threatening condition for which no satisfactory alternative treatment exists, and the benefits from the use of a product with an unapproved companion diagnostic device are so pronounced as to outweigh the risks from the lack of an approved companion diagnostic. Companion diagnostics are generally regulated as medical devices by regulatory authorities, and relevant statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket regulatory review, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance.

Orphan Drug Designation

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

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

In the EEA, the criteria for designating an "orphan medicinal product" are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (a) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating conditions; (b) either such condition that affects no more than five in 10,000 people in the E.U.; or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the E.U. to justify the investment needed for its development; and (c) there exists no satisfactory method of diagnosis, prevention or treatment of the condition concerned, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition. The application for orphan designation must be submitted to the EMA and approved by the European Commission before an application is made for marketing authorization for the product. Once designated, an orphan medicinal product designation also entitles a party to financial incentives such as a reduction of fees or fee waivers. Moreover, ten years of market exclusivity is granted if the product continues to be designated as an orphan medicinal product upon grant of the marketing authorization. During this ten-year period, with a limited number of exceptions, neither the competent authorities of the E.U. Member States, the EMA, nor the European Commission is permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten years with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is demonstrated to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. This period of market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it can be demonstrated based on available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Expedited Programs in the United States and Other Jurisdictions

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

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

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

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

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

Under the centralized procedure in the EEA, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding "clock stops," when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days.

Accelerated evaluation might be granted by CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, which should be justified and assessed on a case-by-case basis. In this circumstance, EMA ensures that the opinion of CHMP is given within 150 days (excluding clock stops).

Expanded Access to an Investigational Drug for Treatment Use

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

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

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

U.S. market exclusivity

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

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

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

Post-approval requirements

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

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

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

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

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

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

Patent Term Restoration and Extension

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

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

Health Care Laws and Regulations

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, directly or indirectly, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or making false statements relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;

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

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

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

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

Pharmaceutical Insurance Coverage and Health Care Reform

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

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

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

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control, and other changes to the health care system in the U.S.

In March 2010, the U.S. Congress enacted the PPACA, which, among other things, included changes to the coverage and payment for drug products under government health care programs. Among other things, the PPACA imposed an annual, nondeductible fee on manufacturers of branded prescription drugs and biologics, expanded Medicaid eligibility and manufacturers' Medicaid rebate obligations, expanded the types of entities eligible for the 340B drug discount program, and established the Medicare Part D coverage gap discount program requiring manufacturers to provide point-of-sale discounts on applicable brand drugs to eligible beneficiaries. Since its enactment, the PPACA has been the subject of numerous legal challenges and legislative amendments, including the repeal of the individual insurance mandate and changes to various PPACA-mandated fees and assessments.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs.

Several healthcare reform proposals culminated in the enactment of the Inflation Reduction Act of 2022 (the "IRA") in August 2022, which, among other things, requires the U.S. Department of Health and Human Services to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations took place in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs, which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or Part D drugs will be selected. Currently, a drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if it is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. However, as a result of a statutory amendment enacted in July 2025, beginning with the 2028 negotiated price applicability year, a drug may be designated for more than one rare disease or condition and still be excluded from price negotiation, as long as the only approved indications are for such rare diseases or conditions. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. Manufacturers that fail to comply with the IRA may be subject to various penalties, including significant civil monetary penalties. These provisions have been and may continue to be subject to legal challenges. Thus, while it is unclear how the IRA will be fully implemented, it will likely have a significant impact on the biopharmaceutical industry and the pricing of prescription drug products.

Additionally, the federal administration is pursuing executive and regulatory actions directing the U.S. Department of Health and Human Services to pursue most favored nation ("MFN") pricing targets for prescription drugs and to evaluate other potential reforms. For example, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, and even companies that do not market drugs in comparator countries could be indirectly affected if their drugs compete with drugs whose prices were reduced as a result of MFN pricing initiatives.

Review and Approval of Medicinal Products in Europe

To market any medicinal product outside of the U.S., a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy, and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of medicinal products. Whether or not it obtains FDA approval for a product candidate, an applicant will need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Some countries outside of the U.S. have a similar process that requires the submission of a CTA, much like the IND, before the commencement of human clinical trials. In the E.U., for example, a CTA must be submitted to the national competent authorities of the E.U. Member States where the clinical trial is conducted and to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

In April 2014, the E.U. adopted a new Clinical Trials Regulation (E.U.) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the E.U. Specifically, the new regulation, which will be directly applicable in all Member States (meaning that no national implementing legislation in each E.U. Member State is required), aims at simplifying and streamlining the approval of clinical trials in the E.U. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications. It is expected that the new Clinical Trials Regulation will come into effect following confirmation of full functionality of the Clinical Trials Information System, the centralized E.U. portal and database for clinical trials foreseen by the new Clinical Trials regulation, through an independent audit. In January 2022, the Clinical Trials Regulation entered into application, harmonizing the submission, assessment, and supervision processes for clinical trials in the E.U.

Clinical Trial Regulations in Italy

Under the E.U. and E.U.-member country legislation, any application for marketing authorization must be accompanied by the results of clinical trials conducted in accordance with applicable regulations. A unified regulation on clinical trial procedures has been approved (E.U. Reg. 536/2014), but it is not yet effective. The currently applicable rule is E.U. Directive 2001/20, as implemented in the various E.U. member countries from time to time through national laws and regulations.

We are currently conducting or planning Phase 1/2a clinical trials on Temferon in Italy, in accordance with the specific regulations applicable to such early-phase trials. As discussed elsewhere in this report, we are currently conducting our TEM-GBM 001 study on UMGMT-GBM patients, while the TEM-GU study on mRCC patients is under termination as resolved by the board of directors held on January 23, 2026.

The applicable Italian regulation is the Decree of April 27, 2015 of the Ministry of Health, providing a precise sequence of approvals for the start of Phase I studies and subsequent amendments to the related protocols. According to such Decree, an initial request must be submitted to AIFA seeking a technical-scientific opinion of Istituto Superiore di Sanità (ISS), acting on behalf of AIFA, on the admissibility of the request. Upon the favorable opinion of ISS, Italian Regulatory Authority ("AIFA") issues an authorization to proceed with the planned study, and the rules generally governing the conduct of clinical trials (Legislative Decree 211 of June 24, 2003, implementing in Italy E.U. Directive 2001/20, Decree of December 17, 2004 of the Ministry of Health for non-profit studies, plus procedural rules such as the Decree of December 21, 2007, so called "CTA decree", for the prescribed formats), are of application.

Based on the AIFA approval, the Independent Ethics Committees ("IECs") of the research centers participating in the trial issue their opinions on the conduct of the study, having evaluated the study protocol and all other relevant documentation such as the informed consent form ("ICF"), the insurance policy underwritten by the sponsor, the information and consent form for data protection purposes. The IEC of the Coordinating Center issues first its opinion – the so-called *Parere Unico*, lit. "sole opinion" ("PU") - and then the IECs of the other participating centers accept or refuse the PU in its entirety (they may seek amendment to the ICF on the basis of local operating circumstances).

All documents pertaining to each specific step of the procedure, in the right sequence, must be loaded on the online database of AIFA ("Osservatorio sulle Sperimentazioni Cliniche", or "OsSC"); the OsSC system provides certain controls to make sure that e.g. no IEC opinion can be loaded before the pertinent AIFA approval, or that the opinions of the participating sites cannot be loaded before the PU is loaded. It may occur however that, due to calendar mismatches in the calendars of IEC meeting (usually held on a monthly basis), an approval may precede by a few days a "prior" one (typically, the PU or the AIFA approval): in such cases the IEC approval is issued under reservation ("*con riserva*") and can be loaded in advance accordingly, under the assumption that the documents subjected to evaluation - protocol (updated) version, ICF and the rest – coincide exactly.

Marketing Authorization Application for Biologic Medicinal Products

To obtain regulatory approval to commercialize a new drug in the EEA (comprising the E.U. Member States plus Iceland, Liechtenstein and Norway, we must submit a marketing authorization application).

In the E.U., a marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or national procedure (single country). The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products, those produced by biotechnology, advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue-engineered products) and those with a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, autoimmune and other immune dysfunctions, viral diseases or diabetes, and is optional for certain other products, including medicinal products with a new active substance for other indications, and products that are a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health.

Under the centralized procedure, the applicant can submit a single application for marketing authorization to the EMA which will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Based on the opinion of the EMA, the European Commission takes a final decision to grant a centralized marketing authorization which permits the marketing of a product throughout the EEA. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA Committee for Medicinal Products for Human Use ("CHMP")). Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a marketing authorization application under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Now that the United Kingdom (which comprises Great Britain and Northern Ireland) has left the E.U., Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA"), the United Kingdom medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

For other countries outside of the E.U., such as the United Kingdom and countries in Eastern Europe, Latin America, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with cGCPs, applicable regulatory requirements of each jurisdiction, and the medical ethics principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Advertising, Promotion and Compliance

In the E.U., the advertising and promotion of our products will also be subject to E.U. laws and E.U. Member States' national laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. The SmPC forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off -label promotion and is prohibited in the E.U. The applicable laws at the E.U. level and in the individual E.U. Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the E.U. could be penalized by administrative measures, fines, and imprisonment. As the United Kingdom's medicinal products legislation is still largely based on E.U. legislation, the promotion of prescription-only medicines to the public and the promotion of medicinal products not in compliance with the SmPC are both also prohibited under United Kingdom law.

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These penalties could include the imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention, or refusal to permit the import or export of products, injunctions, fines, civil penalties, or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

Regulatory Data Protection in the EEA

In the EEA, innovative medicinal products approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Directive 2001/83/EC. Regulation (EC) No 726/2004 repeats this entitlement for medicinal products authorized in accordance with the centralized authorization procedure. Data exclusivity prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator's data when applying for a generic or biosimilar marketing authorization for a period of eight years from the date on which the innovator's product was first authorized in the EEA. During an additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted and authorized, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the E.U. market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on a marketing authorization application with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Periods of Authorization and Renewals

A marketing authorization has an initial validity for five years in principle. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the relevant Member State. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety, and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. The European Commission or the competent authorities of the EEA Member States may decide on justified grounds relating to pharmacovigilance to proceed with one further five-year period of marketing authorization. Once subsequently renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EEA market (in case of centralized procedure) or on the market of the authorizing EEA Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Pediatric Studies and Exclusivity

Prior to obtaining a marketing authorization in the EEA, applicants must demonstrate compliance with all measures included in an EMA-approved PIP covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, commonly referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA ("PDCO") may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of medicine for children is not needed or is not appropriate, such as for diseases that only affect an adult population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA must determine that a company actually complied with the agreed studies and measures listed in each relevant PIP, unless the EMA has granted: (i) a product-specific waiver, (ii) a class waiver or (iii) a deferral for one or more of the measures included in the PIP. If an applicant obtains a marketing authorization in all EEA Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results of the pediatric clinical trials conducted in accordance with the PIP are included in the drug product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Regulatory Requirements after a Marketing Authorization has been Obtained

In case an authorization for a medicinal product in the EEA is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the E.U.'s stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.

- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable E.U. laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("E.U. cGMP"). These requirements include compliance with E.U. cGMP standards when manufacturing medicinal products and APIs, including the manufacture of API outside of the E.U. with the intention of importing the API into the E.U..

- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the E.U. notably under Directive 2001/83EC, as amended, and E. Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the E.U..

General Data Protection Regulation

The collection, use, disclosure, transfer or other processing of personal data of individuals (natural persons) in the E.U., including personal health data, is governed by the GDPR, which became effective and applicable on May 25, 2018. Since the application of the GDPR, the European data protection law background has been constantly implemented through the activity of the European Data Protection Board (EDPB) and the respective national Supervisory Authorities, concerning the correct interpretation and application of the GDPR, as well as through the ruling of the Court of Justice of the E.U. (CJEU). The GDPR and E.U. Member States' national data protection legislation, including Italy, is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data. For example, it is essential to obtain consent of the individuals to whom the personal data relates, providing notice to individuals regarding data processing activities, implementing suitable safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the E.U., including the U.S. and the United Kingdom, and allows data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million or 4% of annual global revenues, whichever is greater. As regards the transfer of (pseudonymized) personal data to the U.S., the CJEU case C-3111/18, also known as Schrems II, invalidated the European Commission's adequacy decision for the E.U.-U.S. Privacy Shield Framework, which the majority of U.S. companies relied on to conduct trans-Atlantic trade in compliance with E.U. data protection rules. The decision reinforced the importance of data protection to global commerce and imposed E.U. companies trading with U.S. companies or organizations to rely on the transfer of personal data on other legal basis or appropriate safeguards provided for in the GDPR, such as Standard Contractual Clauses (SCC), Binding Corporate Rules (BCR) or derogations for specific situations. The Privacy Shield Framework has now been replaced by the so-called "Data Privacy Framework E.U.-U.S. (DPF)", an agreement that entered into force after the adoption of the EU Commission's adequacy decision of 10 July 2023. US companies that adhere to the DPF are considered compliant with the GDPR requirements and data transfer from the E.U. to the U.S. within this framework is thus considered compliant. In June 2021, the E.U. Commission adopted decisions on the United Kingdom's adequacy under the E.U.'s GDPR and Law Enforcement Directive (LED). In both cases, the European Commission found the United Kingdom to be adequate. This means that most data can continue to flow from the E.U. and the EEA without the need for additional safeguards. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages. Compliance with the GDPR and all relevant E.U. data protection rules will be a rigorous and time-intensive process that may increase our cost of doing business.

The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages.

Compliance with the GDPR and all relevant E.U. data protection rules will be a rigorous and time-intensive process that may increase our cost of doing business.

Pricing Decisions for Approved Drug Products

In the E.U., pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the E.U. provides options for the E.U. Member States to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. E.U. Member States may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other E.U. Member States allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the E.U. have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the E.U. The downward pressure on health care costs in general, particularly with respect to prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new drug products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various E.U. Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced E.U. Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any drug products, if approved in those countries.

Intellectual Property Rights

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

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

Temferon

Temferon is protected by the following patent families that contain both issued and/or pending patent applications.

In April 2025, we filed a PCT international patent application claiming priority to a US provisional application filed in April 2024 relating to methods of treating solid cancers with Temferon in combination with a checkpoint inhibitor. In October 2025, we filed a provisional patent application relating to methods of treating renal cell carcinoma with Temferon in combination with a checkpoint inhibitor. These pending applications are wholly owned by us.

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

Focus / Family	U.S.	E.U.	Expiration
Gene Vector comprising mi-RNA (composition and method of treatment claims) PCT/IB2006/002266 (WO 2007/000668).	USP 10,000,757* USP 9,556,438 USP 11,753,643 USSN 18/191,611 (pending)	EP 2002003 B1	5/26/2026*
Gene Vector comprising mi-RNA (composition and method of treatment claims) PCT/IB2010/001166 (WO / 2010/125471)	USP 10,287,579 USP 9,951,328 USP 11,407,996 USSN 17/855,135 (pending)	EP 2424571 B1 EP 20167404.1 (pending)	4/30/2030
Type 1 Interferon Gene Therapy (method of treatment claims) PCT/EP2018/060238 (WO 2018/193119)	USSN 16/604,484 (pending)	EP 3612624 B1 EP 24202037.8 (pending)	4/20/2038**

* Later expiration for certain U.S. patents pursuant to patent term adjustment (35 U.S.C. §154(b)).

** Application pending, anticipated expiration based on 20-year patent term.

Our technology incorporates the use of a lentiviral vector ("LVV") that combines a therapeutic transgene sequence, or payload, with our proprietary platform. Our proprietary platform consists of (i) the Tie-2 promoter, which drives transgene sequence transcription specifically in TEMs, and (ii) miRNA-126 target sequences to downregulate transgene expression post-transcription in those cells where the Tie-2 promoter is active and the miRNA-126 is present. Intellectual property protection for our proprietary platform includes an exclusive license to all issued patents and pending applications (if any) in the PCT/IB2006/002266 (WO 2007/000668) and PCT/IB2010/001166 (WO / 2010/125471) families, as well as trade secrets. [We retain the option to exclusively license the PCT/EP2018/060238 and PCT/EP2024/057093 patent families (which we have not yet exercised), along with any improvements, for additional indications (fields of use) and other product candidates.]

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

Collaboration / Licensing

Amended and Restated License Agreement with Ospedale San Raffaele

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

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

Pursuant to the terms of the ARLA, OSR has granted us an exclusive, royalty-bearing, non-transferrable (except with the prior written consent of OSR), sublicensable, worldwide license, subject to certain retained rights, to: (1) certain patents, patent applications and existing know-how for the use in the field(s) of Interferon ("IFN") gene therapy by lentiviral based- HSPC gene transfer with respect to (a) any solid cancer indication (including glioblastoma and solid liver cancer) and/or (b) any lympho-hematopoietic indication for which we exercise an option (described below); and (2) certain gene therapy products (subject to certain specified exceptions related to replication competent viruses) developed during the license term for use in the aforementioned field(s) consisting of any lentivirals or other viral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter. Lympho-hematopoietic indication means any indication related to lympho-hematopoietic malignancies, and solid cancer indication means any solid cancer indication (e.g., without limitation, breast, pancreas, colon cancer), with each affected human organ counting as a specific solid cancer indication.

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

Pursuant to the ARLA, we have an exclusive option exercisable until April 20, 2026, to any OSR product improvements at no additional cost, which could be useful for the development and/or commercialization of licensed products in the field of use. We also have an exclusive option exercisable until April 20, 2026 (the "LHI Option Period") to any lympho-hematopoietic indication(s) to be included as part of the field of use, on an indication-by-indication basis, subject to the payment of specified option fees and milestone payments:

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

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

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

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

Pursuant to the ARLA, as consideration, we agreed to pay OSR additional license fees equal to up to €875,000 in total, which were paid on April 20, 2023 for €225,000, on December 31, 2023 for €150,000, and the remaining portion of €500,000 are to be paid upon our entering into a sublicense agreement with a third party sublicensee (pursuant to which we are entitled to receive an upfront payment in an amount exceeding a specified threshold from such sublicensee) during the period between September 30, 2022 and April 20, 2028 (with most of these additional license fees being triggered upon our entering into such a sublicense agreement). In addition, we have agreed to pay OSR royalties on a single-digit percentage of the net sales of each licensed product. The royalty may be reduced upon the introduction of generic competition or patent stacking, but in no event would the royalty be less than half of what it would have otherwise been, but for the generic competition or patent stacking. We also agreed to pay OSR a royalty of our net sublicensing income for each licensed product and to pay OSR certain milestone payments upon the achievement of certain milestone events, such as the initiation of different phases of clinical trials of a licensed product, MAA approval by a major market country, MAA approval in the U.S., the first commercial sale of a licensed product in the U.S. and certain E.U. countries, and achievement of certain net sales levels.

As part of the ARLA, we have agreed to use reasonable efforts to involve OSR in Phase I clinical trials for licensed products in the field of use, subject to OSR maintaining any required quality standards and providing its services on customary and reasonable terms and consistent with then-applicable market standards. We are also obligated to carry out our development activities using qualified and experienced professionals and a sufficient level of resources. In particular, consistent with the terms of the Original OSR License Agreement, the ARLA continues to require us to invest (a) at least €5,425,000 with respect to the development of the licensed products, and (b) at least €2,420,000 with respect to the manufacturing of such licensed products (subject to certain adjustments).

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

The ARLA expires upon the expiry of the "Royalty Term" for all licensed products and all countries, unless terminated earlier. The Royalty Term begins on the first commercial sale of a licensed product in each country, on a country by country basis, and ends upon the later of the (a) expiration of the commercial exclusivity for such product in that country (wherein the commercial exclusivity refers to any remaining valid licensed patent claims covering such licensed product, any remaining regulatory exclusivity to market and sell such licensed product or any remaining regulatory data exclusivity for such licensed product), and (b) 10 years from the first commercial sale of such licensed product in such country.

The parties may terminate the agreement in the event the other party breaches its obligations therein, which termination shall become effective 60 business days following written notice thereof to the breaching party. The breaching party shall have the right to cure such breach or default during such 60 business days. OSR may terminate the agreement for failure to pay in the event that we fail to pay any of the upfront payments, additional license fees, sublicensing income or milestone payments within 30 days of due dates for each. In addition, OSR may terminate (with a 60-business-day prior written notice) our rights as to certain fields of use for our failure to achieve certain development milestones for specified licensed products within certain time periods, which may be subject to extension. In addition, OSR may terminate the agreement in the event that commercialization of a licensed product is not started within 24 months from the grant of both (i) the MAA approval and (ii) the pricing approval of such licensed product, provided that such termination will relate solely to such licensed product and to such country or region to which both such MAA approval and pricing approval were granted.

Amendment to Amended and Restated License Agreement with OSR

On September 28, 2023, we entered into an amendment to the ARLA, whereby we and OSR agreed that we had fulfilled the obligations as set forth in the ARLA specific to Candidate Products 1 pursuant to the CP1 SRA (as defined below). Furthermore, the amendment provides that we and OSR have no further obligations to negotiate and execute a sponsored research agreement for the performance of feasibility studies related to certain gene therapy products consisting of any lentiviral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of cytokines and their variants (other than IFN or in addition to IFN) under the control of a Tie2 promoter, either alone or in combination with any immunotherapy ("Candidate Products 2"). Notwithstanding the removal of the obligation to enter into a sponsored research agreement with regards to Candidate Products 2, OSR granted us an exclusive option, to be exercised by sending written notice to OSR on or before September 30, 2025, to include certain intellectual property related to Candidate Products 2 and Candidate Products 2 as part of the licensed patents and licensed products under the ARLA. The option fee and our fee to extend the option period, if necessary, remain consistent with the prior fees to those costs reflected in the ARLA specific to Candidate Products 2. OSR will also have the right to prepare, file and prosecute patents and patent applications with respect to the results of Candidate Products 2. The amendment provides that the costs of the foregoing activities will be borne by us. We did not exercise this option, and we formally notified OSR prior to its expiration that we were waiving such right.

Sponsored Research Agreement

On August 1, 2023, we entered into a Sponsored Research Agreement ("CP1 SRA"), which was contemplated under the ARLA, pursuant to which we will fund feasibility studies for certain gene therapy products consisting of any lentiviral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter, in combination with any immunotherapy ("Candidate Products 1"), along with three additional research projects, to be conducted at OSR. If OSR determines that additional funds are needed, OSR will inform us and provide an estimate for completing the research.

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

Know-How License Agreement with Fondazione Telethon

In February 2016, we entered into a Know-How License Agreement with Telethon (Telethon License Agreement). Telethon granted us a non-exclusive, perpetual, sublicensable (through multiple tiers), royalty-bearing, worldwide license to use its manufacturing know-how in the research and development, sale and export of any product, which is defined therein as any lentiviral vector regulated by miRNA 126 and/or miRNA 130 and/or other miRNAs with the same expression pattern as miRNA 126 and/or miRNA 130 in hematopoietic cells for the expression of any anticancer protein under the control of a Tie2 promoter or INF under the control of any promoter other than Tie2 for any cancer indication. As consideration for the license, we agreed to pay Telethon a royalty equal to a low single digit percentage of any actual payments (excluding taxes) to any CMO for the manufacturing of any product using the licensed know-how. The royalty payments must be made for eight (8) years from the effective date, or until February 2, 2024. At December 31, 2024, there were no royalty payments due. The parties may terminate the agreement in the event the other party breaches its obligations therein, which termination shall become effective sixty (60) business days following written notice thereof to the breaching party.

Legal Proceedings

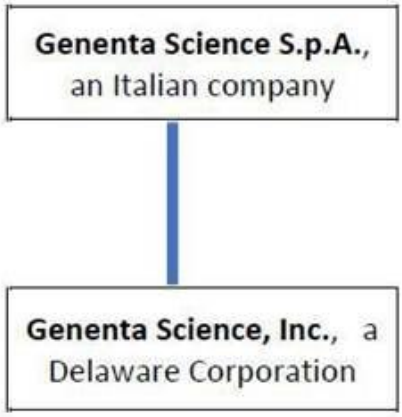
From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations.

In September 2025, we filed a civil action before the Court of Milan against AGC Biologics S.p.A., seeking a declaratory judgment of nullity and/or termination, with retroactive effect, of the Master Service Agreement and related amendments executed on December 24, 2024. The claim is based on the failure of an essential underlying assumption - the availability of a minimum number of patients required to initiate and sustain clinical production activities. As a result, we believe that the manufacturing agreement with AGC is no longer operative; however, we have proposed to continue working with AGC based on the availability of production slots, as in the previous agreement. The proceedings are ongoing. The first hearing was scheduled for March 11, 2026, and the next hearing is scheduled for June 3, 2026 (See Note 19. Subsequent events for more details).

In January 2026, we commenced legal proceedings before the Court of Milan against Fondazione Enea e Tech Biomedical, with which we previously entered into a €20 million convertible bond loan agreement in March 2025. Under the convertible bond loan agreement, we have received, to date, only €7.5 million. The lawsuit seeks, inter alia, to have the convertible bond loan agreement declared null and void and to recover damages. The basis of our claim is that Fondazione Enea e Tech Biomedical, which entered into a memorandum of understanding in 2022 and later (through two different term sheets) postponed signing of the convertible bond loan agreement until March 2025 – at which time it also changed the amount, number of installments, and other loan terms – acted in bad faith and rendered the convertible bond loan agreement void for lack of cause. The proceedings are ongoing (See Note 19. Subsequent events for more details).

C. Organizational Structure

Genenta Science S.p.A. owns 100% of Genenta Science, Inc.



D. Plants, Property and Equipment

Our corporate headquarters were located in Milan, Via Olgettina 58 within OSR - San Raffaele Hospital, Italy, where we lease approximately 51 square meters of office space (three (3) offices). The lease commenced in January 2020 and had a six (6) year initial term. It expired on December 1st, 2025. Please refer to Note 19. Subsequent events, for further details. Our registered office changed on January 27, 2026, to Via dell'Annunciata, 31, 20121, Milan. For further details, please refer to the section entitled "A. History and Development of the Company." We believe that our existing facilities are adequate for our near-term needs, and we believe that suitable additional or alternative office will be available as required in the future on commercially reasonable terms.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and related notes included in this Annual Report beginning on page F-1. The following discussion and analysis contain forward-looking statements 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 various factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report.

A. Operating Results

Overview

We are a clinical-stage biotechnology company engaged in the development of hematopoietic stem cell gene therapies for the treatment of solid tumors, and we are embarking on a strategic transformation to evolve into a next-generation strategic industrial consolidator focused on acquiring privately held businesses operating in national-security regulated sectors contemplated by the Italian "Golden Power" legislation. "Golden Power" is Italy's investment screening framework — broadly comparable to CFIUS in the United States, the IEF regime in France, and the United Kingdom's NSI Act — and covers strategic domains such as biotechnology, biosecurity, defense, cybersecurity, AI-driven intelligence, aerospace, quantum technologies, secure communications, and critical infrastructure. We are targeting majority ownership in companies with established operating profitability, typically generating up to approximately €5 million in EBITDA, which will eventually be consolidated into our financial statements. We will only target companies where we can control the company by owning a majority (i.e., more than 50%) of the company. Historically, we 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 or TEMs). Our biotechnology 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. As we move forward, we intend to pursue a value-creation strategy by acquiring targets at private-market valuations and integrating these companies. Through this integration, we will seek to enhance these businesses through operational upgrades, institutional-grade governance, and improved financial visibility. In connection with the extension of our corporate purpose, we may reconsider a corporate name change and a new Nasdaq ticker symbol in the future. The adoption of a new corporate name will be subject to approval by our shareholders.

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 and convertible debt securities, which through December 31, 2025, aggregated gross cash proceeds of approximately €82.4 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, or on our ability to successfully execute our strategic transformation into a next-generation industrial consolidator. Our net losses for the years ended December 31, 2025, 2024, and 2023 were approximately €6.5 million, €8.9 million, and €11.6 million, respectively. At December 31, 2025, we had an accumulated deficit of approximately €62.6 million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development activities, including preclinical and clinical development of our gene therapy product candidates, namely our leading product candidate, Temferon, and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses for at least the next several years as we advance our product candidates from discovery through preclinical development and clinical trials and seek regulatory approval of our product candidates, combined with our acquisition of privately held businesses operating in national security-regulated sectors. In addition, if we eventually obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution, if we are unable to attract a strategic partner with those capabilities. 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, compliance, and other expenses.

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

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

As of December 31, 2025, we had cash and cash equivalents of approximately €5.5 million and marketable securities of approximately €22.6 million. Our existing cash and cash equivalents as of December 31, 2025, will enable us to fund our operating expenses and capital expenditure requirements at least until December 2027. Although we are prudent with our cash reserves, and are focused on long-term shareholder value, we based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources." To finance our continuing operations, we will need to raise additional capital, which cannot be assured.

Components of Operating Results

Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products until we obtain regulatory approval of, and commercialize, our product candidate(s). We may begin to generate revenue from acquisition targets once we own more than 20% of the acquired company (i.e., through a partial consolidation) or once we own more than 50% of the acquired company (i.e., through a full consolidation).

Operating Expenses

Our current operating expenses consist of two components: research and development expenses; and, general and administrative expenses. Going forward, we intend to charge some of our general and administrative expenses to our acquisition companies for services provided.

Research and Development Expenses

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

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

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

	Year Ended December 31,		
	2025	2024	2023
	(in Euros)		
Direct research and development expenses by program:			
TEM-GBM Phase 1	€ 140,407	€ 1,175,026	€ 1,331,166
TEM-GBM Phase 2	-	10,766	-
TEM-MM	-	-	-
TEM-LT	3,963	2,770	-
TEM-GU Phase 1	87,838	953,794	-
Unallocated costs:			
Personnel (including share-based compensation)	919,340	1,443,510	1,113,489
Consultants and other third party	292,665	412,229	305,289
Materials & supplies	1,227,272	783,880	3,639,920
Travel & entertainment	17,976	29,137	44,242
Other	9,881	1,741	40,335
Total research and development expenses	€ 2,699,342	€ 4,812,854	€ 6,474,441

Research and development activities are central to our historical and current 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. Our research and development efforts may result in significant expenses over time, including costs associated with personnel, clinical activities, contractors, and facilities. We could also incur additional obligations, such as milestone or royalty payments, under existing or future license agreements related to our product candidates. We are actively seeking a strategic partner to assist us with our future development efforts. There can be no assurance that we will identify a strategic partner, or that the strategic partner will offer terms favorable to us to continue the development of Temferon. If we do not find such a partner, we may not be able to continue developing Temferon toward commercialization.

[Starting from 2023, we implemented a new management accounting system, enabling the division of expenses by project, allowing for a more precise allocation of direct costs, including manufacturing costs, to the respective projects. This process has consequently led to a reduction in the balance of manufacturing costs that are not specifically allocated to any project but are incurred for the general benefit of all ongoing research and development activities, as shown in the table above.]

Our research and development expenses decreased in 2025, compared to 2024, due to several factors as explained in the section "Results of Operations - *Comparison of Year Ended December 31, 2025 to Year Ended December 31, 2024*," but we may incur increased research and development expenses over the next several years, depending on the timing and scope of our ongoing and planned clinical and preclinical activities, including any potential expansion of patient enrollment in our clinical trials. Such increases could also result from higher personnel-related costs, including share-based compensation, contractor expenses, and facilities costs, as we continue to evaluate and advance the development of our product candidates. We may also incur additional expenses related to milestone and royalty payments payable to third parties under our license agreements, subject to the achievement of specified development, regulatory, or commercial events.

The successful development and commercialization of our product candidates is highly uncertain. Although we believe that we do not have sufficient cash to fund a full Phase 2 clinical trial for any of our product candidates, we cannot reasonably estimate or know the nature, timing, and total costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

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

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses may increase in the future as we increase our headcount to support our continued research activities, the development of our product candidates, and the acquisition of target companies in national security-regulated sectors contemplated by the Italian Golden Power legislation. We also anticipate that we may continue to incur additional accounting, audit, legal, regulatory, compliance, directors' and officers' insurance costs, as well as investor and public relations expenses associated with being a public company. Additionally, if regulatory approval of a product candidate appears likely, we may incur further expenses in preparation for potential commercialization, including those related to sales and marketing activities. Finally, we may incur additional legal fees either as a result of our strategic transformation or other normal business disputes and activities.

Other Income (Expense)

Other income (expense) consists primarily of interest income (expense), foreign exchange income (loss), and gain (loss) from the sale or maturity of available-for-sale debt securities.

For the year ended December 31, 2025, the net balance of other income (expense) amounted to approximately €74,000 and mainly related to net financial interest income of approximately €620,000, net unrealized foreign exchange loss of approximately € (558,000), and net realized foreign exchange gain of approximately €12,000.

For the year ended December 31, 2024, the net balance of other income/(expense) amounted to approximately €852,000 and mainly related to net financial interest income of approximately €611,000, net unrealized foreign exchange gain of approximately €248,000, and net realized foreign exchange loss of approximately € (7,000).

For the year ended December 31, 2023, the net balance of other income/(expense) amounted to approximately €87,000 and mainly related to net financial interest income of approximately €304,000, net unrealized foreign exchange losses of approximately € (257,000), and net realized foreign exchange gain of approximately €40,000.

The differences between periods in the Other income (expense) category is due to the performance of our investment activities, which are influenced by the price trends of US Treasury Bills and Italian Government Bonds and interest rates, and to the macroeconomic situation that affects the purchasing power of currencies like the US Dollar versus the Euro.

Income taxes

We are subject to taxation in Italy and the U.S. taxes are recorded on an accrual basis. These taxes therefore, represent the allowances for taxes paid or to be paid for the year, calculated according to the current enacted rates and applicable laws. Due to the tax loss position reported, no income taxes were due for the years ended December 31, 2025, 2024 and 2023.

As of each reporting date, we consider existing evidence, both positive and negative, that could impact our view regarding the future realization of deferred tax assets. We believe that it is more likely than not that the benefit for deferred tax assets will not be realized. In recognition of this uncertainty, a full valuation allowance was applied to the deferred tax assets. Future realization depends on our future earnings, if any, the timing, and amount of which are uncertain as of December 31, 2025. In the future, should we conclude that it is more likely than not that the deferred tax assets are partially or fully realizable, the valuation allowance would be reduced to the extent of such expected realization, and the amount would be recognized as a deferred income tax benefit in our Consolidated Statements of Operations and Comprehensive Loss.

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

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

In line with the legislation in force, as updated by the Italian Budget Law 2022, companies in Italy that invested in eligible research and development activities, regardless of the legal form and economic sector in which they operate, can benefit from a tax credit up to 10% of the increase of annual research and development expenses incurred, up to a maximum of €5.0 million, which can be used as compensation to reduce most taxes payable, including income tax or regional tax on productive activities, as well as of social security contributions. In addition, the tax credit due can only be used as compensation in three equal annual installments. The measure is provided up to the tax period ending December 31, 2031; however, starting with the fiscal year 2023, and in respect to subsequent fiscal periods, the tax credit rate was reduced from 20% to 10% of the eligible expenses, and the annual ceiling of the credit was increased from €4.0 million to €5.0 million.

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

For the years ended December 31, 2025, 2024, and 2023, we recorded research and development tax benefits of approximately €264,183, €373,000, and €428,000, respectively.

Results of Operations

Comparison of Year Ended December 31, 2025 to Year Ended December 31, 2024

The following table summarizes our results of operations for the years ended December 31, 2025, and 2024, where we had only the biotechnology segment:

	Year Ended December 31,	
	2025	2024
	(in Euros)	
Operating expenses		
Research and development	€ 2,699,342	€ 4,812,854
General and administrative	3,904,398	4,951,456
Total operating expenses	6,603,740	9,764,310
Loss from operations	(6,603,740)	(9,764,310)
Other income (expense)		
Other income	11,456	529,683
Finance income	608,508	81,140
Net exchange rate gain (loss)	(546,051)	240,992
Total other income, net	73,913	851,815
Loss before income taxes	(6,529,827)	(8,912,495)
Income tax benefit (expense)	-	-
Net loss	€ (6,529,827)	€ (8,912,495)
Net loss per share - basic	€ (0.33)	€ (0.49)
Weighted average number of shares outstanding - basic and diluted	19,710,187	18,273,490
Other comprehensive income (loss)		
Total change of marketable debt securities	7,205	(118,750)
Change in foreign currency translation	70,360	(23,446)
Total other comprehensive income (loss)	77,565	(142,196)
Comprehensive loss	€ (6,452,262)	€ (9,054,691)

We have presented basic and diluted loss per share as of December 31, 2025, which consists of our historical loss divided by the basic and diluted weighted average number of ordinary shares outstanding of December 31, 2025. There was no dilutive impact due to our net loss position.

Research and Development Expenses

Research and development expenses were approximately €2.7 million for the year ended December 31, 2025, as compared to approximately €4.8 million for the year ended December 31, 2024.

The decrease of €2.1 million was mainly due to:

(1) a decrease in manufacturing costs of approximately €1.2 million primarily due to: (i) lower Drug Product manufacturing activity in 2025, with costs incurred for two batch slots for TEM-GU and none for TEM-GBM, compared to 2024, when four batch slots for TEM-GBM and one batch slot for TEM-GU were produced; (ii) the reclassification of Lentiviral Vector (LVV) production costs, which in 2024 were recorded within manufacturing costs but in 2025 were allocated to manufacturing associated activities account, as such costs relate across multiple studies and projects; and (iii) the benefit of an R&D tax credit offset recognized in 2025;

(2) a decrease in CRO fees of approximately €0.4 million primarily due to: (i) changes in clinical trial activity, as both the TEM-GBM and TEM-GU trials were active in 2024, whereas in 2025 the Company's focus shifted primarily to TEM-GU, resulting in reduced CRO activity and costs for TEM-GBM; (ii) higher CRO costs recorded in 2024 in connection with the TEM-GU trial, including the upfront billing of 15% of total project costs at project commencement; (iii) a slowdown in patient enrollment for the TEM-GU trial beginning in the second half of 2025, which reduced CRO-related activity; and (iv) amendments to the CRO contracts in November 2025 introducing an "on-hold" period, which reduced CRO fees to minimum levels and resulted in the reimbursement of the previously billed 15% upfront TEM-GU project costs;

(3) a decrease in clinical trial costs of approximately €0.2 million, primarily due to the absence in 2025 of patient enrolment and site-related activities incurred in 2024 in connection with the TEM-GBM study;
(4) a decrease in external research and development of approximately €0.1 million, primarily related to lower costs for exploratory analyses and Data Monitoring Committee activities. Exploratory analysis costs were higher in 2024 in connection with the TEM-GBM study, while in 2025 the Company's activities were mainly focused on the TEM-GU study, which was in its initial clinical trial phase and did not require comparable analyses. The decrease was further impacted by lower patient enrollment during the second half of 2025. In addition, DMC-related costs decreased due to one DMC meeting held in 2025 compared to two DMC meetings held in 2024;
(5) an increase of approximately €0.4 million in manufacturing activities, mainly due to an exclusive GMP suite and dedicated team costs incurred under an agreement entered into with AGC at the beginning of fiscal year 2025. Manufacturing activities in 2025 benefited from an R&D tax credit offset, and accordingly, the underlying increase would have been higher in the absence of this offset.
(6) a decrease of approximately €0.1 million in consultant costs, primarily due to cost-saving amendments to existing consulting contracts and reduced consulting activity in 2025. Consulting agreements with our co-founders (Drs. Naldini and Gentner) were reviewed and reduced, and several consultant contracts were not renewed. In addition, recurring R&D consulting activities were significantly reduced during the second half of 2025.
(7) a decrease in compensation of approximately €0.5 million primarily due to: (1) the reversal of bonus accruals recorded in during 2023 and 2024 for the CMO, which were not subsequently confirmed and therefore were not paid during 2025; (2) the absence of any bonus accruals for the year 2025 following a change in our bonus recognition policy, whereby bonuses are recognized only upon Board approval; and (3) the resignation of our CMO at the end of September 2025.

General and Administrative Expenses

General and administrative expenses were approximately €3.9 million for the year ended December 31, 2025, compared to approximately €5.0 million for the year ended December 31, 2024. The decrease of approximately €1.1 million was primarily driven by a reduction in personnel-related costs of approximately €0.5 million, mainly attributable to lower employee and related-party compensation following changes in our headcount and bonus compensation arrangements during 2025. In addition, consulting, legal, and professional fees and other expenses decreased by approximately €0.5 million, primarily reflecting the conclusion of certain consulting engagements, lower audit-related costs compared to the prior year, and a decrease in patent maintenance costs.

Other income (expense)

Other income was €11,456 for the year ended December 31, 2025, compared to approximately €0.5 million for the year ended December 31, 2024. The decrease was primarily due to a reclassification from other income to finance income, mainly relating to interest income and the reimbursement of financial fees from BNY related to our American Depositary Shares ("ADSs"), to better reflect the nature of the income.

Net finance income was approximately €0.6 million for the year ended December 31, 2025, compared to net finance income of approximately €0.1 million for the year ended December 31, 2024. The increase primarily reflects the reclassification described above.

Finance income amounted to approximately €1.1 million and included financial interest income of approximately €0.4 million and the reimbursement of financial fees from BNY of approximately €0.7 million. Finance expenses amounted to approximately €0.5 million, mainly related to due diligence expenses and the unrealized fair value adjustment associated with the mandatory convertible bond.

Net exchange rate gain (loss)

We had a net exchange loss of approximately €0.5 million for the year ended December 31, 2025, compared to a net exchange gain of approximately €0.2 million for the year ended December 31, 2024. The change compared to the preceding year was mainly due to the adverse fluctuation of the USD versus the Euro exchange rate.

Net Loss

As a result of the foregoing, our net loss was approximately €6.5 million for the year ended December 31, 2025, as compared to approximately €8.9 million for the year ended December 31, 2024. The decrease in our net loss of approximately €2.4 million was primarily due to a decrease in research and development expenses of approximately €2.1 million, a decrease in general and administrative expenses of approximately €1.0 million, and an adverse exchange rate fluctuation effect of approximately €0.8 million compared to the previous year.

Comparison of Year Ended December 31, 2024 to Year Ended December 31, 2023

The following table summarizes our results of operations for the years ended December 31, 2024, and 2023:

	Year Ended December 31,	
	2024	2023
	(in Euros)	
Operating expenses		
Research and development	€ 4,812,853	€ 6,474,441
General and administrative	4,951,456	5,258,501
Total operating expenses	9,764,310	11,732,942
Loss from operations	(9,764,310)	(11,732,942)
Other income (expense)		
Others income (expense)	529,683	(4,875)
Finance income	81,140	309,253
Net exchange rate gain (loss)	240,992	(216,891)
Total other income, net	851,815	87,487
Loss before income taxes	(8,912,495)	(11,645,455)
Income tax benefit (expense)	-	-
Net loss	€ (8,912,495)	€ (11,645,455)
Net loss per share - basic	€ (0.49)	€ (0.64)
Weighted average number of shares outstanding - basic and diluted	18,273,490	18,216,907
Other comprehensive income (loss)		
Total change of marketable debt securities	(118,750)	214,984
Change in foreign currency translation	(23,446)	(15,853)
Total other comprehensive income (loss)	(142,196)	199,131
Comprehensive loss	€ (9,054,691)	€ (11,446,324)

We have presented basic and diluted loss per share of December 31, 2024, which consists of our historical loss divided by the basic and diluted weighted average number of ordinary shares outstanding of December 31, 2024. There was no dilutive impact due to our net loss position.

Research and Development Expenses

Research and development expenses were approximately €4.8 million for the year ended December 31, 2024, as compared to approximately €6.5 million for the year ended December 31, 2023.

The decrease of €1.7 million was mainly due to:

(1) a decrease in manufacturing costs of approximately €0.4 million, as a net result of: i) a decrease in manufacturing activities and plasmid preparation of Lentiviral Vector ("LVV") of approximately €0.7 million; and ii) an increase in CRO fees due to the commencement in October 2024 of the TEM-GU clinical trial of approximately €0.3 million;
(2) a decrease in manufacturing costs of approximately €0.4 million related to the final phase of the scale-up manufacturing of LVV for gene therapy, mostly incurred in 2023;
(3) a decrease of approximately €0.3 million in the costs associated with the technology transfer from the AGC Biologics' Olgettina facility to its Bresso site for drug product manufacturing, mostly completed in 2023;
(4) a decrease in trial costs of approximately €0.1 million as a net result of: i) a decrease in trial costs related to the last cohort of our TEM-GBM Phase 1 dose-ranging study completed in May 2024, for approximately €0.2 million; and ii) an increase in trial costs related to TEM-GU clinical trial commenced in October 2024 of approximately €0.1 million; and
(5) a decrease in fees to OSR of approximately €0.5 million in line with the fee payment schedule provided by the ARLA and related Sponsored Research Agreement.

General and Administrative Expenses

General and administrative expenses were approximately €5.0 million for the year ended December 31, 2024, as compared to approximately €5.3 million for the year ended December 31, 2023. The decrease of approximately €0.3 million was primarily due to a reduction in compensation expense, including stock option expenses of approximately €0.2 million as a result of two (2) employees who left the company in the second half of 2024, and a cumulative reduction of approximately €0.1 million in other general and administrative expenses mainly related to audit costs and insurance costs.

Other income (expense)

Other income (expense) was approximately €0.5 million at December 31, 2024, while other income (expense) was not material for the year ended December 31, 2023. The reason for this change was due to an increase in capital gain income from favorable performance of our financial investments.

Our net financial income was approximately €0.1 million for the year ended December 31, 2024, compared to a net financial income of approximately €0.3 million for the year ended December 31, 2023. The change was mainly related to financial interest income on financial investments made in 2024 and 2023 in U.S. Treasury bills and Italian government bonds.

Net exchange rate gain (loss)

The net exchange gain was approximately €0.3 million for the year ended December 31, 2024, compared to a net exchange loss of approximately €0.2 million for the year ended December 31, 2023. The change in respect of the preceding year was due to the fluctuation of the USD versus Euro exchange rate.

Net Loss

As a result of the foregoing, our net loss was approximately €8.9 million for the year ended December 31, 2024, as compared to approximately €11.6 million for the year ended December 31, 2023. The decrease in our net loss of approximately €2.7 million was primarily due to a decrease in research and development expenses of approximately €1.6 million, a decrease in general and administrative expenses of approximately €0.3 million, an increase in net financial income of approximately €0.3 million, and a positive exchange rate fluctuation effect of approximately €0.5 million compared to the previous year.

Critical Accounting Policies

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

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

Accrued Research and Development Expenses

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

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

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

Share-based compensation

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

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

Research and Development Tax Credit Receivables

We recognize our research and development tax credit receivable 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 taxes can be carried forward indefinitely, we recognized an amount that reflects management's best estimate of the amount that is reasonably assured to be realized or utilized in the foreseeable future based on historical benefits realized, adjusted for expected changes, as applicable.

Emerging Growth Company Status

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

Off-Balance Sheet Arrangements

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

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

Quantitative and Qualitative Disclosure About Market Risk

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

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

Foreign Currency Exchange Risk

Our results of operations and cash flow may be subject to significant fluctuations due to changes in foreign currency exchange rates. Our liquid assets and our expenses are denominated in EUR and USD.

As we continue to grow our business, our results of operations and our cash flows might be subject to significant fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations.

A hypothetical movement of 10% in USD to the EUR exchange rate would have had an impact of approximately €0.3 million on our net result for the year ended December 31, 2025.

Currently, 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.

B. Liquidity and Capital Resources

Overview

Since inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sales of quotas, in prior years as an S.r.l., and through our shares, in our IPO and follow on offerings as an S.p.A. We received gross cash proceeds of approximately €33.6 million from sales of quotas prior to our IPO, approximately €32.7 million of gross proceeds from the IPO and approximately €3.4 million from our at-the-market ("ATM") offerings. Additionally, we received approximately €11.8, net cash proceeds from the registered direct offering (the "Registered Offering") in October 2025.

As of December 31, 2025, we had approximately €28.1 million in cash and cash equivalents and marketable securities.

The table below presents our cash flow for the years indicated:

	For the Year Ended December 31,		
	2025	**2024**	**2023**
	(in Euros)		
Net cash used in operating activities	€ (6,867,959)	€ (6,240,174)	€ (11,205,023)
Net cash (used in)/produced by investing activities	(14,543,936)	6,883,064	(14,892,666)
Net cash provided by financing activities	22,287,458	270,885	531
Effect of exchange rate changes	70,360	(23,446)	(6,278)
Net (decrease) increase in cash and cash equivalents	€ 945,923	€ 890,329	€ (26,103,436)
Cash and cash equivalents at beginning of the year	4,581,749	3,691,420	29,794,856
Cash and cash equivalents at end of the year	€ 5,527,672	€ 4,581,749	€ 3,691,420

Operating Activities

During the year ended December 31, 2025, operating activities used approximately €6.9 million of cash, cash equivalents, and marketable securities. This cash outflow resulted from our net loss of approximately €6.5 million, adjusted for non-cash charges of approximately €1.2 million, and further impacted by net cash used in changes in operating assets and liabilities of approximately €1.6 million.

Non-cash charges primarily included €1.0 million of share-based compensation expense, €0.1 million of retirement benefit obligation expense, €0.1 million of fair value loss on the convertible bond and other minor amounts, including depreciation expense and a fair value adjustment on available-for-sale financial instruments.

Net changes in operating assets and liabilities primarily reflected an increase in other non-current assets of approximately €1.6 million and a decrease in accrued expenses-related parties of approximately €1.1 million, which were partially offset by an increase in accounts payable of approximately €1.2 million.

During the year ended December 31, 2024, operating activities used approximately €6.2 million of cash, cash equivalents, and marketable securities, resulting from our net loss of approximately €8.9 million, partially offset by non-cash charges of approximately €1.0 million and the cash generated by our operating assets and liabilities of approximately €1.7 million. The non-cash charges primarily included approximately €0.8 million of share-based compensation expense, and approximately €0.1 million of depreciation and retirement benefit obligation expense.

The net cash inflow from operating assets and liabilities was primarily driven by a decrease in other non-current assets of approximately €0.7 million (manly due to a long-term VAT refund of approximately €0.4 million) and a decrease in prepaid expenses and other current assets of approximately €0.7 million (mainly due to a decrease in the R&D tax credit valuation), partially offset by modest increases in accrued expenses – related parties and accounts payable.
During the year ended December 31, 2023, operating activities used approximately €11.0 million of cash and cash equivalents, resulting from our net loss of approximately €11.6 million, partially offset by non-cash charges of approximately €1.1 million and the cash generated by our operating assets and liabilities of approximately €0.4 million. The non-cash charges primarily included approximately €0.7 million of share-based compensation expense, approximately €0.2 million of unrealized gain on purchase of marketable securities, and other minor amounts of depreciation, retirement benefit obligation expense and cumulative translation adjustment. The net changes in our operating assets and liabilities were primarily due to a decrease in accounts payable. The decrease in accounts payable compared to the prior period, was mainly due to bills from certain suppliers, advisors, and legal consultants received in December 2022 that were paid in 2023.

Investing Activities

We invest liquidity not immediately required for current operations in accordance with our internal treasury policy, which provides for investments in low-risk, highly liquid financial instruments, primarily government securities. These investments are intended to preserve capital while generating modest returns on excess cash balances.

During the year ended December 31, 2025, investing activities used approximately €14.5 million of cash, cash equivalents, and marketable securities, primarily reflecting net investments in marketable securities. Purchases of marketable securities, consisting of U.S. Treasury bills and Italian government bonds, amounted to approximately €33.2 million and were partially offset by proceeds from maturities of marketable securities of approximately €18.6 million. Investing activities also included purchases of fixed assets of approximately €7,600, mainly consisting of laptops and other work tools for employees.

During the year ended December 31, 2024, investing activities used approximately €16.4 million for the purchase of marketable securities, consisting of U.S. Treasury bills and Italian government bonds. Proceeds from maturities and sales of marketable securities amounted to approximately €23.2 million.

In addition, approximately €4,000 of our cash and cash equivalents were used to primarily purchase laptops and other work tools for new employees hired during the fiscal year ending on December 31, 2024.
During the year ended December 31, 2023, investing activities used approximately €14.9 million to purchase marketable securities (U.S. treasury bills and Italian government bonds), in order to deploy the liquidity available and not used in current operations more profitably, while respecting the principle of selecting low-risk profile assets. In addition, approximately €14,000 of our cash and cash equivalents were used to primarily purchase laptops and other work tools for new employees hired during the fiscal year ending on December 31, 2023.

Financing Activities

During the year ended December 31, 2025, the net cash provided by financing activities mainly relates to net proceeds of €7.5 million from the issuance of a convertible bond, net proceeds of approximately €3.0 million raised through our ATM program, and net proceeds of approximately €11.8 million from our registered direct offering.

During the year ended December 31, 2024, the net cash provided by financing activities of approximately €0.3 million related to the proceeds from our ATM offerings.

During the year ended December 31, 2023, there was no cash provided by financing activities.

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. We may begin to generate revenue from acquisition targets once we own more than 20% of an acquired company (i.e., through a partial consolidation) or once we own more than 50% of an acquired company (i.e., through a full consolidation).

As of December 31, 2025, our cash, cash equivalents, and marketable securities were approximately €28.1 million.

Based on our existing cash and anticipated cash from short-term financing activities, we estimate that such funds will be sufficient to fund our operations and capital expenditure requirements to at least December 31, 2027. 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.

Our operating plans may change as a result of factors that are currently uncertain, including ongoing legal proceedings, our strategic transformation into a next-generation industrial consolidator, and/or the results of our research and development activities.

Our future capital requirements and financial condition will depend on many factors, including:

● the costs, timing, and outcome of ongoing and potential legal proceedings and related matters;

● expenses associated with the continuation or suspension of our research and development activities, including employee-related costs;
● our ability to restructure, renegotiate, or terminate existing agreements, including manufacturing, licensing, and collaboration arrangements;
● the costs of maintaining, defending, or monetizing our intellectual property portfolio;
● any obligations arising under existing in-licensing or other contractual arrangements;
● our ability to pursue strategic alternatives, including business combinations, licensing transactions, or other restructuring transactions;
● the costs of future acquisition activities, as we evolve into a next-generation strategic industrial consolidator, including the cost related to acquiring and supporting businesses operating in national-security regulated sectors contemplated by the "Golden Power" legislation;
● the administrative and compliance costs of transitioning to an industrial consolidator; and,
● the magnitude of our remaining general and administrative expenses necessary to maintain our corporate existence and comply with applicable legal and regulatory requirements.

Until we can generate significant revenues, if ever, we expect to satisfy our future cash needs through our existing cash, cash equivalents, short-term deposits, and short-term marketable securities as well as through additional financings, which we may seek through a combination of private and public equity offerings, debt financings and collaboration, in-licensing arrangements, joint ventures, strategic alliances or partnerships.

For example, on May 12, 2023, we filed with the SEC a shelf registration statement, which was declared effective by the SEC on May 24, 2023 and permits us to sell from time to time additional ordinary shares, ordinary shares represented by ADSs or rights exercisable for ordinary shares or ADSs in one or more offerings in amounts, at prices and on the terms that we will determine at the time of offering for aggregate gross sales proceeds of up to $100.0 million. As of December 31, 2025, approximately $86.0 million worth of securities remained available under this registration statement. Furthermore, we have entered into an ATM sales agreement, as amended (the "Sales Agreement"), with Virtu Americas LLC and Rodman & Renshaw LLC (the "Sales Agents") pursuant to which we may, but are not obligated to, offer and sell, from time to time, ADSs with an aggregate offering price up to $29,696,999 through the Sales Agents, subject to the terms and conditions described in the Sales Agreement and SEC rules and regulations (our "ATM offering"). As of December 31, 2025, approximately $26.4 million of capacity remained available under this ATM offering.

In addition, in March 2025, we completed a mandatory convertible bond financing, pursuant to which we received the first tranche of €7,500,000, as part of a broader financing transaction totaling €20,000,000, pursuant to the agreement with Fondazione Enea Tech e Biomedical (the "Investor") signed on March 12, 2025.

In October 2025, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors (each, an "Investor") relating to the offer and sale of 4,285,715 ADSs, at a purchase price of $3.50 per ADS, for net proceeds of €11,810,398 (gross proceeds of $15,000,000) in a registered direct offering (the "Registered Offering"). Please see Note 1 – Nature of business and history – Shelf Registration Statement and Sales Agreement of our audited consolidated financial statements for further information.

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 our available cash, cash equivalents, and marketable securities to in-license, acquire, or invest in additional businesses, technologies, products, or assets.

C. Research and Development

See "Item 4. Information on the Company -B. Business Overview -Intellectual Property Rights."

D. Trend Information

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events for the fiscal year ended December 31, 2025 that are reasonably likely to have a material and adverse effect on our net revenues, income, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future results of operations or financial conditions.

E. Critical Accounting Estimates

For our critical accounting estimates, see "Item 5. Operating and Financial Review and Prospects - A. Operating Results - Critical Accounting Policies."

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The members of the Board of Directors (the "Board") at December 31, 2025 were: Pierluigi Paracchi, who is the Chairman, Francesco Galimi, MD, PhD, Miguel Maria Mutti, Giacomoantonio Paracchi, and Armon R. Sharei, PhD.

The following table sets forth the name, age as of March 26, 2026, and position of the individuals who serve as our directors and executive officers. The following also includes certain information regarding the individual experience, qualifications, attributes, and skills of our directors and executive officers, as well as brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors:

Name	Age	Position	Year elected or appointed
Pierluigi Paracchi	52	Chief Executive Officer, Chairman of the Board of Directors, and General Manager	2014
Francesco Galimi	58	Director, Acting Chief Medical Officer and Head of Development (4)	2025
Miguel Maria Mutti	51	Director (1) (2)	2025
Giacomoantonio Paracchi	48	Director (3)	2025
Armon Reza Sharei	38	Director (1) (2)	2024
Richard B. Slansky	68	Chief Financial Officer	2021

(1) Independent Director (as defined under Nasdaq Stock Market rules)

(2) Member of the Compensation, Nomination, and Governance Committee

(3) Non – independent Director - Mr. Giacomoantonio Paracchi is the brother of Pierluigi Paracchi, the Company's Chief Executive Officer

(4) Non – independent Director – Dr. Galimi assumed the role of Acting Chief Medical Officer and Head of Development in October 2025

The Board consists of five (5) members, and each of their terms will expire at our general shareholders' meeting called to approve the financial statements for the year ending December 31, 2025 to be held in June/July 2026, or earlier upon resignation. The aggregate annual directors' compensation for the entire board is €165,000.

Pierluigi Paracchi, Chief Executive Officer, Chairman of the Board of Directors, and General Manager

Mr. Paracchi has over 15 years of combined experience as an investor and director of life science companies, including as Founder and CEO of Quantica SGR and in senior roles at Axòn Capital, Sofinnova Partners, and AurorA Science. He was also a board member and investor in Ethical Oncology Science, which was acquired in 2013 for a total deal of $470 million. Mr. Paracchi is a member of the Assobiotec Steering Committee, the Italian Association for the development of biotechnology. He also serves on the board of directors of the autoimmune disease and cancer company Altheia Science, as non-executive Chairman, at a medical device company, Lipogems International, and is a venture partner with AurorA Science, an independent biotech investment vehicle.

Richard B. Slansky, Chief Financial Officer

Mr. Slansky is a senior financial executive with more than 30 years of experience as Chief Financial Officer in various biopharmaceutical, diagnostic, high-tech, and life science companies, including Biological Dynamics, OncoSec Medical, GenMark Diagnostics, (now part of Roche), and C-N Biosciences, (now a part of Millipore Sigma, a division of Merck KGaA). His experience spans across public and private healthcare and technology companies at various stages of growth, from pre-revenue to commercial. He has been responsible for strategic vision and oversight of financial and operational teams, organizational leadership, creating maximum stakeholder value, financial and governmental compliance, among other activities. He also serves on the board of directors of several private companies in the life science, aerospace, and real estate market segments.

Francesco Galimi, M.D., Ph.D., Acting Chief Medical Officer and Head of Development

Dr. Galimi is a physician-executive with over 30 years of experience in healthcare R&D, including leadership roles in private and public biotechs, as well as large pharma companies. Most recently, he was Senior Vice President and Chief Medical Officer at Adicet Bio, a company focused on allogeneic cell therapy technologies in hemato-oncology and autoimmune disorders. Previously, he served as Global Program General Manager at Amgen, where he led a portfolio of oncology programs, from pre-IND to late-stage. Prior to Amgen, Dr. Galimi was Head of Clinical Development at Onyx Pharmaceuticals and Executive Medical Leader at GNF/Novartis. Dr. Galimi holds an M.D. from the University of Torino Medical School with a specialty certification in Medical Oncology, and a Ph.D. in Oncology from the University of Torino Medical School. He conducted his post-doctoral research, focused on gene transfer models in hematology, at the Salk Institute in La Jolla, California.

Board of Directors

Armon Reza Sharei, Ph.D., Director

Armon is Founder and CEO of Portal Bio and formerly the CEO and Founder of SQZ Biotechnologies (NYSE: SQZ), where he led the company from invention to post-IPO with over $300M in equity financing, a $1Bn collaboration with Roche, and three clinical trials. He graduated from Stanford University, obtained his PhD at Massachusetts Institute of Technology, and received his Post-Doctoral at Harvard Medical School.

Miguel Maria Mutti, Director

Mr. Mutti is a senior executive with over 25 years of international experience in the pharmaceutical and investment banking sectors. He has a proven track record in corporate and business development, M&A, licensing, and general management, having led major growth, restructuring, and integration projects across Europe, Latin America, and Asia. Currently, he serves as Managing Partner at Sinergetica Healthcare, a strategic consulting and investment firm focused on pharma, biotech, and medtech. Previously, he held senior leadership roles at Lupin Limited, Grünenthal GmbH, Chemo Group, and Citigroup. Mr. Mutti combines strategic vision, financial expertise, and hands-on operational leadership, supported by an MBA from ISTUD and executive training at INSEAD. He is fluent in Italian, Spanish, and English.

Giacomoantonio Paracchi, Director

Mr. Paracchi is a business lawyer with extensive experience as General Counsel and Head of Legal & Corporate Affairs within structured multinational groups. Since September 2023, he has been serving as General Counsel of the Geodis Group, and since May 2025, he has also joined LEXIA as a Partner in the Corporate, M&A, and Capital Markets Department. Previously, he held senior legal and corporate positions at Comifar Group, Valtellina Group, and Techint Group, overseeing legal, corporate affairs, and compliance functions. His professional background is complemented by an excellent command of the English language and a strong focus on business-oriented legal strategy. Mr. Paracchi is the brother of Pierluigi Paracchi, the Company's Chief Executive Officer, Chairman, General Manager, and cofounder.

Executive Scientific Board

As of December 31, 2025, the mandates of the members of our Executive Scientific Board expired and were not renewed. Accordingly, the Executive Scientific Board is no longer active, and we do not currently maintain an Executive Scientific Board.

Until December 31, 2025, the Executive Scientific Board provided scientific and strategic advisory support to us in connection with our research and development activities.

Strategic Advisors

Advisors to the Company include:

Daiwa Corporate Advisory

Following the achievement of key clinical milestones, we engaged DC Advisory as our exclusive financial advisor to support strategic partnering initiatives relating to our cell therapy platform and the Temferon clinical program. DC Advisory's mandate includes identifying potential pharmaceutical and biotechnology partners to advance Temferon, leveraging available clinical data, including information on tumour microenvironment modulation ("TME"), safety profile, and certain observed long-term survival outcomes. Our partnering strategy is intended to support the continued development of Temferon, including as a monotherapy in glioblastoma multiforme, as well as to explore broader applications of our technology platform, including combination therapy approaches and additional solid tumor indications, while maintaining a capital-efficient development strategy and continuing the ongoing GBM clinical trial.

Family Relationships

As mentioned above, Mr. Giacomoantonio Paracchi, a member of the Company's Board of Directors, is the brother of Pierluigi Paracchi, the Company's Chief Executive Officer, Chairman, General Manager, and co-founder.

Arrangements Concerning Election of Directors and Members of Management

There are no arrangements or understandings with major shareholders, customers, suppliers, or others pursuant to which any of our directors or members of senior management were selected as such.

B. Compensation

The following table presents in the aggregate all compensation we paid to all our directors and senior management as a group for the year ended December 31, 2025. The table does not include any amounts we paid to reimburse any of such persons for costs incurred in providing us with services during this period. We are not required to provide the compensation, on an individual basis, of our executive officers and directors under Italian law. As a matter of Italian law, the compensation of directors is established at the time of their appointment or by the shareholders' meeting. The compensation of the managing directors shall be established by the board of directors, with the opinion of the board of statutory auditors. Our bylaws provide that the shareholders' meeting may determine a total amount for the compensation of the directors, including managing directors.

The total amount paid to all directors and senior managers as a group was approximately €1.4 million for the year ended December 31, 2025.

	Salary, Bonuses, and Related Benefits	Pension, Retirement, and Other Similar Benefits	Share-Based Compensation
All directors and senior management as a group, consisting of six (6) persons	€ 1,415,414	€ -	€ -

The total cost to us for the year ended December 31, 2025, related to all directors and senior managers as a group was approximately €1.5 million.

	Salary, Bonuses and Related Benefits	Pension, Retirement and Other Similar Benefits	Share-Based Compensation
All directors and senior management as a group, consisting of six (6) persons	€ 1,059,419	€ 60,154	€ 510,014

The difference between the total amount paid by us and the total cost to us, stems from the fact that the cost for each employee is higher than what is actually paid out during each fiscal year due to tax and contribution charges affecting labor costs. Additionally, according to the regulations applicable to Italian employees, severance pay is set aside annually, and thus constitutes a cost to us, while it is disbursed and paid out only in the event of the employee's resignation or dismissal. Furthermore, provisions for unexercised stock options during the fiscal year are also included in our cost based on a Black-Scholes calculation, regardless of the exercise price, (i.e., the options could be "in-the-money" or "out-of-the-money").

C. Board Practices

Committees of the Board of Directors

We currently follow the historical Italian corporate governance system, with a board of directors (*consiglio di amministrazione*) and a separate board of statutory auditors (*collegio sindacale*) with supervisory functions. The two boards are separate, and no individual may be a member of both corporate bodies. Both the members of the board of directors and the members of the board of statutory auditors owe duties of loyalty and care to us. The board of statutory auditors acts as the Board's audit committee for purposes of SEC and Nasdaq compliance (see *Differences between Italian Laws and Nasdaq Requirements* below).

Board of Statutory Auditors

Our Board of Statutory Auditors for the three-year period of 2024-2026 consists of: Carlo Alberto Nicchio (Chairman), Jacopo Doveri, and Giuseppe Gentile, while Luca Domenico Maranzana and Adalberto Adriano Minazzi were appointed as alternates. The annual Board of Statutory Auditor compensation is €18,000 for the chairman and €12,000 for each active member, while no compensation is provided for the alternates unless they replace an active member.

During 2025, our Board of Statutory Auditors received aggregate compensation of approximately €44,000 for their services to us, of which €31,200 related to compensation accrued as of December 31, 2025, for invoices not yet received.

Our Board of Statutory Auditors' term will expire with our general shareholders' meeting called to approve the financial statements for the year ending December 31, 2026, to be held in 2027. The following table sets forth the name, age as of March 26, 2026, and position of the individuals who serve as our Board of Statutory Auditors, and their alternates.

Name	Age	Position	Year elected or re-appointed
Carlo-Alberto Nicchio	51	Chairman of the Board of Statutory Auditors	2024
Giuseppe Gentile	58	Statutory auditor	2024
Jacopo Doveri	53	Statutory auditor	2024
Luca Domenico Maranzana	58	Alternate auditor	2024
Adalberto Adriano Minazzi	76	Alternate auditor	2024

Each shareholder and shareholders belonging to the same group shall not submit, or contribute to submit, or to cast their vote for more than one slate, including through a nominee. Each candidate may only be listed on a single slate or, otherwise, will be ineligible for election if named in multiple slates.

We rely on an exemption from the Rule 10A-3 requirements provided by Rule 10A-3(c)(3) of the Exchange Act for foreign private issuers with a board of statutory auditors established in accordance with local law or listing requirements and subject to independence requirements under local law or listing requirements.

Additional Board Committees

Although Italian law does not require that we adopt a Compensation, Nomination and Governance Committee according to Nasdaq Listing Rule 5615(a)(3). The members of our Compensation, Nomination, and Governance Committee include: Armon R. Sharei and Miguel Maria Mutti. They were nominated on April 30, 2025. The Compensation, Nomination, and Governance Committee assists our Board of Directors in overseeing our compensation and equity award recommendations for our executive officers, along with the rationale for such recommendations, as well as summary information regarding the aggregate compensation provided to our executive officers, among other functions.

Differences between Italian Laws and Nasdaq Requirements

The Sarbanes-Oxley Act, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, such as us, to comply with various corporate governance practices. In addition, following the listing of the ADSs on Nasdaq, we are required to comply with the Nasdaq Stock Market Rules. Under those rules, we may elect to follow certain corporate governance practices permitted under Italian law in lieu of compliance with corresponding corporate governance requirements otherwise imposed by the Nasdaq Stock Market Rules for U.S. domestic registrants.

In accordance with Italian law and practice and subject to the exemption set forth in Rule 5615 of the Nasdaq Stock Market Rules, as a foreign private issuer, we have elected to rely on home country governance requirements and certain exemptions thereunder rather than the Nasdaq Stock Market Rules, with respect to the following requirements:

- *Composition of the board of directors*. Italian law does not require that the majority of our board of directors consist of independent directors. Our board of directors, therefore, may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present.

- *Quorum*. In accordance with Italian law quorum requirements generally applicable to general meetings of shareholders are set forth in the Italian Civil Code, therefore, our bylaws may not provide a specific regulation of them. Our practice thus varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

  According to Italian law, the management report and the annual financial statements shall be presented to our auditors and to the board of statutory auditors at least 30 days prior to the general meeting of shareholders convened for its approval. The board of statutory auditors must report to the shareholders' meeting on the results of the financial year and on the activities carried out in the performance of its duties, and make observations and proposals regarding the financial statements and their approval. The financial statements, together with the reports of the directors, statutory auditors, and our auditors, must remain deposited at our registered office for the 15 days preceding the shareholders' meeting called to approve them.

- *Proxy Solicitations*. Under Italian law shareholders may appoint attorneys-in-fact by delivering in writing an appropriate power of attorney to represent them in an ordinary or extraordinary shareholders' meeting of the Company. Our directors, auditors, and employees may not be proxies. Italian law does not have a specific regulatory regime for the solicitation of proxies in private companies; thus, our practice varies from the requirements of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies.

- *Share Issuances*. Pursuant to Italian law, we have opted out of shareholder approval requirements by way of including authorized and conditional share capital for the issuance of securities in connection with certain events such as the acquisition of stock, assets, or convertible notes, certain private placements, and/or public offerings. To this extent, our practice varies from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

- *Audit Committee*. U.S. companies listed on Nasdaq are required to have an audit committee that satisfies the requirements of Rule 10A-3 under the Exchange Act and certain additional requirements set by the Nasdaq. All members of this committee must be independent, and the committee must adopt a written charter. The committee's prescribed responsibilities include: (i) the appointment, compensation, retention and oversight of the external auditors; (ii) establishing procedures for handling "whistle blower" complaints regarding accounting, internal accounting controls, or auditing matters; (iii) engaging independent counsel and other advisers, as it determines necessary to carry out its duties; and (iv) determine appropriate funding for payments to the external auditor, advisors employed by the audit committee and other necessary administrative expenses of the audit committee. A company must also have an internal audit function, which may be outsourced, but not to the independent auditor. We follow the "traditional" model of corporate governance for Italian companies and accordingly have established a board of statutory auditors established in accordance with Italian law, which performs substantially the same functions and is accordingly exempt from the audit committee requirements established by Rule 10A-3 and Nasdaq rules. Our reliance on such exemption is based on the circumstance that our board of statutory auditors meets the following requirements set forth in Exchange Act Rule 10A-3(c)(3):

    (i) the board of statutory auditors is established and selected pursuant to Italian law expressly permitting such a board;

    (ii) the board of statutory auditors is required under Italian law to be separate from our board of directors;

    (iii) the board of statutory auditors is not elected by us, and none of our executive officers are a member of the board of statutory auditors;

    (iv) Italian law provides for standards for the independence of the board of statutory auditors from us; and

    (v) the board of statutory auditors, in accordance with applicable Italian law and our governing documents, is responsible, to the extent permitted by Italian law, for the appointment, retention and oversight of the work (including, to the extent permitted by law, the resolution of disagreements between management and the auditor regarding financial reporting) of any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us.

  Our reliance on Rule 10A-3(c)(3) does not, in our opinion, materially adversely affect the ability of its board of statutory auditors to act independently and to satisfy the other requirements of Rule 10A-3.

- *Compensation Committee*. Italian law does not require the appointment of a compensation committee composed of independent directors as required by the Nasdaq Listing Rules. As a matter of Italian law applicable to Italian stock corporations whose shares are not listed on a regulated market in the E.U. and under our bylaws, the compensation of executive directors, including the CEO, is determined by the board of directors, after consultation with the board of statutory auditors, while our shareholders, according to Italian law and our bylaws, may determine a total amount for the compensation of the directors, including managing directors. Compensation of our executive officers is determined by Board of Directors or by the CEO, if duly empowered. Nevertheless, although not required under Italian law, we have established a Compensation, Nomination, and Governance Committee.

- *Code of Conduct*. Pursuant to Italian law, we have adopted an "Organization and Operational Model" as required by Italian Legislative Decree of June 8, 2001, No. 231 (relating to administrative responsibility) that consists of: (i) a Code of Ethics; and (ii) operating procedures and reporting systems applicable to all of our directors, officers and employees, which may not comply with the requirements for a code of conduct meeting the criteria under Nasdaq Listing Rule 5610.

- *Loyalty Share Program*. As described in more detail in "Item 10. Additional Information. B. Memorandum and Articles of Association" we have established a loyalty share program. Under our loyalty share program, each ordinary share held in registered form entitles the shareholder to a double vote (i.e. two votes for each ordinary share) if the ordinary share has been held by the same shareholder for a continuous period of not less than twenty-four months from the date of its registration in the special list maintained by us, and an additional vote is also granted upon the expiration of each 12-month period following the expiration of the period referred to above, in which such ordinary share has been held by the shareholder, up to a total maximum of ten votes per ordinary share. Pursuant to the home country exemption set forth under Nasdaq Stock Market Rule 5640, in establishing the loyalty share program, we elected to be exempt from the requirement under Nasdaq Stock Market Rule 5640, which provides that the voting rights of existing shareholders of publicly traded common stock registered under Section 12 of the Exchange Act cannot be disparately reduced or restricted through any corporate action or issuance.

As we are a foreign private issuer, our officers, directors and principal shareholders have historically been exempt from the reporting and short-swing profit disclosure and recovery provisions under Section 16 of the Exchange Act. The Holding Foreign Insiders Accountable Act was signed into law on December 18, 2025, and requires directors and officers of foreign private issuers, like us, to file insider reports under Section 16(a) of the Exchange Act, including the requirements to file Forms 3, 4 and 5, effective March 18, 2026. Directors and officers of foreign private issuers will remain exempt from the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act.

D. Employees

As of March 31, 2026, we had nine (9) full-time employees, eight (8) located in Milan, Italy, and one (1) located in the U.S. We also rely on consultants and several collaborators at SR-TIGET and OSR. Our full-time employees are engaged in clinical, research and development, product development, quality assurance, finance, accounting, legal support, and administrative activities. We consider our relationship with our employees to be good.

E. Share Ownership

See "Item 7.A. – Major Shareholders" below.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

None.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information regarding beneficial ownership of our ordinary shares as of March 30, 2026 by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of more than 5% of our outstanding ordinary shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Percentage ownership is based on 23,591,020 ordinary shares (including ordinary shares represented by ADSs) outstanding on March 30, 2026. Beneficial ownership is determined in accordance with the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she, or it possesses sole or shared voting or investment power over that security or has the right to acquire a security, such as through the exercise of stock options, within 60 days. Shares subject to options that are currently exercisable or exercisable within 60 days of the date above are considered outstanding and beneficially owned by the person holding such options for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Our major shareholders do not have different voting rights from other holders of our ordinary shares. The information is not necessarily indicative of beneficial ownership for any other purpose. Unless otherwise noted below, each beneficial owner's address is: c/o Genenta Science S.p.A., Via dell'Annunciata, 31, 20121, Milan, Italy.

	No. of Shares Owned	No. of Shares Vested	No. of Shares Beneficially Owned	Percentage Owned	Voting Rights	Percentage	Notes
Directors and executive officers							
Pierluigi Paracchi	2,302,516	129,936	2,432,452	10.31%	22,755,160	24.11%	1
Richard B. Slansky	22,147	124,596	146,743	*	19,947	*	2
Giacomoantonio Paracchi	-	-	-	*	-	*	3
Miguel M. Mutti	33,333	-	33,333	*	-	*	4
Francesco Galimi	-	46,891	46,891	*	-	*	5
Armon R. Sharei	-	24,274	24,274	*	-	*	6
All directors and executive officers as a group (6 persons)	**2,357,996**	**325,697**	**2,683,693**	**11.38%**	**22,775,107**	**24.13%**	
5% Shareholders							
OSR - San Raffaele Hospital	1,896,730	-	1,896,730	8.04%	18,967,300	20.10%	7
Luigi Naldini	1,386,145	-	1,386,145	5.88%	12,783,667	13.54%	8

* Less than 1%.

(1) Consists of 2,302,516 shares (2,275,516 ordinary shares plus 27,000 ADSs) held by Mr. Paracchi and 129,936 shares underlying options to acquire ADSs of Genenta Science S.p.A. exercisable within 60 days of March 30, 2026. Mr. Paracchi is also enrolled in our loyalty share program and, based on his more than ten-year investment in Genenta Science S.p.A, has the right to 10 votes per share with respect to his ordinary shares.
(2) Consists of 22,147 shares (19,947 ordinary shares plus 2,200 ADSs acquired through a 10b5-1 plan in July & August 2024) held directly by Mr. Slansky and 124,596 ordinary shares underlying options to acquire ordinary shares of Genenta Science S.p.A. exercisable within 60 days of March 30, 2026. Mr. Slansky is not enrolled in our loyalty share program.
(3) Currently, Mr. G. Paracchi holds no shares or options in Genenta Science S.p.A.
(4) Consists of 33,333 ADSs of Genenta Science S.p.A held by Mr. Mutti.
(5) Consists of 46,891 shares underlying options to acquire ADSs of Genenta Science S.p.A. exercisable within 60 days of March 30, 2026.
6) Consists of 24,274 shares underlying options to acquire ADSs of Genenta Science S.p.A. exercisable within 60 days of March 30, 2026.
(7) Consists of 1,896,730 ordinary shares. San Raffaele Hospital is enrolled in our loyalty share program.
(8) Consists of 1,386,145 ordinary shares. Dr. Naldini is enrolled in our loyalty share program.

Significant Changes in Percentage Ownership

Although there have been no significant changes in the percentage ownership held by our major shareholders since the IPO in December 2021, our loyalty share program which was established pursuant to shareholder approval at our 2024 Ordinary and Extraordinary Shareholders' Meeting, gives shareholders the opportunity to receive increased votes for each ordinary share held in registered form after certain continuous periods of ownership of such ordinary shares. Accordingly, shareholders enrolled in the loyalty share program have received increased voting power with respect to qualifying ordinary shares. For more information regarding our loyalty share program, see "Item 10. Additional Information. B. Memorandum and Articles of Association.

Shareholders in the U.S.

To our knowledge, as of March 16, 2026, on the same basis of calculation as above, 59% of our total issued and outstanding ordinary shares were held by one record shareholder in the U.S., namely, The Bank of New York (formerly The Bank of New York Mellon), the depositary of our ADS program, which held 13,960,661 ordinary shares represented by 13,960,661 ADSs, or forty-two (42) brokers and institutional record holders. The actual number of holders is likely greater than these numbers of record holders and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. The number of holders of record also does not include holders whose shares may be held in trust by other entities.

Except for the above, we are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

B. Related Party Transactions

We have not during the most recently completed financial year entered into transactions or loans with any (a) enterprises that are directly or indirectly controlled by or under common control with us; (b) our associates; (c) individuals directly or indirectly owning voting right which give them significant influence over us or close members of their respective families; (d) our directors, senior management or close members of their respective families; or (e) enterprises in which a substantial interest in the voting power is held or significantly influenced by any of the foregoing individuals (a "Related Party"), except as indicated below:

Agreements with OSR - San Raffaele Hospital

We have a longstanding relationship with OSR. Beginning January 1, 2020, we entered into a six-year lease agreement for the use of office space in the OSR building. We paid OSR annual rent of approximately €15,000 in 2025 with a security deposit of €3,350.

We entered into an Amended and Restated License Agreement (the "ARLA") with OSR in March 2023, replacing its prior license arrangement.

The ARLA became effective following the required authorization under Italy's Golden Power regulations (Law Decree No. 21/2012), which was granted by the competent Italian authority on April 20, 2023.

Pursuant to the terms of the ARLA, OSR has granted us an exclusive, royalty-bearing, non-transferrable (except with the prior written consent of OSR), sublicensable, worldwide license, subject to certain retained rights, to: (1) certain patents, patent applications and existing know-how for the use in the field(s) of Interferon ("IFN") gene therapy by lentiviral based-hematopoietic stem and progenitor cells ("HSPC") gene transfer with respect to: any solid cancer indication (including glioblastoma and solid liver cancer) and/or any lympho-hematopoietic indication for which we exercise an option (described below); and (2) certain gene therapy products (subject to certain specified exceptions related to replication competent viruses) developed during the license term for use in the aforementioned field(s) consisting of any lentivirals or other viral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter. Lympho-hematopoietic indication means any indication related to lympho-hematopoietic malignancies and solid cancer indication means any solid cancer indication (e.g., without limitation, breast, pancreas, colon cancer), with each affected human organ counting as a specific solid cancer indication.

On August 1, 2023, we entered into a Sponsored Research Agreement ("CP1 SRA"), which was contemplated under the ARLA, pursuant to which we will fund feasibility studies for certain gene therapy products consisting of any lentiviral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter, in combination with any immunotherapy ("Candidate Products 1"), along with three additional research projects, to be conducted at OSR. If OSR determines that additional funds are needed, OSR will inform us and provide an estimate for completing the research.

On September 28, 2023, we entered into an amendment to the ARLA, whereby we and OSR agreed that we had fulfilled the obligations as set forth in the ARLA specific to Candidate Products 1 pursuant to the CP1 SRA. Furthermore, the amendment provides that we and OSR have no further obligations to negotiate and execute a sponsored research agreement for the performance of feasibility studies related to certain gene therapy products consisting of any lentiviral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of cytokines and their variants (other than IFN or in addition to IFN) under the control of a Tie2 promoter, either alone or in combination with any immunotherapy ("Candidate Products 2"). Notwithstanding the removal of the obligation to enter into a sponsored research agreement with regards to Candidate Products 2, OSR granted us an exclusive option, to be exercised by sending written notice to OSR on or before September 30, 2025, to include certain intellectual property related to Candidate Products 2 and Candidate Products 2 as part of the licensed patents and licensed products under the ARLA. The option fee and our fee to extend the option period, if necessary, remain consistent with the prior fees to those costs reflected in the ARLA specific to Candidate Products 2. OSR will also have the right to prepare, file and prosecute patents and patent applications with respect to the results of Candidate Products 2. The amendment provides that the costs of the foregoing activities will be borne by us.

For more information regarding the ALRA, CP1 SRA and the amendment to the ARLA, see "Item 4. Information on the Company—B. Business Overview —Collaboration / Licensing—Amended and Restated License Agreement with Ospedale San Raffaele" and "—Sponsored Research Agreement."

Employment Agreements with Senior Management

We have employment agreements with our CEO, Mr. Pierluigi Paracchi, and our CFO, Mr. Slansky, while the employment agreement of Dr. Russo, the former Chief Medical Officer and Head of Development, ended with his resignation on September 30, 2025. Dr. Russo's successor, Dr. Galimi, was retained under a consulting agreement.

Mr. Pierluigi Paracchi and Mr. Slansky are entitled to gross annual base salaries of €451,560 and $375,000, respectively. All these employment agreements are subject to annual review by and at the sole discretion of the Compensation, Nomination, and Governance Committee of our board of directors. Mr. Paracchi is also eligible to receive an annual cash bonus of up to 40% of base salary, and Mr. Slansky is eligible to receive an annual cash bonus of up to 30% of base salary, provided that such individual achieves performance targets determined by the Compensation, Nomination and Governance Committee of the board of directors. Neither Mr. Pierluigi Paracchi nor Mr. Slansky received a bonus in 2025. In 2024, Mr. Pierluigi Paracchi received a cash bonus of €168,000, and Mr. Slansky received a cash bonus of $21,093.75 and a fully vested stock option on 7,669 ADSs in lieu of cash at an exercise price of $3.67 per ADS.

The employment agreement of Mr. Slansky, is governed by U.S. law and includes the following terms and conditions, among others:

(a) a term commencing on November 1, 2021, and continuing until terminated: (i) upon death of Mr. Slansky; (ii) upon his disability; (iii) for cause or good reason; (iv) without cause; or (v) voluntarily. The employment agreement also contains, among other things, the following material provisions: (i) reimbursement for all reasonable travel and other out-of-pocket expenses incurred in connection with such individual's employment; (ii) paid vacation leave; (iii) health benefits; and (iv) a severance payment equal to twelve (12) months of base salary and a prorated portion of the applicable cash bonus upon termination by such individual for just cause or by us without cause (each as defined in the agreement), with restrictive covenants applicable for a corresponding period after termination.

(b) in the event Mr. Slansky is terminated three months prior to, or one year after, a Change of Control (as defined in the agreement) by us for any reason other than cause, or by Mr. Slansky for good reason, then Mr. Slansky shall be entitled to receive a cash payment equal to a multiple of his then-current annual base salary determined by the time elapsed since the commencement of the agreement two times such salary, in the case of Mr. Slansky. Such payment shall be in lieu of the severance payment described in the agreement.

The employment agreement of Mr. Pierluigi Paracchi is governed by Italian law and includes the following terms and conditions, among others:

(a) the duties of general manager (*direttore generale*) with direct report to our board of directors;

(b) reimbursement of reasonable expenses incurred in the performance of his work duties, health benefits and, subject to the approval of the board of directors, a grant of an equity award under an equity incentive plan;

(c) in case of Change of Control (as defined in the relevant agreement), in the event of termination not for "cause" by us of resignation for "cause" by Mr. Pierluigi Paracchi (such terms as understood in accordance with Article 2119 of the Italian Civil Code), Mr. Pierluigi Paracchi shall be entitled to receive a cash payment equal to three times his then-current annual base salary (such indemnity will replace any indemnity provided for by the applicable National Collective Labour Agreement in case of termination); and

(d) non-competition and non-solicitation obligations of Mr. Pierluigi Paracchi for a 12-month period after the termination of his employment in consideration for compensation equal to 12 months after termination at his then-current monthly base salary for each obligation.

Such agreement is continuing until terminated, among other things: (a) upon death of Mr. Pierluigi Paracchi; (b) for just cause; (c) with objective or subjective reason; (d) by resignation of Mr, Pierluigi Paracchi; or (e) voluntarily by mutual agreement between the parties.

Consultancy Agreements

Prof. Naldini and Dr. Gentner entered into consulting agreements in connection with their service on our Executive Scientific Board. In October 2025, Prof. Naldini's agreement was amended to shorten its term to December 31, 2025, without automatic renewal. Similarly, Dr. Gentner's agreement was amended to shorten its term to December 31, 2025, without automatic renewal.

On October 1, 2025, we entered into a consulting agreement with FG Consulting Inc. in connection with the provision of ongoing scientific and strategic advisory services. Under this agreement, the Consultant, Francesco Galimi, supports the strengthening of our scientific credibility and visibility in the U.S., facilitates introductions to principal investigators and potential pharmaceutical development partners, and collaborates with external financial and strategic advisors regarding potential alliances, licensing, or co-development opportunities. Dr. Galimi would also provide expert guidance on clinical trial design and regulatory planning, including support for pivotal-trial readiness, and leading efforts to expand our scientific advisory board. In addition, Dr. Galimi now serves as acting Chief Medical Officer and Head of Development and advises the Chief Executive Officer on corporate strategy, pipeline development, and related personnel matters.

Indemnification Agreements

We have entered into an indemnification agreement with our directors and executive officers which requires us to indemnify our directors and executive officers to the fullest extent permitted by law, save for a limited number of instances, including when: (i) officers and directors' acts or omissions constituted willful misconduct or gross negligence; (ii) officers and directors did not act in good faith, for a purpose which they reasonably believed to be in, or not opposed to, the best interests of our company; and (iii) officers and directors are held liable towards our company.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to executive officers and board members or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

C. Interests of Experts and Counsel

Not Applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information.

Our consolidated financial statements are stated in EUROs and are prepared in accordance with US GAAP.

Audited Financial Statements

Our consolidated financial statements for the 2025, 2024, and 2023 fiscal years as required under Item 18 are included immediately following the text of this Annual Report. Our audit reports are included herein immediately preceding the consolidated financial statements.

Policy on Dividend Distributions

We have not paid any dividends on our outstanding ordinary shares since our incorporation and do not anticipate that we will do so in the foreseeable future. The payment of dividends in the future, if any, is within the discretion of our Board of Directors and will depend upon our earnings, our capital requirements, and our financial condition and other relevant factors. We do not anticipate declaring or paying any dividends in the foreseeable future.

Legal Proceedings

See "Item 4. Information on the Company-B. Business Overview-Legal Proceedings."

B. Significant Changes

Except as disclosed elsewhere in this Annual Report, we have not experienced any significant changes since the date of our audited consolidated financial statements included in this Annual Report.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares are listed on The Nasdaq Capital Market in the form of ADSs under the symbol "GNTA." Neither the Company's ordinary shares nor its ADSs are listed on a securities exchange outside the U.S. Bank of New York (formerly the Bank of New York Mellon) is our depositary for purposes of issuing ADSs. Trading in the ADSs on The Nasdaq Capital Market commenced on December 15, 2021.

B. Plan of Distribution

Not applicable.

C. Markets

See "Item 9. The Offer and Listing-A. Offer and Listing Details.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The description of certain terms and provisions of our bylaws (our "Bylaws") is incorporated by reference to our Registration Statement on Form F-1 (File No. 333-260923) filed with the SEC and as declared effective on December 14, 2021, and to our Form 6-K filed with the SEC on May 3, 2024.

At our 2024 Ordinary and Extraordinary Shareholders' Meeting, our shareholders approved an amendment to our Bylaws that established a loyalty share program. Under the loyalty share program, each ordinary share held in registered form entitles the shareholder to a double vote (i.e., two votes for each ordinary share) if the ordinary share has been held by the same shareholder for a continuous period of not less than twenty-four months from the date of its registration in the special list maintained by us, and an additional vote is also granted upon the expiration of each 12-month period, following the expiration of the period referred to above, in which such ordinary share has been held by the shareholder, up to a total maximum of ten votes per ordinary share.

To effect the loyalty share program, a special list (the "Special List") is maintained by us. To be added to the Special List, the registered shareholder would need to submit a specific application, enclosing a communication certifying the ordinary share ownership – which may also concern only part of the ordinary shares held by the registered shareholder – issued by the intermediary with whom the ordinary shares are deposited pursuant to the laws in force. In the case of entities other than individuals, the application would need to specify whether the entity is subject to direct or indirect control by third parties and the identification data of the controlling entity, if any. The Special List is updated by us. Cancellation from the Special List results from the following cases: renunciation of the interested party; communication of the interested party or of the intermediary proving the loss of the prerequisites for the increase of the voting right or the loss of the ownership of the right; ex officio, when we are informed of the occurrence of facts that entail the loss of the prerequisites for the increase of the voting right or the loss of the ownership of the right.

At our October 2025 Ordinary and Extraordinary Shareholder's Meeting, our shareholders approved an amendment to our Bylaws, specifically an amendment to Article 4, to expand our corporate purpose to include all sectors covered by the Italian Law Decree 21/2012 (i.e. Golden Power legislation).

Under the amended Article 4 of our Bylaws, we achieve the following purpose: a) research, development, production, mass production and sale of new therapeutic compounds of bio-technological, biologic and chemical origin relating to the pharmaceutical, biotechnological, molecular and cellular medicine, genetic and diagnostic segments of industry (hereinafter also the "Business"); b) production, processing of materials and provision of services in relation to the Business; c) development and improvement of new technologies and procedures in relation to the Business; d) mass production, production and distribution on own behalf and on behalf of third parties of pharmaceutical and para-pharmaceutical products, bio-technological, biologic and chemical products and their derivatives; and, e) promotion and organization or updates to its offering of scientific courses.

We also have as our purpose the research, development, production, and commercialization, both in Italy and abroad, of products, services, technologies, and applications in all sectors contemplated by the Italian legislation on the exercise of special powers (so-called "Golden Power") in force from time to time, as well as any related, instrumental and complementary activities.

In order to achieve this purpose, we may execute any transaction we consider necessary or useful, albeit only secondarily and only as a means to achieving our stated purpose, which may involve transactions in securities, real property, commercial, industrial or financial in nature, including taking on mortgages and unsecured debt, in any form, with private individuals, companies, and banks, and issue collateral and other guarantees, including personal guarantees, letters of indemnity and guarantee.

We may also take on and sell, directly or indirectly, interests or investments in other companies or enterprises whether established or in the process of establishment, whose purpose is similar, related, or in any way connected to our own. Expressly excluded from this purpose is any activity vis-à-vis the public that the law defines as "financial activity" and, except in certain cases and in full compliance with the related provisions set forth by law, any reserved professional activities and activities allowed by law only to certain individuals and legal entities.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business or other than those described in "Item 4. Information on the Company" or elsewhere in this Annual Report.

D. Exchange Controls

Under Italian law, there are no exchange control restrictions on investments in, or payments on, the Genenta ordinary shares. There are no special restrictions in the Genenta Articles of Association or Italian law that limit the right of shareholders who are not citizens or residents of Italy to hold or vote the Genenta ordinary shares.

E. Taxation

Italian Tax Consequences

General. Under Italian law, financial instruments issued by an Italian company are subject to the same tax regime as shares, provided that their remuneration is entirely represented by participation in the economic results of the issuer. Pursuant to Article 10(3) of the Income Tax Convention, the tax regime of dividends applies to income from corporate rights of an Italian company, which is subject to the same taxation treatment as income from shares under the laws of Italy.

Income Tax Withholding on Dividends. We do not anticipate making any distributions on our ordinary shares in the foreseeable future. However, if we were to make distributions on our ordinary shares, we would generally be required under Italian law, except as otherwise discussed below, to apply a definitive withholding tax on payments made to holders of our ordinary shares who are not residents of Italy for tax purposes.

Notably, dividends paid to beneficial owners who are not Italian residents and do not have a permanent establishment in Italy are generally subject to a 26 percent substitute tax rate. Therefore, the amount of the dividends that the holders of American Depository Receipts ("ADRs") or holders of equity shares not residing in Italy will initially receive will be net of such Italian substitute tax.

All non-Italian resident owners of equity shares or ADRs may benefit from reduced withholding tax settled in the relevant anti-double tax treaty undersigned between Italy and the country of residence for tax purposes of the owners of equity shares or ADRs. The reduced withholding tax rate under the relevant anti-double tax treaty will be applicable provided that the non-resident owners of the equity shares or ADRs are able to produce the documentation attesting the requirements to be eligible for the application of the relevant anti-double tax treaty.

Under Italian law, U.S. owners can claim, in accordance with Presidential Decree No. 600 of October 16, 1973, Article 27(3), a refund of up to eleven-twenty-sixths (*i.e.,* 11/26) of the Italian withholding tax withheld on dividends upon presenting evidence to the Italian tax authorities that income taxes have been fully paid on the dividends in the country of residence of the U.S. owners in an amount at least equal to the total refund claimed. U.S. holders should consult an independent tax advisor concerning the availability of this refund, which has traditionally become payable only after extensive delays.

Under the double tax treaty in force between Italy and the U.S. ("U.S./Italy Income Tax Treaty"), if the payee is the beneficial owner of the payment, dividends paid to U.S. owners will be subject to Italian withholding tax at a reduced rate of: 1) 5%, if the beneficiary is a company owning at least 25% of the payer's voting shares (for at least 12 months preceding the dividend distribution); or 2) 15% in any other case. The aforementioned regime (both 1 and 2) is applicable only if the payee does not carry out an entrepreneurial activity in Italy through a permanent establishment or performs independent personal services through a fixed place situated therein.

Companies or entities subject to corporation tax and resident in States that are E.U. Member States or participants in the EEA (included in the list provided for by Italian Ministerial Decree, September 4, 1996, amended and supplemented by Ministerial Decree March 23, 2017) may be entitled to a reduced tax rate of 1.2% on dividends distributed. The pension funds established in an E.U. Member State or EEA country may be entitled to a reduced tax rate of 11% or, under certain conditions, to exemption from Italian taxation on dividends.

Income Tax on Capital Gains

Generally, gains from shares in Italian companies, under custody in Italy, could give rise to a taxable income for the non-resident transferor.

Capital gains exempt from taxation in Italy - "Non-qualified shareholdings" are those which are below 2% of the voting rights and 5% of the capital of an exchange-listed company. Gains from the disposal of non-qualified share investments in Italian listed companies by non-Italian residents are not subject to Italian income tax under domestic rule.

Capital gains subject to tax in Italy - "Qualified shareholdings" in a listed company are those representing more than the 2% of the voting rights or more than the 5% of the capital of an exchange-listed company. Capital gains from the disposal of a qualified shareholding in a listed company are subject to a withholding tax of 26% under the domestic rule.

The "qualified shareholding" thresholds must be verified over a 12-month monitoring period, starting from the day on which the investor has held at least a qualifying stake, either actual or potential (this rule aimed at preventing that a buy/sale kind of trading resulting in an overall disposition of over 2% in 12 months may result in a qualifying gain having to be declared even when the investor has never owned an actual or potential qualifying stake). Consequently, all trades cumulatively carried out in a 12-month period should be considered. More in details: (i) until the investor holds a qualifying shareholding at any point in time, trades are not relevant for capital gain purposes, even if the overall amount disposed in a 12-month period exceeds the relevant thresholds; and (ii) starting from the day when the taxpayer holds a qualifying shareholding, all the trades carried out in any consecutive 12 months give rise to qualified capital gains if the overall amount disposed of exceeds one of the relevant thresholds.

However, please be informed that in accordance with the rules stated in the anti-double tax treaty, in force between Italy and the country of residence for tax purposes of the transferor, it is possible to claim the benefit of exemption from the 26% taxation on capital gains. In principle, and in more detail, the art. 13 of the OECD model convention basically states that the capital gain is only taxed in the transferor's country of tax residence. The Italy – U.S. anti-double tax treaty convention states a taxation criterion in line with the above. In light of the above and upon conditions that all the requirements relevant to the application of the Italy – U.S. anti-double tax treaty convention are met, a U.S. investor may benefit from full exemption of taxation in Italy.

Furthermore, save for any applicable anti-avoidance provision, pursuant to the Income Tax Convention, a U.S. owner will not be subject to Italian capital gain tax or to Italian individual or corporate income tax unless such U.S. owner has a permanent establishment or fixed base in Italy to which the owner's ordinary shares are effectively connected. To this end, U.S. owners selling ordinary shares and claiming benefits under the Income Tax Convention may be required to produce appropriate documentation establishing that the above-mentioned conditions have been met.

Estate and Gift Tax. Inheritance and gift taxes, which were abolished in 2001, have been re-introduced in the Italian system by Law Decree No. 262 of October 3, 2006 (converted into law, with amendments, by Law Decree No. 286 of November 24, 2006), as amended. Such taxes will apply to the overall net value of the relevant assets, at the following rates, depending on the relationship between the testate (or donor) and the beneficiary (or donee): (a) 4%, if the beneficiary (or donee) is the spouse or a direct ascendant or descendant (such rate only applying on the net asset value exceeding, for each person, €1.0 million); (b) 6%, if the beneficiary (or donee) is a brother or sister (such rate only applying on the net asset value exceeding, for each person, €0.1 million); (c) 6% if the beneficiary (or donee) is another relative within the fourth degree or a direct relative-in-law as well as an indirect relative-in-law within the third degree; and (d) 8% if the beneficiary is a person other than those mentioned under (a), (b) and (c), above. If the beneficiary has a serious disability recognized under applicable law, inheritance and gift taxes will apply to its portion of the net asset value exceeding €1.5 million.

Transfer tax. In connection with the Italian stamp duty tax on the transfer of shares, according to Article 37 of Law No. 248 of December 31, 2007, converted with amendments into Law No. 31 of February 28, 2008, the stamp duty has been abolished regarding contracts having as their object the transfer of shares. In certain cases, the relevant transfer acts would be subject to the registration tax at a flat amount equal to €200.

Communications Stamp Duty. A stamp duty has been introduced under Article 19 of Law Decree No. 201 of December 6, 2011, converted into Law No. 214 of December 22, 2011, to be imposed on communications (issued by banks and financial intermediaries) to clients relating to securities, even where the deposit of such securities is not mandatory (although certain entities are excluded). The amount of the stamp duty is based on the market value of the securities or, in the absence of a market value, on the nominal amount or the amount payable on redemption. As a general comment, the stamp duty rate is 0.2% on a yearly *pro-rata temporis* basis (from January 1 up to December 31). The minimum amount is fixed at €34.20 up to a maximum amount of €14,000 for persons other than individuals. The communication is deemed to be sent to clients at least once a year, even where there is no obligation to issue any such communication.

Financial Transaction Tax. Law 228 of December 24, 2012, Article 1(491 – 500) introduced the Italian Financial Transaction Tax applicable: (i) to the transfer of shares and other participative financial instruments issued by companies resident in Italy ("Italian Equity") and securities representing Italian Equity, regardless of the country where the issuer has its residence (together with Italian Equity are referred to as "Qualifying Equity"); (ii) on the basis of the "value of the transaction"; (iii) regardless of the place where the transaction is concluded and of the State where the parties have their residence; (iv) to transactions on "regulated markets and on multilateral trading facilities" with a reduced rate; and (v) to over-the-counter transactions with a full rate.

The taxable event, triggering Italian Financial Transaction Tax, is the transfer of ownership of Qualifying Equity. Securities representing Italian Equity are in scope of the Italian Financial Transaction Tax, regardless of the State where the issuer has its residence. This provision is aimed at including in the scope of the Italian Financial Transaction Tax, ADRs, Global Depository Receipts and any other certificate of deposit, where the underlying securities are Italian Equity.

The value of the transaction is determined based on the net balance of the transactions settled daily, calculated for each taxpayer with reference to the number of securities traded under the transactions settled in the same day and relating to the same financial instrument.

The calculation is made by the financial intermediary responsible for the payment of the tax, i.e., the one receiving the order to execute the transaction directly from the purchaser or final counterparty.

The Italian Financial Transaction Tax is due by the person in whose favor the transfer of ownership of the Qualifying Equities occurs.

The tax rate applicable is 0.20% while the reduced rate for transactions on "regulated markets and on multilateral trading facilities" is 0.10%.

The tax shall be paid by the 16th day of the month following the one in which the relevant triggering event occurs.

The Italian Financial Transaction Tax does not apply to the transfer of ownership of Italian Equity where the issuing companies are listed in regulated markets and have a market capitalization below 500 million Euros. Such exclusion also applies to the transfer of ownership of securities representing Italian Equity.

U.S. Federal Income Taxation

THE FOLLOWING SUMMARY IS INCLUDED HEREIN FOR GENERAL INFORMATION AND IS NOT INTENDED TO BE, AND SHOULD NOT BE, CONSIDERED TO BE LEGAL OR TAX ADVICE. EACH U.S. HOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND SALE OF ADS'S, INCLUDING THE EFFECTS OF APPLICABLE STATE, LOCAL, FOREIGN OR OTHER TAX LAWS AND POSSIBLE CHANGES IN THE TAX LAWS.

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a "U.S. Holder" arising from the purchase, ownership, and sale of the ADSs. For this purpose, a "U.S. Holder" is a holder of ADSs that is: (1) an individual citizen or resident of the U.S., including an alien individual who is a lawful permanent resident of the U.S. or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) or a partnership (other than a partnership that is not treated as a U.S. person under any applicable U.S. Treasury regulations) created or organized under the laws of the U.S. or the District of Columbia or any political subdivision thereof; (3) an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; (4) a trust if a court within the U.S. is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; or (5) a trust that has a valid election in effect to be treated as a domestic trust to the extent provided in U.S. Treasury regulations.

This summary is for general information purposes only and does not purport to be a comprehensive description of all the U.S. federal income tax considerations that may be relevant to a decision to invest in or dispose of the ADSs. This summary generally considers only U.S. Holders that will own the ADSs as capital assets and who will not hold the ADSs as part of a permanent establishment in Italy. This summary does not consider the U.S. federal tax consequences to a person that is not a U.S. Holder, nor does it describe the rules applicable to determine a taxpayer's status as a U.S. Holder. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended, or the Code, final, temporary and proposed U.S. Treasury regulations promulgated thereunder, administrative and judicial interpretations thereof, and the U.S./Italy Income Tax Treaty, all as available and in effect as of the date hereof and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. We will not seek a ruling from the IRS regarding the U.S. federal income tax treatment of an investment in the ADSs by U.S. Holders and, therefore, can provide no assurances that the IRS will agree with the conclusions set forth below.

This discussion does not address all the aspects of U.S. federal income taxation that may be relevant to a particular U.S. holder based on such holder's particular circumstances and does not discuss any estate, gift, generation-skipping, transfer, state, local, excise or foreign tax considerations. In addition, this discussion does not address the U.S. federal income tax treatment of a U.S. Holder who is: (1) a bank, life insurance company, regulated investment company, or other financial institution or "financial services entity;" (2) a broker or dealer in securities or foreign currency; (3) a person who acquired our securities in connection with employment or other performance of services; (4) a U.S. Holder that is subject to the U.S. alternative minimum tax; (5) a U.S. Holder that holds our securities as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) a tax-exempt entity; (7) a real estate investment trust or grantor trust; (8) certain expatriates or former long-term residents of the U.S.; (9) an accrual method taxpayer subject to the rules of Section 451(b) by reason of using certain financial statements; or (10) a U.S. Holder having a functional currency other than the U.S. dollar. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly or constructively, at any time, securities representing 10% or more of the voting power or value of our shares.

Additionally, the U.S. federal income tax treatment of partnerships (or other pass-through entities) or persons who hold securities through a partnership or other pass-through entity are not addressed. If a partnership (including any entity treated as a partnership for U.S. federal income tax purposes) holds ADSs, the U.S. federal income tax consequences to such partnership or the partners of such partnership will depend on the activities of the partnership and the status of the partners.

Each investor is advised to consult his or her own tax adviser for the specific tax consequences to that investor of purchasing, holding, or disposing of our securities, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

Taxation of Dividends Paid on Ordinary Shares

We do not intend to pay dividends in the foreseeable future. In the event that we do pay dividends, and subject to the discussion under the heading "Passive Foreign Investment Companies" below and the discussion of "qualified dividend income" below, a U.S. Holder, other than certain U.S. Holders that are U.S. corporations, will be required to include in gross income as ordinary income the U.S. dollar amount of any distribution paid on ordinary shares (including the amount of any Italy tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current and accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution that exceeds our earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder's tax basis for the ordinary shares to the extent thereof, and then as capital gain. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income. Any dividends we pay with respect to the ADSs, or ordinary shares, are expected to constitute foreign source income for U.S. foreign tax credit purposes.

In general, preferential tax rates for "qualified dividend income" and long-term capital gains are applicable for U.S. Holders that are individuals, estates, or trusts. For this purpose, "qualified dividend income" means, inter alia, dividends received from a "qualified foreign corporation." A "qualified foreign corporation" is a corporation that is entitled to the benefits of a comprehensive tax treaty with the U.S., which includes an exchange of information program. The IRS has stated that the Italy/U.S. Tax Treaty satisfies this requirement, and we believe we are eligible for the benefits of that treaty.

In addition, our dividends will be qualified dividend income if our ordinary shares are readily tradable on Nasdaq or another established securities market in the U.S. Dividends will not qualify for the preferential rates if we are treated, in the year the dividend is paid or in the prior year, as a PFIC, as described below under "Passive Foreign Investment Companies." A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our ordinary shares for at least 61 days of the 121 day period beginning on the date which is 60 days before the ex-dividend date; or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our ordinary shares are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as "investment income" pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

The amount of a distribution with respect to our ordinary shares will be measured by the amount of the fair market value of any property distributed, and for U.S. federal income tax purposes, the amount of any Italian taxes withheld therefrom. Cash distributions paid by us in Euros will be included in the income of U.S. Holders at a U.S. dollar amount based upon the spot rate of exchange in effect on the date the dividend is includible in the income of the U.S. Holder, and U.S. Holders will have a tax basis in such Euros for U.S. federal income tax purposes equal to such U.S. dollar value. If the U.S. Holder subsequently converts the Euros into U.S. dollars or otherwise disposes of it, any subsequent gain or loss in respect of such Euros arising from exchange rate fluctuations will be U.S. source ordinary exchange gain or loss.

Subject to certain limitations, Italian withholding tax, if any, paid in connection with any distribution with respect to ADSs may be claimed as a credit against a U.S. Holder's U.S. federal income tax liability if the U.S. Holder elects not to take a deduction for any non-U.S. income taxes for that taxable year; otherwise, such Italian withholding tax may be taken as a deduction. If a U.S. Holder is eligible for benefits under the Treaty or is otherwise entitled to a refund for the taxes withheld, the U.S. Holder will not be entitled to a foreign tax credit or deduction for the amount of any Italian taxes withheld in excess of the maximum rate under the Treaty or for the taxes with respect to which the U.S. Holder can obtain a refund from the Italian taxing authorities. As the relevant rules are very complex, U.S. Holders should consult their own tax advisors concerning the availability and utilization of the foreign tax credit or deductions for non-U.S. taxes in their circumstances.

Taxation of the Disposition of Ordinary Shares

Except as provided under the PFIC rules described below under "Passive Foreign Investment Companies," upon the sale, exchange or other disposition of our ordinary shares, a U.S. Holder will recognize capital gain or loss in an amount equal to the difference between such U.S. Holder's tax basis for the ordinary shares in U.S. dollars and the amount realized on the disposition in U.S. dollar (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale, exchange or other disposition of ordinary shares will be long-term capital gain or loss if the U.S. Holder has a holding period of more than one year at the time of the disposition. Individuals who recognize long-term capital gains may be taxed on such gains at reduced rates of tax. The deduction of capital losses is subject to various limitations.

Passive Foreign Investment Companies

Special U.S. federal income tax laws apply to U.S. taxpayers who own shares of a corporation that is a PFIC. We will be treated as a PFIC for U.S. federal income tax purposes for any taxable year that either:

- 75% or more of our gross income (including our pro rata share of gross income for any company, in which we are considered to own 25% or more of the shares by value), in a taxable year is passive; or

- At least 50% of our assets, averaged over the year and generally determined based upon fair market value (including our pro rata share of the assets of any company in which we are considered to own 25% or more of the shares by value) are held for the production of, or produce, passive income.

For this purpose, passive income generally consists of dividends, interest, rents, royalties, annuities, and income from certain commodities transactions and from notional principal contracts. Cash is treated as generating passive income.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets. Our status may also depend, in part, on how quickly we utilize cash proceeds received from previous offerings of our ADSs or ordinary shares in our business. Based on preliminary analysis, we believe that we were likely classified as a PFIC in 2025, and we may be classified as a PFIC for 2026 and future years.

If we currently are or become a PFIC during the holding period of a U.S. Holder, the U.S. Holder would be subject to potentially materially greater amounts of tax and subject to additional U.S. tax form filing requirements. In addition, as noted above, a non-corporate U.S. Holder will not be eligible for qualified dividend income treatment on dividends received from us if we are treated as a PFIC for the taxable year in which the dividends are received or for the preceding taxable year. Specifically, each U.S. Holder who has not elected to mark the shares to market (as discussed below), would, upon receipt of certain distributions by us and upon disposition of our ordinary shares at a gain: (1) have such distribution or gain allocated ratably over the U.S. Holder's holding period for the ordinary shares, as the case may be; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, when shares of a PFIC are acquired by reason of death from a decedent that was a U.S. Holder, the tax basis of such shares would not receive a step-up to fair market value as of the date of the decedent's death, but instead would be equal to the decedent's basis if lower, unless all gain were recognized by the decedent. Indirect investments in a PFIC may also be subject to these special U.S. federal income tax rules.

The PFIC rules described above would not apply to a U.S. Holder who makes a QEF election for all taxable years that such U.S. Holder has held the ordinary shares while we are a PFIC, provided that we comply with specified reporting requirements. Instead, each U.S. Holder who has made such a QEF election is required for each taxable year that we are a PFIC to include in income such U.S. Holder's pro rata share of our ordinary earnings as ordinary income and such U.S. Holder's pro rata share of our net capital gains as long-term capital gain, regardless of whether we make any distributions of such earnings or gain. In general, a QEF election is effective only if we make available certain required information. However, we provide no assurance as to whether we will calculate our "ordinary earnings" or "net capital gain" under U.S. tax principles or supply U.S. Holders with the required "PFIC Annual Information Statement." If we do not provide this information for any reason, it generally will not be possible for a U.S. Holder to make a QEF election if we are, or if we become, a PFIC.

In addition, the PFIC rules described above would not apply if we were a PFIC and a U.S. Holder made a mark-to-market election. A U.S. Holder of our ordinary shares which are regularly traded on a qualifying exchange, including the Nasdaq Capital Market, can elect to mark the ordinary shares to market annually, recognizing as ordinary income or loss each year an amount equal to the difference as of the close of the taxable year between the fair market value of the ordinary shares and the U.S. Holder's adjusted tax basis in the ordinary shares. Losses are allowed only to the extent of net mark-to-market gain previously included income by the U.S. Holder under the election for prior taxable years.

U.S. Holders who hold our ordinary shares during a period when we are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC. U.S. Holders are strongly urged to consult their tax advisors about the PFIC rules.

Tax on Net Investment Income

U.S. Holders who are individuals, estates, or trusts will generally be required to pay a 3.8% Medicare tax on their net investment income (including dividends on and gains from the sale or other disposition of our ordinary shares), or in the case of estates and trusts on their net investment income that is not distributed. In each case, the 3.8% Medicare tax applies only to the extent the U.S. Holder's total adjusted income exceeds applicable thresholds.

Information Reporting and Withholding

A U.S. Holder may be subject to backup withholding at a rate of 24% with respect to cash dividends and proceeds from a disposition of ordinary shares. In general, backup withholding will apply only if a U.S. Holder fails to comply with specified identification procedures. Backup withholding will not apply with respect to payments made to designated exempt recipients, such as corporations and tax-exempt organizations. Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a U.S. Holder, provided that the required information is timely furnished to the IRS.

U.S. federal income tax law requires certain U.S. investors to disclose information relating to investments in securities of a non-U.S. issuer. Failure to comply with applicable disclosure requirements could result in the imposition of substantial penalties. U.S. Holders should consult their own tax advisors regarding any disclosure obligations.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

Documents concerning us that are referred to in this document may be inspected at our office at Via dell'Annunciata, n. 31, 20121 Milan, Italy.

In addition, we file annual reports and other information with the Securities and Exchange Commission. We file annual reports on Form 20-F and submit other information under cover of Form 6-K. As a foreign private issuer, we are exempt from the proxy requirements of Section 14 of the Exchange Act and our officers, directors, and principal shareholders are exempt from the insider short-swing disclosure and profit recovery rules of Section 16 of the Exchange Act. However, effective March 18, 2026, our directors and officers became subject to the insider reporting requirements of Section 16(a) of the Exchange Act. The Commission maintains a web site that contains reports and other information regarding registrants (including us) that file electronically with the Commission which can be assessed at http://www.sec.gov.

I. Subsidiary Information

Not required.

J. Annual Report to Security Holders

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our activities expose us to a variety of financial risks: market risk (including foreign currency risk and interest rate risk), credit risk, and liquidity risk. The overall risk management strategy focuses on the unpredictability of the financial markets and seeks to minimize the potential adverse effects on financial performance. We use different methods to measure different types of risk to which we are exposed. These methods include sensitivity analysis in the case of interest rate, foreign exchange, and other price risks, aging analysis for credit risk, and beta analysis with respect to investment portfolios to determine market risk. Risk management is carried out under the direction of the Board. Please see Note 1 – Nature of business and history - to our audited consolidated financial statements for further information with respect to certain of these risks.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

The Bank of New York (formerly The Bank of New York Mellon), as depositary, collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

Persons depositing or withdrawing shares or ADS holders must pay:	***For:***
$2.50 (or less) per 100 ADSs (or portion of 100 ADSs).	Issuance of ADSs, including issuances resulting from a distribution of shares, or rights, or other property. Cancellation of ADSs for the purpose of withdrawal, including, if the deposit agreement terminates.
$.025 (or less) per ADS. A fee equivalent to the fee that would be payable if securities distributed to you had been shares, and the shares had been deposited for issuance of ADSs.	Any cash distribution to ADS holders, distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holder depositary services.
$.025 (or less) per ADS per calendar year. Registration or transfer fees. Expenses of the depositary.	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares. Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars, as necessary.
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty, or withholding taxes. Any charges incurred by the depositary or its agents for servicing the deposited securities.	As necessary.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of the establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary, or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers, or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads, or commissions.

The depositary may convert currency itself or through any of its affiliates, or the custodian, or we may convert currency and pay U.S. dollars to the depositary. Where the depositary converts currency itself or through any of its affiliates, the depositary acts as principal for its own account and not as agent, advisor, broker, or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation to act without negligence or bad faith. The methodology used to determine exchange rates used in currency conversions made by the depositary is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions from the us in U.S. dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS Material Modifications to the Rights of Security Holders

See "Item 10. Additional Information" for a description of the rights of securities holders, which remain unchanged.

ITEM 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed under the Exchange Act is accumulated and communicated to management, including principal executive and financial officers, as appropriate, to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

We carried out an evaluation, under the supervision of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act as of December 31, 2025. Based on that evaluation, we, including our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures were effective as of December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Our internal control over financial reporting is a process designed under the supervision of our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance as to the reliability of our financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with generally accepted accounting principles. We are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with U.S. GAAP and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of a company's assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of a company's management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of a company's assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance with respect to consolidated financial statements preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

We evaluated the effectiveness of our internal control over financial reporting as of December 31, 2025 and concluded our internal control over financial reporting was effective as of December 31, 2025. In making this evaluation, we used the framework established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The COSO framework summarizes each of the components of a company's internal control system, including the control environment, risk assessment, control activities, information and communication, and monitoring activities.

Attestation Report of Independent Registered Public Accounting Firm

Not required.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act, as amended) that occurred during the year ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT.

Our Board of Directors has determined that, because of the existence and nature of our board of statutory auditors, we qualify for an exemption provided by Rule 10A-3(c)(3) of the Exchange Act from many of the Rule 10A-3 audit committee requirements. The board of statutory auditors has determined that each of its members is an "audit committee financial expert" as defined in Item 16A of Form 20-F. For the names of the members of the board of statutory auditors, see "Item 6. Directors, Senior Management and Employees-Statutory Auditors".

Each member of the board of statutory auditors is considered a financial expert and is independent under the Nasdaq Independence Standards that would apply to audit committee members in the absence of our reliance on the exemption in Rule 10A-3(c)(3).

ITEM 16B. CODE OF ETHICS.

We adopted a Code of Conduct that applies to our Chief Executive Officer and all of our directors, officers, and employees, or persons performing similar functions. A copy of our Code of Conduct is available on our website. Any future changes to the Code of Conduct will be posted on our website or filed as an exhibit to a report filed with the SEC within five business days of the change being effective.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The following table represents aggregate audit fees billed to the Company for fiscal years ended December 31, 2025, 2024, and 2023.

Accountant Fees and Services (in Euros)	2025	2024	2023
Audit Fees	€ 146,086	€ 257,006	€ 433,884
	€ 146,086	€ 257,006	€ 433,884

For the fiscal year ended December 31, 2025, audit fees of €130,086 were billed by Dannible & McKee LLP, the Company's principal auditing firm.

For the fiscal year ended December 31, 2024, Dannible & McKee LLP billed €270,006.

For the fiscal year ended December 31, 2023, Dannible & McKee LLP billed €312,629.

Audit Fees

The audit fees for the years ended December 31, 2025, 2024 and 2023, respectively, were paid for professional services rendered for the audits of our consolidated financial statements, half-year reviews, consents, and assistance with reviews of documents filed with the SEC.

Tax Fees

Not applicable.

Other Fees

Not applicable.

Pre-Approval Policies and Procedures

Prior to engaging Dannible & McKee LLP to perform audit services, our Board obtains an estimate for the service to be performed. All of the services described above were approved by the members of the Board of Statutory Auditors in accordance with its procedures.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES.

We are relying on the exemption from listing standards for audit committees provided by Exchange Act Rule 10A-3(c)(3). The basis for this reliance is that our board of statutory auditors meets the following requirements set forth in Exchange Act Rule 10A-3(c)(3):

- the board of statutory auditors is established and selected pursuant to Italian law expressly permitting such a board;
- the board of statutory auditors is required under Italian law to be separate from our board of directors;
- the board of statutory auditors is not elected by us, and none of our executive officers is a member of the board of statutory auditors;
- Italian law provides for standards for the independence of the board of statutory auditors from us and our management;
- the board of statutory auditors, in accordance with applicable Italian law and our governing documents, is responsible, to the extent permitted by Italian law, for the appointment, retention and oversight of the work (including, to the extent permitted by law, the resolution of disagreements between management and the auditor regarding financial reporting) of any registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us, and
- to the extent permitted by Italian law, the audit committee requirements of paragraphs (b)(3), (b)(4) and (b)(5) of Rule 10A-3 apply to the board of statutory auditors.

Our reliance on Rule 10A-3(c)(3) does not, in its opinion, materially adversely affect the ability of our board of statutory auditors to act independently and to satisfy the other requirements of Rule 10A-3.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS.

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT.

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE.

See "Item 6. Directors, Senior Management and Employees – C. Board Practices – Differences between Italian Laws and Nasdaq Requirements."

ITEM 16H. MINE SAFETY DISCLOSURE.

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

We have adopted an insider trading policy and related procedures that govern the purchase, sale, and other disposition of our securities by directors, officers, and employees, as well as consultants and contractors who have access to material non-public information. We believe our insider trading policy and procedures are reasonably designed to promote compliance with insider trading laws, rules, and regulations, and applicable Nasdaq listing standards. Our insider trading policy and procedures prohibit our directors, officers and employees, consultants and contractors who have access to material non-public information, from trading in our securities while in possession of material, non-public information, among other things.

The foregoing description of our insider trading policy and procedures does not purport to be complete and is qualified in its entirety by the terms and conditions of our insider trading policy, a copy of which is attached hereto as Exhibit 11.2 and is incorporated herein by reference.

ITEM 16K. CYBERSECURITY.

We recognize that maintaining the trust and confidence of our patients, business partners, and employees is integral to our long-term success. Central to this commitment is our comprehensive approach to cybersecurity and the protection of sensitive data.

We maintain processes and systems designed to identify, assess, manage, and mitigate risks arising from cybersecurity threats as part of our overall enterprise risk management framework. Cybersecurity risk management activities are embedded within our broader operational risk and compliance processes and are intended to support the protection of information systems, research and development data, corporate information, and other critical business operations.

We maintain a comprehensive cybersecurity framework consisting of formal policies, procedures, and systems designed to identify, assess, and manage cybersecurity risks, including the implementation of structured and periodic cyber risk assessment activities. In 2025, we further strengthened our cybersecurity and operational resilience capabilities, including enhancements to business continuity preparedness, vulnerability detection, and related remediation processes. We conduct periodic cybersecurity assessments to evaluate potential threats and vulnerabilities affecting our information systems and third-party service providers. These assessments consider internal systems, external service providers, and supply chain relationships. We leverage qualified third-party service providers to support continuous monitoring activities, specialized cybersecurity services, and vulnerability management functions, while maintaining internal oversight and accountability.

In 2025, we implemented additional business continuity initiatives designed to enhance our preparedness for potential disruptive events, including cybersecurity incidents. These initiatives included the formalization and testing of business continuity procedures for critical processes, improved alignment between disaster recovery mechanisms and incident response protocols, and the planning and execution of periodic exercises to evaluate response effectiveness and recovery readiness. These efforts are intended to reduce potential operational disruption and support the timely restoration of IT resources in the event of an incident.

We utilize a Security Operations Center (SOC) model to support continuous monitoring of networks, endpoints, and systems. Monitoring activities incorporate threat intelligence capabilities designed to identify, analyze, and respond to potential cybersecurity events promptly. During 2025, we expanded the scope and automation of vulnerability scanning activities and enhanced endpoint protection and remediation capabilities. These enhancements were designed to strengthen proactive risk mitigation and reduce potential exposure to exploitation of identified system weaknesses through timely corrective actions.

We maintain a structured incident response process that includes procedures for detection, assessment, containment, eradication, remediation, and post-incident review, consistent with principles set forth in the National Institute of Standards and Technology (NIST) Cybersecurity Framework. Escalation protocols are established to facilitate timely communication of significant cybersecurity matters to senior management and, where appropriate, to our Board of Directors, including consideration of disclosure obligations under applicable laws and regulations. Our Board of Directors oversees cybersecurity risk as part of its overall risk oversight responsibilities and receives periodic updates from management regarding our cybersecurity posture, risk landscape, operational resilience preparedness, and mitigation initiatives, which are finally approved by them.

We have ultimate accountability for cybersecurity risk management and are responsible for making critical decisions in connection with cybersecurity incident response. Furthermore, we designated a Chief Information Security Officer (CISO) responsible for leading the cybersecurity program. The CISO's responsibilities include defining cybersecurity strategy based on the results of periodic cyber risk assessments, overseeing the implementation of technical and organizational security controls, supervising incident response activities, and coordinating risk mitigation initiatives. The CISO has professional experience in information security governance and risk management, including experience in regulated environments, and works in coordination with the Security Committee. The Security Committee, coordinated by our Finance Director, supports oversight of cybersecurity risk management activities and provides periodic briefings to our senior management and our Board of Directors regarding cybersecurity risks, monitoring activities, vulnerability management efforts, business continuity readiness, and other significant developments.

We also maintain a security awareness program applicable to all personnel. This program includes periodic training sessions addressing cybersecurity risks, evolving threat scenarios, and best practices for information protection, as well as simulated phishing exercises designed to enhance awareness and preparedness. Participation in such training activities is mandatory and forms part of our broader culture of security and risk awareness.

As of the date of this report, we are not aware of any cybersecurity incidents that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. Cybersecurity threats continue to evolve, and despite the implementation of protective and detective measures, we cannot be considered immune from potential impacts arising from emerging cybersecurity threats, which could result in future incidents. We intend to continue enhancing our cybersecurity and operational resilience capabilities, including improvements in detection technologies, vulnerability management processes, and business continuity preparedness, consistent with international security frameworks and evolving regulatory expectations.

PART III

ITEM 17. CONSOLIDATED FINANCIAL STATEMENTS

We have elected to provide consolidated financial statements pursuant to ITEM 18.

ITEM 18. CONSOLIDATED FINANCIAL STATEMENTS

Our audited Consolidated Financial Statements are included as the "F" pages attached to this report.

All consolidated financial statements in this Annual Report, unless otherwise stated, are presented in accordance with US GAAP.

ITEM 19. EXHIBITS

Exhibit No.	Description
2.4****	Description of Securities
3.1*	Deed of Incorporation of Genenta Science S.p.A.
3.2*****	Amended and Restated Bylaws of Genenta Science S.p.A.
4.1*	Deposit Agreement dated December 17, 2021 between the Company and The Bank of New York Mellon, as depositary.
4.2*	Form of American Depositary Receipt (included in exhibit 4.1)
4.3**	Underwriter Warrants dated December 17, 2021
8.1****	List of subsidiaries of the registrant
10.1***†	Amended and Restated License Agreement between Genenta Science S.p.A. and Ospedale San Raffaele S.r.l. ("OSR") dated March 23, 2023 (the "ARLA")
10.2##†	Amendment to ARLA dated September 28, 2023
10.3##†	Sponsored Research Agreement with OSR dated August 1, 2023
10.4*†	Sponsored Research Agreement with OSR dated February 12, 2021
10.5*	Know-How License Agreement with Fondazione Telethon dated February 2, 2016
10.6*†	Master Service Agreement dated March 6, 2019, between Molecular Medicine S.p.A. and Genenta Science S.p.A.
10.7*	2021-2025 Genenta Science Employee Share Option Plan with Chairman Sub-Plan
10.8*	Employment Agreement of Pierluigi Paracchi
10.11*	Employment Agreement of Richard B. Slansky
10.12#†	Development and Manufacturing Services Agreement dated January 20, 2023 between AGC Biologics S.p.A. and Genenta Science S.p.A.
10.13###	Amendment to the AGC Master Service Agreement dated September 19, 2024.
10.14###	Agreement for the Conduct of Clinical Trials on Medicinal Products with OSR dated October 14, 2024.
10.15####	ATM Sales Agreement, dated April 26, 2024, among the Company and the Sales Agents
10.16#####	Amendment No. 1 to ATM Sales Agreement, dated December 20, 2024, among the Company and the Sales Agents
10.17######†	Second Amendment to Development and Master Services Agreement, by and between the Company and AGC Biologics S.p.A., effective as of December 24, 2024.
10.18#######	Subscription Agreement
10.19#######	Mandatory Convertible Bond Regulation
10.20******	Investment Agreement dated January 24, 2026, between the Company and A.T.C. S.r.l.
10.21******	Shareholders' Agreement dated January 25, 2026 between the Company, Pierluigi Paracchi, and Fondazione Praexidia.
11.1**	Code of Business Conduct and Ethics of the Registrant
11.2****	Insider Trading Policy
12.1	Certification of the Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act, as amended
12.2	Certification of the Chief Financial Officer (Principal Financial Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act, as amended
13.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
23.1	Consent of Dannible & McKee, LLP
97.1**	Compensation Recovery Policy of Registrant
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Incorporated by reference to the registration statement on Form F-1 of the Registrant (File No. 333-260923).

** Incorporated by reference to the Annual Report on Form 20-F of the Registrant filed on March 29, 2024.

*** Incorporated by reference to the Annual Report on Form 20-F of the Registrant filed on April 21, 2023.

**** Incorporated by reference to the Annual Report on Form 20-F of the Registrant filed on March 28, 2025

***** Incorporated by reference to the Form 6-K of the Registrant filed on November 4, 2025.

****** Incorporated by reference to the Form 6-K of the Registrant filed on January 27, 2026.

Incorporated by reference to the Form 6-K of the Registrant filed on February 1, 2023.

Incorporated by reference to the Form 6-K of the Registrant filed on October 20, 2023.

Incorporated by reference to the Form 6-K of the Registrant filed on October 29, 2024.

Incorporated by reference to the Form 6-K of the Registrant filed on April 26, 2024.

Incorporated by reference to the Form 6-K of the Registrant filed on December 20, 2024.

Incorporated by reference to the Form 6-K of the Registrant filed on December 30, 2024.

####### Incorporated by reference to the Form 6-K of the Registrant filed on March 19, 2025.

† Portions of these exhibits (indicated with markouts) have been redacted in accordance with Item 601(b)(10)(iv).

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

GENENTA SCIENCE S.P.A.

By: ***/s/ Pierluigi Paracchi***	**By:** ***/s/ Richard B. Slansky***
Name: Pierluigi Paracchi	**Name: Richard B. Slansky**
Title: Chief Executive Officer (Principal Executive Officer)	**Title: Chief Financial Officer (Principal Financial and Accounting Officer)**
Date: March 31, 2026	**Date: March 31, 2026**

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DANNIBLE & MCKEE, LLP
Certified Public Accountants and Consultants
Financial Plaza, 221 S. Warren St., Syracuse, New York 13202-1628
(315) 472-9127 Fax (315) 472-0026

Report of Independent Registered Public Accounting Firm

March 31, 2026

To the Board of Directors and Shareholders of
Genenta Science S.p.A.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Genenta Science S.p.A. ("the Company") as of December 31, 2025, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2025, and the related notes to the consolidated financial statements (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. Federal Securities Laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2021.

/s/ Dannible & McKee, LLP
Dannible & McKee, LLP
Syracuse, New York
March 31, 2026

DANNIBLE & MCKEE, LLP

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

	Year Ended December 31,		
	2025	2024	2023
	(in Euros)		
Operating expenses			
Research and development	€ 2,699,342	€ 4,812,854	€ 6,474,441
General and administrative	3,904,398	4,951,456	5,258,501
Total operating expenses	6,603,740	9,764,310	11,732,942
Loss from operations	(6,603,740)	(9,764,310)	(11,732,942)
Other income (expense)			
Other income	11,456	529,683	(4,875)
Finance income	608,508	81,140	309,253
Net exchange rate gain (loss)	(546,051)	240,992	(216,891)
Total other income, net	73,913	851,815	87,487
Loss before income taxes	(6,529,827)	(8,912,495)	(11,645,455)
Income tax benefit (expense)	-	-	-
Net loss	€ (6,529,827)	€ (8,912,495)	€ (11,645,455)
Net loss per share - basic	€ (0.33)	€ (0.49)	€ (0.64)
Weighted average number of shares outstanding - basic and diluted	19,710,187	18,273,490	18,216,907
Other comprehensive income (loss)			
Total change of marketable debt securities	7,205	(118,750)	214,984
Change in foreign currency translation	70,360	(23,446)	(15,853)
Total other comprehensive income (loss)	77,565	(142,196)	199,131
Comprehensive loss	€ (6,452,262)	€ (9,054,691)	€ (11,446,324)

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

Genenta Science S.p.A.
Consolidated Balance Sheets

	At December 31, 2025	At December 31, 2024	At December 31, 2023
	(in Euros)		
Assets			
Current assets			
Cash and cash equivalents	€ 5,527,672	€ 4,581,749	€ 3,691,420
Marketable Securities	22,621,518	8,078,002	15,084,284
Prepaid expenses and other current assets	1,830,362	1,813,226	2,480,554
Total current assets	29,979,552	14,472,977	21,256,258
Non-current assets			
Fixed assets, net	€ 22,465	€ 42,922	€ 82,977
Other non-current assets	1,883,943	304,744	1,004,560
Other non-current assets - related party	3,350	3,350	3,350
Total non-current assets	1,909,758	351,016	1,090,887
Total assets	€ 31,889,310	€ 14,823,993	€ 22,347,145
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable	€ 1,509,267	€ 317,830	€ 294,975
Accounts payable - related party	300,328	180,116	170,888
Accrued expenses	111,118	232,307	153,136
Accrued expenses - related party	78,172	1,031,345	861,578
Other current liabilities	119,000	337,764	255,062
Total current liabilities	2,117,885	2,099,362	1,735,639
Non-current liabilities			
Mandatory convertible bond - at fair value	7,603,000	-	-
Other non-current liabilities	-	1,158	14,594
Retirement benefit obligation	327,785	227,767	164,655
Total long-term liabilities	7,930,785	228,925	179,249
Commitments and contingencies	-	-	-
Shareholders' equity			
Ordinary shares authorized, no par value, 59,700,000 and 23,432,183, 18,289,866 and 18,216,958 issued and outstanding respectively	84,259,476	68,462,280	67,344,140
Accumulated deficit	(62,585,347)	(56,055,520)	(47,143,025)
Accumulated other comprehensive income	166,511	88,946	231,142
Total shareholders' equity	21,840,640	12,495,706	20,432,257
Total liabilities and shareholders' equity	€ 31,889,310	€ 14,823,993	€ 22,347,145

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

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

	Common shares outstanding	Common stock, no par value	Accumulated deficit	Accumulated other comprehensive income	Total
Balance at December 31, 2022	18,216,858	€ 66,603,725	€ (35,465,559)	€ -	€ 31,138,166
Share-based compensation	-	739,884	-	-	739,884
Capital increase ATM program	100	531	-	-	531
Other comprehensive income	-	-	(32,011)	231,142	199,131
Net loss	-	-	(11,645,455)	-	(11,645,455)
Balance at December 31, 2023	18,216,958	€ 67,344,140	€ (47,143,025)	€ 231,142	€ 20,432,257
Share-based compensation	-	847,255	-	-	847,255
Capital increase ATM program	72,908	270,885	-	-	270,885
Other comprehensive income	-	-	-	(142,196)	(142,196)
Net loss	-	-	(8,912,495)	-	(8,912,495)
Balance at December 31, 2024	18,289,866	€ 68,462,280	€ (56,055,520)	€ 88,946	€ 12,495,706
Share-based compensation	-	1,009,738	-	-	1,009,738
Capital increase ATM program and Registered Direct Offering	5,142,317	14,787,458	-	-	14,787,458
Other comprehensive income	-	-	-	77,565	77,565
Net loss	-	-	(6,529,827)	-	(6,529,827)
Balance at December 31, 2025	23,432,183	€ 84,259,476	€ (62,585,347)	€ 166,511	€ 21,840,640

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

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

	At December 31,		
	2025	**2024**	**2023**
	(in Euros)		
Cash flows from operating activities			
Net loss	€ (6,529,827)	€ (8,912,495)	€ (11,645,455)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	28,082	44,523	42,453
Retirement benefit obligation	100,018	63,112	75,692
Share-based compensation	1,009,738	847,255	739,884
Fair value loss on convertible bond	103,000	-	-
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(17,136)	667,328	(554,042)
Other non-current assets	(1,579,199)	699,816	596,943
Accounts payable	1,191,437	22,855	(747,079)
Accounts payable - related party	120,212	9,228	18,900
Accrued expenses	(121,189)	79,171	(49,253)
Accrued expenses - related party	(953,173)	169,767	372,371
Other current liabilities	(218,764)	82,702	(42,813)
Other non-current liabilities	(1,158)	(13,436)	(12,624)
Net cash used in operating activities	(6,867,959)	(6,240,174)	(11,205,023)
Cash flows from investing activities			
Purchases of marketable securities	(33,165,127)	(16,380,363)	(14,878,875)
Proceeds from maturities of marketable securities	18,628,816	23,267,895	-
Purchases of fixed assets	(7,625)	(4,468)	(13,791)
Net cash (used in) provided by investing activities	(14,543,936)	6,883,064	(14,892,666)
Cash flows from financing activities			
Proceeds from the ATM program	14,787,458	270,885	531
Proceeds from the convertible bond	7,500,000	-	-
Net cash provided by financing activities	22,287,458	270,885	531
Effect of exchange rate changes	70,360	(23,446)	(6,278)
Net increase (decrease) in cash and cash equivalents	945,923	890,329	(26,103,436)
Cash and cash equivalents at the beginning of the period	4,581,749	3,691,420	29,794,856
Cash and cash equivalents at the end of the period	€ 5,527,672	€ 4,581,749	€ 3,691,420

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") was founded in Milan, Italy by San Raffaele Hospital ("OSR"), Pierluigi Paracchi, Luigi Naldini, and Bernhard Gentner, and was incorporated in July 2014. The registered office (or headquarters) is located in Milan, Italy. The Company's reporting currency is Euros ("EUR" or "€"). The Company formed a wholly owned, Delaware incorporated subsidiary, Genenta Science, Inc., intended for future operations in the U.S. ("U.S. Subsidiary"). The U.S. Subsidiary operates in U.S. Dollars ("USD" or "$").

American Depository Shares ("ADSs") representing the Company's ordinary shares have been publicly traded on the NASDAQ Capital Market since December 15, 2021.

Genenta is embarking on a strategic transformation to evolve into a next-generation strategic industrial consolidator focusing on acquiring privately held businesses operating in national-security regulated sectors contemplated by the Italian "Golden Power" legislation; however, we are and have been an early-stage company developing first-in-class cell and gene therapies to address unmet medical needs in solid tumors. The Company has been developing its clinical leading product, Temferon™, to treat glioblastoma multiforme ("GBM"), a solid tumor affecting the brain. The Company is conducting its clinical trials in Italy and may eventually begin a clinical trial in other parts of Europe and the U.S. to study Temferon™. In June 2023, the Company's Board of Directors selected metastatic Renal Cell Cancer ("mRCC") as the second solid tumor indication for Temferon. The Company discontinued its mRCC trial in early 2026. The Company engaged DC Advisory at the end of 2025 to assist in the identification of a strategic partner to advance the development of Temferon.

The Company is subject to risks and uncertainties common to clinical-stage companies in the life-science and biotechnology industries, including, but not limited to, risks associated with the development and potential discontinuation of product candidates, the conduct and completion of clinical activities, the receipt of regulatory approvals, competition from other biotechnology and pharmaceutical companies, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations.

The Company's product development efforts will require significant additional resources, including capital, personnel, and infrastructure, as well as compliance and reporting capabilities. The Company may also evaluate changes to its development priorities and operational plans from time to time. Even if development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales or achieve profitability. The Company is embarking on a strategic transformation to evolve into a next-generation strategic industrial consolidator focused on acquiring privately held businesses operating in national-security regulated sectors contemplated by the Italian Golden Power legislation. The "Golden Power" is Italy's investment screening framework — broadly comparable to CFIUS in the United States, the IEF regime in France, and the United Kingdom's NSI Act — and covers strategic domains such as biotechnology, biosecurity, defense, cybersecurity, AI-driven intelligence, aerospace, quantum technologies, secure communications, and critical infrastructure. These proposed activities did not affect the Company's financial statements at December 31, 2025.

Shelf Registration Statement, At-the-Market Sales Agreement, and Registered Direct Offering

In 2023, the Company filed with the Securities and Exchange Commission (the "SEC") a shelf registration statement on Form F-3 (File No. 333-271901) (the "Shelf Registration Statement") that was subsequently declared effective in May 2023. It permits the Company to sell from time to time ordinary shares, including ordinary shares represented by ADSs, or rights to subscribe for ordinary shares or ordinary shares represented by ADSs in one or more offerings in amounts, at prices, and on the terms that the Company will determine at the time of offering for aggregate gross sale proceeds of up to $100 million.

In May 2023, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as agent (the "Prior ATM"), for the offer and sale of up to $30.0 million ordinary shares represented by ADSs from time to time in accordance with the terms of the agreement and SEC rules and regulations. This Prior ATM was subsequently mutually terminated in March 2024.

Pursuant to the Company's Shelf Registration Statement and that certain ATM Sales Agreement dated April 26, 2024, as amended on December 20, 2024 (as so amended, the "Sales Agreement"), with Virtu Americas LLC and Rodman & Renshaw LLC (collectively, the "Sales Agents"), pursuant to which the Company may offer and sell ADSs with an aggregate offering price up to $29,696,999 from time to time through or to the Sales Agents, acting as sales agents or principals, subject to the terms and conditions described in the Sales Agreement and SEC rules and regulations (the "ATM"). For as long as the aggregate market value the Company's outstanding ordinary shares held by non-affiliates remains below $75.0 million, the Company is subject to the offering limits in General Instruction I.B.5 of Form F-3 and in no event will the Company sell securities in public primary offerings on Form F-3, including through the ATM, with a value exceeding one-third of its outstanding ordinary shares held by non-affiliates in any 12 calendar month period.

As of December 20, 2024, 73,008 ADSs were sold through the Prior ATM for gross proceeds of €271,416 (or $303,001). In March 2025, the Company sold 856,602 ADSs through the ATM for gross proceeds of €3,007,131 (or $3,255,430).

Sales of ADSs under the Sales Agreement may be made by any method that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended (the "Securities Act"). The Sales Agents are not required to sell any specific number or dollar amount of ADSs but will act as our sales agents and use commercially reasonable efforts consistent with their normal trading and sales practices, on mutually agreed terms between the Sales Agents and the Company. There is no arrangement for funds to be received in any escrow, trust, or similar arrangement.

The Sales Agents will receive from the Company a commission of up to 3.0% of the gross proceeds of any ADSs sold through them under the Sales Agreement. In connection with the sale of ADSs on behalf of the Company, each of the Sales Agents will be deemed to be an "underwriter" within the meaning of the Securities Act, and the compensation of the Sales Agents may be deemed to be underwriting commissions or discounts. The Company has also agreed to provide indemnification and contribution to the Sales Agents with respect to certain liabilities, including liabilities under the Securities Act.

In October 2025, the Company entered into a Securities Purchase Agreement with certain institutional investors relating to the offer and sale of 4,285,715 ADSs, at a purchase price of $3.50 per ADS, for gross proceeds of approximately €12,867,805 (or $15,000,000) in a registered direct offering (the "Registered Offering").

The Company also entered into a Placement Agency Agreement with Maxim Group LLC and Rodman & Renshaw LLC, pursuant to which Maxim Group LLC acted as the lead placement agent and Rodman & Renshaw LLC acted as the co-placement agent for the Registered Offering. Pursuant to the terms and conditions stated in the Placement Agency Agreement, the Company has agreed to pay the Placement Agents a cash fee equal to 6.0% of the aggregate gross proceeds of the Registered Offering. The Company also agreed to pay the Placement Agents an expense allowance of up to $75,000 for legal fees and other out-of-pocket expenses.

Liquidity and risks

The Company has incurred losses since its inception, including a net loss of €6.5 million, €8.9 million, and €11.6 million for the years ended December 31, 2025, 2024 and 2023, respectively. In addition, as of December 31, 2025, the Company had an accumulated deficit of €62.6 million.

The Company has primarily funded these losses through the proceeds from sales of convertible debt and equity. The Company has incurred recurring losses and expects to continue to incur losses for the foreseeable future. In addition, the Company expects that its existing cash, cash equivalents, and marketable securities on hand as of December 31, 2025, of €28.1 million will be sufficient to fund current planned operations and capital expenditure requirements for at least the next twelve months. However, the future viability of the Company is dependent on its ability to raise additional capital to finance its operations, and/or generate positive cash flows from its proposed acquisitions. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to continue as a going concern, as well as the ability to pursue its business strategies. There can be no assurance that the current or proposed operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company's historical business model, typical of biotechnology companies developing new therapeutic products, has not reached a balanced income and financial position, and features negative cash flows. This is because, at this stage, costs must be borne in relation to services and personnel, directly connected to research and development activities, and the 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 costs for research and development in the foreseeable future. Although the Company intends to target majority ownership in companies with established operating profitability as part of its strategic transformation, there is no certainty that the Company will become profitable in the future.

The Company may require additional capital to meet its long-term operating requirements. It expects to raise additional capital through, among other things, the sale of equity, debt, or convertible securities through public offerings or private placements, including, but not limited to, sales of ADSs pursuant to the ATM. If adequate funds are not available in the future, the Company may be forced to delay, reorganize, or cancel research and development programs, or to enter into financing, licensing or collaboration agreements with unfavorable conditions or waive rights to certain products which otherwise it would not have waived, resulting in negative effects on the activity and on the economic, and /or financial situation of the Company.

The Company's ability to raise additional capital may be adversely impacted by the potential worsening of global economic and political conditions and volatility in the credit and financial markets in the U.S. and worldwide. This could be exacerbated by, among other factors, inflation, fluctuating interest rates, tariffs, and geopolitical conflicts, as well as shareholder concerns over the Company's strategic transformation to evolve into a next-generation industrial consolidator. The Company's failure to raise capital as and when needed, or on acceptable terms could have a negative impact on the Company's financial condition, its ability continue as a going concern, and its ability to pursue its current and proposed business strategy, and the Company may have to delay, reduce the scope of, suspend or eliminate one or more of its research-stage programs, clinical trials, or future commercialization efforts.

2. Summary of significant accounting policies

Basis of presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for consolidated financial information and in accordance with the instructions to Form 20-F and Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP guidance as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB") unless otherwise stated.

A summary of the significant accounting policies applied in the preparation of these 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 consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the consolidated 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 expenses and related milestone payments, share-based compensation expense, valuation of Research & Development ("R&D") tax credits, the valuation of equity, and the recoverability of the Company's net deferred tax assets and related valuation allowance. Estimates are periodically reviewed considering changes in circumstances, facts, and experience. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are recorded in the period in which they become known. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the 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, whose amounts may at times exceed 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.

Marketable securities

Investments with an original maturity of more than (3) three months are classified as available-for-sale ("AFS") marketable securities, with those having a remaining maturity of more than one year presented as non-current assets.

AFS securities are measured at fair value, with unrealized gains and losses recorded in Other Comprehensive Income (Loss) until realized. Purchase premiums are amortized to the earliest call date, and discounts are accreted to maturity, with related amounts recorded in interest income, net. Realized gains and losses are determined using the specific identification method and reported in other income (expense), net.

The Company evaluates AFS securities each reporting period under ASC 326 to identify any credit losses. Any credit loss is recognized in earnings, limited to the difference between fair value and amortized cost. Accrued interest receivable is reported within prepaids and other current assets and is excluded from impairment testing. Write-offs of accrued interest are recorded through the reversal of interest income and/or credit loss expense. To date, no credit losses or write-offs have been recognized. Accrued interest receivable related to AFS debt securities is presented within prepaids and other current assets and is excluded from both fair value and amortized cost when assessing impairment. The Company writes off accrued interest only when it is deemed uncollectible, recording such write-offs through reversal of interest income, credit loss expense, or both. To date, no write-offs have been necessary.

Mandatory convertible bond

The Company has issued a mandatory convertible bond ("MCB"), which does not meet the "fixed-for-fixed" equity classification test under ASC 480, as the number of shares to be delivered is variable while the monetary value of the obligation is predetermined by reference to the nominal amount and interest. Accordingly, under ASC 480-10-25-14, the MCB is classified as a liability and accounted for at fair value through profit or loss.

The MCB contains embedded features, including conversion rights, ownership caps, and conversion price ceilings, which represent embedded derivatives requiring fair value measurement in accordance with ASC 815. However, the Company has elected to value the instrument in its entirety, including the embedded derivatives under ASC 825 - the Fair Value Option. As a result, the MCB is measured at fair value, with changes in fair value recognized in the Consolidated Statement of Operations and Comprehensive Loss within "Unrealized fair value gain/loss on MCB" in the period in which they arise.

Consistent with ASC 825-10-25-3, the election of the fair value option requires that issuance costs, transaction fees, and any other directly attributable costs, including legal and due diligence expenses, be expensed immediately as incurred.

Net loss and comprehensive income (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 record 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 year ended December 31, 2025, the net loss was equal to €6.5 million, other comprehensive income was €77,565, and total comprehensive loss was equal to €6.5 million.

For the year ended December 31, 2024, the net loss was approximately €8.9 million, with other comprehensive loss being €142,196, and total comprehensive loss was approximately €9.1 million.

For the year ended December 31, 2023, net loss was €11.6 million with other comprehensive income being €199,131 and total comprehensive loss was €11.4 million.

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.

At December 31, 2025, the Company had 23,432,183 ordinary shares issued and outstanding, with 2.3 million ordinary shares reserved for the Company's Equity Incentive Plan 2021–2035.

At December 31, 2025, the Company had 1.9 million outstanding options and 23,502 ordinary share equivalents, in the form of underwriters' ordinary share warrants.

Diluted EPS was not relevant at December 31, 2025, 2024, or 2023, as the effect of ordinary share equivalents, in the form of 1.9 million stock options, and 23,502 underwriters' ordinary share warrants, would have been anti-dilutive. (See Note 14. Shareholders' equity and Note 15. 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 the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the Consolidated Statements of Operations and Comprehensive Loss. For financial reporting purposes, the assets and liabilities of the U.S. Subsidiary are translated into EUR using exchange rates in effect at the balance sheet date. The net income/(loss) of the U.S. Subsidiary is translated into EUR using average exchange rates in effect during the reporting period. The resulting currency translation impact is recorded in Shareholders' equity as a cumulative translation adjustment.

For the year ended 2025, the currency translation impact was approximately €70,400.

For the year ended 2024, the currency translation impact was approximately €23,400.

For the year ended 2023, the currency translation impact was approximately €15,800.

Any change in the net foreign exchange rate effect is due to the fluctuation in the USD exchange rate with the Euro.

Emerging growth company status

The Company is an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act, or U.S. 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 U.S. JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the U.S. 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 initial public offering ("IPO") or such earlier time that it is no longer an "emerging growth company."

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 ("CODM") in making decisions regarding resource allocation and assessing performance. The Company and its chief operating decision-maker view the Company's current operations and the management of its biotech business in one (1) operating segment.

Tax credit on investments in research and development

In line with the legislation in force at December 31, 2025, 2024, and 2023, and for the fiscal year 2026, 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 to reduce most taxes payable, including income tax or regional tax on productive activities, as well as social security contributions and payroll withholding taxes.

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

The eligible activities consist of fundamental research, industrial research, and experimental development as defined in 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 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 research and development expenditure net of related tax credit benefit 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 Consolidated Statements of Operations and Comprehensive Loss.

Share-based compensation

To reward the efforts of employees, officers, directors, and certain consultants, and to promote the Company's growth and development, the Board may approve, upon occasion, various share-based awards based on the Company's stock option plan (the "Equity Incentive Plan 2021–2035" or the "Plan", originally approved on May 20, 2021 and subsequently modified to extend the final deadline for the issuance of the common shares until December 31, 2035). The Plan was amended to ensure that all stock options granted during its term are exercisable for a period of 10 years from their respective grant dates. (Refer to Note 15. Share-Based Compensation.)

Currently, the Company has authorized options on 2,343,218 common shares (i.e., 10% of the number of shares outstanding, which was 23,432,183 common shares outstanding at December 31, 2025); however, as provided by the Plan, the Company may increase the authorized shares under the Plan up to a maximum of 2,700,000 common shares without further shareholder approval. Therefore, as the Company raises additional capital, and the total number of outstanding shares increases, the Board has the authority to issue additional options up to 2,700,000 common shares limit, without the need to obtain further authorization from shareholders, unless the number of outstanding common shares (aka ordinary shares) exceeds 27,000,000.

The Company measures its stock option awards granted to employees, officers, directors, and consultants under the Plan based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is normally the vesting period of the respective award. Forfeitures are accounted for as they occur. The measurement date for option awards is the date of the grant. The Company classifies stock-based compensation expense in its Consolidated Statement of Operations and Comprehensive Loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

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

Representative warrants

Upon the closing of the Company's IPO, the Company issued 23,502 warrants to the underwriters of the offering ("Warrants"). The Warrants are exercisable at a per share exercise price equal to $14.375. The Warrants are exercisable at any time and from time to time, in whole or in part, until December 13, 2026.

The Warrants 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 transactions, or a future financing undertaken by the Company. The Warrants were evaluated under applicable guidance and accordingly classified as equity in the consolidated financial statements.

Non-current assets right-of-use

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

Fixed assets

Fixed assets are stated at cost, including any accessories and direct costs that are necessary to make the assets fit for use, and adjusted by the corresponding accumulated depreciation. Depreciation is systematically recorded in the consolidated financial statements, taking into consideration the use, purpose, and financial-technical duration of the assets, based on their estimated useful economic lives. Leasehold improvements depreciation is recorded 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 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 on the terms of the applicable lease or estimated useful life of the improvements, whichever is shorter.

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 years ended December 31, 2025, 2024 and 2023.

Deferred offering costs

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

For the year ended December 31, 2025, the Company incurred offering-related costs of approximately €1.1 million. Of this amount, approximately €12,918 related to ATM offering costs incurred in connection with the sale of ADSs pursuant to the Sales Agreement and were fully expensed as general and administrative costs in the Consolidated Statement of Operations and Comprehensive Loss. The remaining €1,057,408 related to offering costs incurred in connection with the registered direct offering and were offset against additional paid-in capital.

For the year ended December 31, 2024, the Company incurred approximately €0.2 million of costs in connection with its sales of ADSs pursuant to the Sales Agreement that were fully expensed in the Consolidated Statement of Operations and Comprehensive Loss and approximately €0.2 million of deferred due diligence costs and other preliminary activities connected to the issuance of the mandatory convertible bond which was completed in February 2025.

For the year ended December 31, 2023, the Company incurred approximately €0.3 million of ATM Offering costs that were fully expensed in the Consolidated Statement of Operations and Comprehensive Loss.

Recently issued accounting pronouncements

In November 2023, FASB issued ASU 2023-07, which amends ASC 280 to improve the information that a public entity discloses about its reportable segments and to address investor requests for more information about reportable segment expenses by requiring incremental disclosures for segment reporting. The effective date for ASU 2023-07 is for fiscal years beginning after December 15, 2023, and interim periods with fiscal years beginning after December 15, 2024. The amendment requires companies to disclose more information about their reportable segments, including: (1) significant segment expenses, (2) 'other' segment items, (3) the title and position of the chief operating decision maker ("CODM"), (4) how the CODM uses the reported measure(s) of segment profit or loss and (5) annual disclosures about a reportable segment's profit or loss and assets. The Company believes that this ASU does not have a material impact on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which modifies the rules on income tax disclosures to require disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. The Company believes that this ASU does not have a material impact on its consolidated financial statements and related disclosures.

In March 2024, FASB issued ASU 2024-01, Scope Application of Profits Interest and Similar Awards, which clarifies how an entity determines whether a profits interest or similar award (hereafter a "profits interest award") is (1) within the scope of Accounting Standards Codification (ASC) 718, Compensation - Stock Compensation, or (2) not a share-based payment arrangement and therefore within the scope of other guidance. For public business entities, ASU 2024-01 is effective for annual periods beginning after December 15, 2024, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after December 15, 2025, and interim periods within those annual periods. The Company believes that this ASU does not have a material impact on its consolidated financial statements and related disclosures.

In November 2024, FASB issued ASU 2024-04, Debt – Debt with conversion and other options (subtopic 470-20): Induced conversions of convertible debt instruments which provides guidance on accounting for induced conversions of convertible debt instruments. For public business entities, ASU 2024-04 is effective for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual periods. The Company currently does not expect this standard to have a material impact on its financial statements, as its outstanding convertible instruments are mandatory in nature and not subject to induced conversions. The Company will continue to monitor future developments for applicability.

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 a manufacturing processes, perform analytical testing and manufacture clinical trial materials, (e.g., contract manufacturing organizations, or CMOs). Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered. In addition, funding from research grants, if any, is recognized as an offset to research and development expense based on costs incurred on the research program.

The Company annually incurs research costs to meet its biotech 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 Note 17. Related Parties.

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, as well as in the U.S., due to the Company's wholly owned American subsidiary. Taxation in Italy includes the standard corporate income tax ("IRES") and a regional business tax ("IRAP"). Taxation in the U.S. includes federal corporate income tax, 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 rates enacted and applicable laws. In the future, the Company may be taxed in various other countries where it may have permanent establishments, as applicable.

For the year ending December 31, 2025, due to the tax loss position reported, no income taxes were due in Italy, while in the U.S., there was no material tax charge.

For the year ending December 31, 2024, due to the tax loss position reported, no income taxes were due in Italy or the U.S., although the subsidiary in the U.S. had an immaterial tax charge.

For the year ending December 31, 2023, due to the tax loss position reported, no income taxes were due in Italy or the U.S.

The Company uses the asset and liability method of accounting for deferred income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities, measured at tax rates expected to be enacted at the time of their reversals. These temporary differences primarily relate to net operating losses carried forward available to offset future taxable income.

At each reporting date, the Company considers existing evidence, both positive and negative, that could impact its view with regard to future realization of deferred tax assets. In consideration of the start-up status of the Company, a valuation allowance has been established to offset the deferred tax assets, as the related realization is currently uncertain. In the future, should the Company conclude that it is more likely than not that the deferred tax assets are partially or fully realizable, the valuation allowance will be reduced to the extent of such expected realization, and the corresponding amount will be recognized as income tax benefit in the Company's Consolidated Statements of Operations and Comprehensive Loss.

The Company recognizes tax liabilities arising from an uncertain tax position if it is more likely than not that the tax position would be upheld upon examination by the taxing authorities, based on the technical merits. There are no uncertain tax positions that have been recognized in the accompanying consolidated financial statements. For the Company, the prior five years of tax returns (2021-2025) are potentially subject to audit, for the subsidiary in the U.S., the open years for tax examination are 2023, 2024, and 2025.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. A reconciliation of the Company's tax provisions is summarized as follows:

	At December 31,		
	2025	**2024**	**2023**
	(in Euros)		
Income taxes at Italy statutory rate	€ (2,325,858)	€ (2,037,277)	€ (2,794,909)
Permanent differences	126,200	(39,935)	309,512
Other	8,743	71,627	(171,032)
Federal income tax for Genenta Science, Inc.	108,004	(62,825)	(89,910)
Change in valuation allowance	2,082,911	2,068,410	2,746,339
Total provision expense for income taxes	€ -	€ -	€ -

Significant components of the Company's net deferred tax assets are summarized as follows:

	At December 31,		
	2025	2024	2023
	(in Euros)		
Deferred tax assets			
Net operating loss carryforwards	€ 16,084,600	€ 13,876,117	€ 11,772,870
Other temporary differences	4,558	130,130	150,347
Allowance for corporate equity	481,071	481,071	495,692
Total deferred tax assets	16,570,239	14,487,319	12,418,909
Valuation allowance	(16,570,239)	(14,487,319)	(12,418,909)
Net deferred tax assets	€ -	€ -	€ -

At December 31, 2025, 2024, and 2023, the Company believes there are no significant differences concerning 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 applicable law, all existing tax loss carry forwards will never expire, but they can offset only 80% of the taxable income of the year. The rules do not affect the tax loss carryforward that refers to the start-up period, defined as the first three years of operations starting from the inception of the Company.

The following table shows the amount of deferred tax assets that can be carried forward indefinitely and used without limitation or with the limit of 80% of taxable income generated in Italy, as provided by Legislative Decree 98/2011:

	At December 31,		
	2025	2024	2023
	(in Euros)		
No expiration date	€ 5,487,085	€ 5,487,085	€ 5,487,085
No expiration date - DL 98/2011	61,371,643	51,680,567	43,191,915
Total	€ 66,858,728	€ 57,167,652	€ 48,679,000

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 trials. Since the Company's clinical trials are still in an early phase, the time frame and uncertainties regarding the outcome of the completion justify the full allowance of deferred tax assets.

6. Cash and cash equivalents

Cash and cash equivalents are detailed as follows:

	At December 31,		
	2025	2024	2023
	(Euro)		
Cash in bank	€ 3,835,190	€ 2,530,549	€ 3,687,402
Cash in short-term marketable securities	1,692,482	2,047,200	-
Cash in hand & prepaid cards	-	4,000	4,018
Total cash and cash equivalents	€ 5,527,672	€ 4,581,749	€ 3,691,420

7. Marketable securities

The Company invests available liquid assets (i.e., not used or expected to be needed in short/very short-term operations), in marketable securities consisting of highly rated domestic and foreign government debt securities, specifically U.S. Treasury Bills and Notes, and Italian Government Bonds. Since the Company's intent was not to sell the securities immediately, but the Company was uncertain if the securities would be held until maturity, it was determined that the debt securities were to be classified as AFS.

Available-for-sale ("AFS") debt securities are detailed as follows:

	December 31, 2025			
	Amortized cost	Fair value	Unrealized gain (loss)	Allowance for credit losses
Available-for-sale ("AFS")	€ 22,518,281	€ 22,621,518	€ 103,439	€ -
Total debt securities	**€ 22,518,281**	**€ 22,621,518**	**€ 103,439**	**€ -**

	December 31, 2024			
	Amortized cost	Fair value	Unrealized gain (loss)	Allowance for credit losses
Available-for-sale ("AFS")	€ 7,992,891	€ 8,078,002	€ 96,234	€ -
Total debt securities	**€ 7,992,891**	**€ 8,078,002**	**€ 96,234**	**€ -**

	December 31, 2023			
	Amortized cost	Fair value	Unrealized gain (loss)	Allowance for credit losses
Available-for-sale ("AFS")	€ 15,123,831	€ 15,084,284	€ 214,984	€ -
Total debt securities	**€ 15,123,831**	**€ 15,084,284**	**€ 214,984**	**€ -**

8. Fair value measurements

The Company measures certain assets and liabilities at fair value in accordance with ASC 820. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction in the principal or most advantageous market at the measurement date. Valuation techniques are designed to maximize the use of observable inputs and minimize 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 fair value of assets classification is represented as follows:

	December 31, 2025			
	Total	**Level 1**	**Level 2**	**Level 3**
Cash and cash equivalents	€ 5,527,672	€ 5,527,672	€ -	€ -
Marketable securities	€ 22,621,518	€ 22,621,518	€ -	€ -
Total financial assets	€ 28,149,190	€ 28,149,190	€ -	€ -

	December 31, 2024			
	Total	**Level 1**	**Level 2**	**Level 3**
Cash and cash equivalents	€ 4,581,749	€ 4,581,749	€ -	€ -
Marketable securities	€ 8,078,002	€ 8,078,002	€ -	€ -
Total financial assets	€ 12,659,751	€ 12,659,751	€ -	€ -

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

The fair value of liabilities classification is represented as follows:

	December 31, 2025			
	Total	**Level 1**	**Level 2**	**Level 3**
Mandatory convertible bond	€ 7,603,000	-	-	€ 7,603,000
Mandatory convertible bond	€ 7,603,000	**€ -**	**€ -**	**€ 7,603,000**

The instrument is classified as a Level 3 fair value liability under ASC 820, based on the use of significant unobservable inputs in its valuation (See Note 13. Mandatory convertible bond issuance for more details).

No transfers between level of fair value hierarchy occurred during the period.

The Company had no assets or liabilities classified as Level 3 fair value as of December 31, 2024 and 2023.

The carrying values of the Company's R&D tax credits, VAT credits, accounts payable, accrued expenses, and other current liabilities were evaluated and determined to approximate their fair values due to the short-term nature of these assets and liabilities.

9. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	At December 31,		
	2025	**2024**	**2023**
		(in Euros)	
Value Added Tax (VAT)	€ 685,630	€ 698,735€	1,170,634
Research and development tax credit	600,000	749,676	833,000
Advances payments to suppliers	16,373	35,991	34,108
Other current assets	337,438	210,830	64,664
Other prepaids	190,921	117,994	378,148
Total	€ 1,830,362	€ 1,813,226€	2,480,554

Value Added Tax (VAT) receivable is 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 2025, 2024, and 2023 was 22%. Reduced rates are provided for specifically listed supplies of goods and services. The VAT receivable is carried forward indefinitely and does not expire.

During the year ended December 31, 2025, the Company received a short-term VAT refund amounting to approximately €868,000.

The Company reclassified to other non-current assets a portion of the VAT receivable, which is expected to be realized beyond 12 months.

Tax credits on research and development represent a special tax relief offered to Italian companies operating in the research and development sector and can be used to offset most taxes payable. The Company has a total research and development tax credit available to be used of approximately €3.0 million at December 31, 2025, €3.8 million at December 31, 2024, and €4.1 million at December 31, 2023, which can be carried forward indefinitely and do not expire. However, in light of the Company's current stage of operations and the uncertainties affecting its near-term outlook, management reassessed the recoverability of the tax credit for purposes of the consolidated financial statements prepared in accordance with U.S. GAAP. As a result of this reassessment, and applying a conservative approach, the Company recognized a receivable balance of €1.9 million, representing management's best estimate of the portion of the tax credit that is expected to be utilized in future periods beyond December 31, 2025. This estimate takes into account the impact of recent fundraising activities, which have extended the Company's liquidity horizon.

During the 12-month period ended December 31, 2025, 2024, and 2023, the Company utilized approximately €1.1 million, €750,000, and €732,000 to offset certain social contributions and taxes payable. The benefit recorded for the 12-months ended December 31, 2025, 2024, and 2023, to offset research and development expenses was approximately €2.2 million, €0.5, and €0.4, million respectively. The increase in the benefit recorded for the year ended December 31, 2025 compared to the prior year primarily reflects management's reassessment of the recoverability of the related tax credits, based on updated projections and recent financing activities.

Advance payments to suppliers at December 31, 2025, 2024, and 2023, mainly relate to R&D operating services.

Other current assets at December 31, 2025, primarily relate to the recognition of an accrued receivable of approximately €0.3 million under the BNY revenue sharing program.

Other current assets at December 31, 2024, mainly relate to interest maturing on investment in marketable securities and the allowance for corporate equity ("ACE") of approximately €180,000 that were subsequently collected in 2025.

Other current assets at December 31, 2023, mainly relate to interests maturing on investment in marketable securities.

At December 31, 2025 and 2024, other prepaids refer to accrual adjustments for services that have already been fully invoiced and paid, but whose economic usefulness is distributed over multiple periods beyond the current closing period. These costs mainly concern IT services, licenses, insurance, and manufacturing activities.

At December 31, 2023, Other prepaid expenses mainly relate to the directors and officers ("D&O") insurance policy paid in December 2023 of approximately €0.2 million.

10. Fixed assets, net

Fixed assets consist of the following:

	At December 31,		
	2025	**2024**	**2023**
	(In Euros)		
Software (ERP Implementation)	€ 87,800	€ 87,800	87,800
Equipment	61,070	53,445	48,976
Total fixed assets	148,870	141,245	136,776
Less: accumulated depreciation	(126,405)	(98,323)	(53,799)
Fixed assets, net	€ 22,465	€ 42,922	€ 82,977

Software included software customization and development costs related to information technology security infrastructure and the Company's ERP system.

Equipment consists of computers, furniture, and fixtures in our office space in Milan, Italy.

There were no significant purchases, disposals, or impairments during the current and previous 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.

11. Other non-current assets

Other non-current assets consist of the following:

	At December 31,		
	2025	2024	2023
		(in Euros)	
Value Added Tax (VAT)	€ 582,785	€ 290,150	€ 630,342
Research and development tax credit	1,300,000	-	167,000
Other non-current assets	1,158	14,594	207,218
Other non-current assets - related parties	3,350	3,350	3,350
Total other non-current assets	€ 1,887,293	€ 308,094	€ 1,007,910

The non-current VAT balance reflects the portion of the VAT credit that management does not expect to recover within the next twelve months as of the respective reporting dates.

As of December 31, 2025, the Company recognized a long-term R&D tax credit asset, reflecting the portion of the credit expected to be utilized beyond the next twelve months.

As of December 31, 2025, other non-current assets include the right-of-use ("ROU") asset related to a finance lease for a company vehicle entered into in February 2022 with a 48-month term ending in January 2026.

The lease was accounted for as a finance lease under ASC 842. As of December 31, 2025, the remaining net book value of the ROU asset and the corresponding lease liability amounted to €1,158, with the lease liability classified as current due to the imminent expiration of the lease term.

In February 2026, upon expiration of the lease term, the Company exercised its contractual purchase option and acquired the vehicle. The related ROU asset and lease liability were accordingly reversed.

In addition, other non-current assets - related party includes a security deposit of €3,350 paid to OSR - San Raffaele Hospital as a security guarantee for the office lease contract. (See Note 18. Commitments and contingencies).

12. 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 December 31, 2025, 2024, and 2023 was approximately €0.3 million, €0.2 million and €0.2 million, respectively. The increase was due to the payment of performance bonuses in June 2025, on which a portion of the TFR accrues.

13. Mandatory convertible bond issuance

On March 19, 2025, the Company issued the first tranche of a mandatory convertible bond (the "MCB" or the "POC" – *Prestito Obbligazionario Convertibile*) for a nominal amount of €7,500,000, as part of a broader issuance totaling €20,000,000, pursuant to the agreement with Fondazione Enea Tech e Biomedical (the "Investor") signed on March 12, 2025.

The instrument denominated "Genenta 2025–2028," is structured as a three-year mandatory convertible bond, with no cash redemption at maturity. A second tranche of €12,500,000 may be issued contingent on the achievement of clinical, regulatory, and financial milestones, or as otherwise agreed between the parties.

The key terms, including conversion terms of the instrument are summarized as follows:

- *Total nominal value*: €20,000,000 (two tranches)
- *Tranche 1 issued:* €7,500,000 on March 19, 2025
- *Tranche 2 (conditional)*: €12,500,000, contingent on R&D and financial milestones
- *Maturity*: March 19, 2028 (of Tranche 1)
- *Mandatory conversion*: *mandatory and automatic* at maturity, or earlier based on specific conditions (e.g., change of control or investment round)
- *Conversion formula*: 55% based on the 90-day VWAP of ADS + 45% based on the fair market value determined by a third party
- *Conversion price cap*: USD 17.64 per share
- *Equity cap*: Conversion limited to a maximum of 29% of share capital
- *Discount (if applicable)*: 6% or 3%, depending on market conditions
- *Interest*:
  - 6% per annum if paid in ordinary shares ("equity-settled")
  - 4% per annum if paid in cash
  - Interest is accrued annually and payable in full upon conversion
- *Redemption rights*: No right of early redemption by the bondholder, except in the case of default or material breach
- *Price of conversion*: Weighted average of 55% market ADS price and 45% fair value (as determined by an independent advisor), with caps and anti-dilution adjustments (see Conversion Formula above)
- *Lock-up*: Converted shares are subject to lock-up (2 years, or 1 year if converted early)
- *Classification*: No embedded derivative requiring bifurcation, no cash settlement feature

The Company's Board has formally resolved at its meeting on June 4, 2025, to pay interest in ordinary shares at the annual rate of 6%, not in cash, subject to any extraordinary activity of the Company requiring cash payment, such as a merger, acquisition, or other change in control.

Interest is accrued annually at a rate of 6% and fully payable in ordinary shares ("equity-settled") upon conversion of the MCB. Since the instrument is measured at fair value, interest is not accrued separately; instead, it is embedded in the liability's fair value. Consequently, the total fair value of the liability (including the implicit interest) is remeasured at each reporting date, and any change in fair value is a gain (loss) of the reporting period.

The amount of due diligence costs related to the agreement with the Investor and the issuance of the MCB, recognized in the Consolidated Statements of Operations and Comprehensive Loss as financial expenses as of December 31, 2025, is approximately €0.4 million.

Fair valuation at initial recognition

The conversion terms are contingent upon specific corporate scenarios such as an investment round, a change of control, maturity, and dissolution, with scenario-based probabilities assigned to each. Given the presence of non-linear payoffs, optionality features, and market-linked triggers, a Monte Carlo simulation model was employed to value the instrument at initial recognition.

The valuation was made using a risk-neutral Monte Carlo simulation model consisting of 20,000 paths, projecting the issuer's stock price via Geometric Brownian Motion with volatility calibrated over a three (3) year forward-looking horizon.

Key inputs included:

Parameter	**Value / Source**
Effective date	March 19, 2025
Maturity	March 19, 2028
Nominal value	$8.165 million (converted from €7.5 million FX as of 3/19/2025)
Risk-free rate	4.00% (U.S. Treasury, 3.0-year term)
Equity volatility (annualized)	83.0% (Historical, 3.0-year horizon)
Stock price on valuation date	$3.82 (Nasdaq CM: GNTA – S&P Capital IQ)
Simulated term	3.0 years
Number of simulations	20,000

Scenarios modeled:

Scenario	Probability	Event date	Average bond balance (USD 000s)	Average payoff (USD 000s)	Discount rate	PV factor	PV (USD 000s)
Investment round	2.5%	3/31/2026	$ 8,678	$ 9,321	7.3%	0.9299	$ 217
Change of control	5.0%	12/31/2027	$ 9,548	$ 9,776	7.3%	0.8221	$ 402
Maturity	90.0%	3/19/2028	$ 9,656	$ 10,317	7.3%	0.8098	$ 7,519
Dissolution	2.5%	9/30/2026	$ 8,927	$ 1,225	7.3%	0.8977	$ 27
Total Fair Value							**$ 8,165**

Fair value in euros (at spot FX rate): **€7,500,000.**

Fair value subsequent measurement at December 31, 2025

The fair value was updated as of December 31, 2025, using a Monte Carlo simulation with 20,000 price paths, calibrated using a Geometric Brownian Motion model to simulate GNTA share prices and scenario-specific conversion payoffs.

Key valuation inputs:

Parameter	As of March 19, 2025	As of December 31, 2025
GNTA share price	$ 3.82	$ 1.49
Stock volatility (3.0-year horizon)	83.0%	107.0%
Risk-free rate (3.0 years)	4.0%	3.5%
Implied yield (adjusted yield for June 30, 2025)	7.3%	6.7%
Expected term	3.0 years	2.2 years

Scenarios modeled:

Scenario	Probability	Event date	Average bond balance (USD 000s)	Average payoff (USD 000s)	Discount rate	PV factor	PV (USD 000s)
Investment round	2.5%	6/30/2026	$ 9,493	$ 9,900	6.7%	0.9684	$ 240
Change of control	5.0%	12/31/2027	$ 10,299	$ 10,179	6.7%	0.8784	$ 447
Maturity	90.0%	3/19/2028	$ 10,414	$ 10,530	6.7%	0.8663	$ 8,210
Dissolution	2.5%	12/31/2026	$ 9,763	$ 1,321	6.7%	0.9372	$ 31
Total Fair Value							**$ 8,927**

Fair value in euros (at spot FX rate): **€7,603,000.**

Scenario modeling rationale

The fair value of the Mandatory Convertible Bond ("MCB") depends on discrete corporate events that may trigger different conversion or settlement outcomes (investment round, change of control, maturity, or dissolution). Because these outcomes are mutually exclusive and have different payoff structures, the Company adopted a scenario-weighted valuation framework. Each scenario was assigned an explicit probability based on management's assessment of corporate plans, historical market precedents, and input from independent advisors.

Model mechanics

- The model uses a Monte Carlo simulation under a risk-neutral framework to project potential paths of the issuer's stock price until maturity.
- For each simulated path, the model applies the rules of the relevant scenario:
  - Investment round → all bonds convert into shares at the capped conversion price.
  - Change of control → mixed settlement, with partial share conversion subject to the 29% ownership cap, and residual settled in cash.
  - Maturity → bondholders receive accrued Payment-In-Kind ("PIK") interest plus conversion into shares, again capped at 29% ownership, with any residual in cash.
  - Dissolution → recovery is modeled as a stressed case with reduced payoff.
- The simulation accounts for optionality (conversion right), non-linear features (caps on ownership and price), and market-linked triggers (stock volatility and risk-free rates).

Probability-weighted outcomes

- The simulation generates distributions of payoffs under each scenario.
- Expected payoffs are then weighted by the assigned probabilities (e.g., 90% for maturity, 5% for change of control).
- Discounting is applied using a market-adjusted yield to produce the present values that sum to the reported fair value. The market-adjusted yield begins with the inception-date implied yield and is adjusted for the observed shifts in the index yield curve between the inception date and June 30, 2025.

Why Monte Carlo is required

Unlike a straight bond or simple option, the MCB embeds several contingent features (ownership caps, conversion price ceiling, event-driven triggers). These make analytical closed-form valuation impractical. Monte Carlo simulation allows the Company to:

- capture the path dependency of stock prices,
- model probabilistic corporate events, and,
- ensure the payoff profile is consistent with both contractual terms and market risk.

Interpretation for investors

- The model shows that maturity is the dominant scenario (90%), anchoring most of the fair value.
- Less likely events (investment round, dissolution) still affect valuation because of their asymmetric payoffs.
- The final fair value ($8,927m as of December 31, 2025) reflects both the equity-linked upside and the downside protection features of the instrument.

Dissolution scenario recovery basis

In a low-probability dissolution scenario, the expected recovery was assumed at 15% of cash proceeds, based on sector benchmarks for distressed biotech asset liquidations, implying a recovery of $1.32 million.

Summary Table – Fair value reconciliation (USD '000s)

Period	Opening FV	Δ FV (P&L)	Closing FV
December 31, 2025	$ 8,165	+$762	$ 8,927

Summary Table – Fair Value Reconciliation (Euro '000s)

Period	Opening FV	Δ FV (P&L)	Closing FV
December 31, 2025	€ 7,500	+€103	€ 7,603

Fair value increase primarily reflects currency translation movement, the lower market yield, time decay, accumulation of accrued PIK interest, and minor equity path shifts despite a lower stock price.

14. Shareholders' equity

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

For the year ended December 31, 2023, the Company accrued €739,884 as the fair value of stock options granted as per the Equity Incentive Plan 2021-2025. (See Note 15. Share-based compensation for more details.)

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

In March 2024, 72,908 new ordinary shares were issued pursuant to the Sales Agreement and the Company recorded an increase in common stock, no par value of €270,885.

For the year ended December 31, 2024, the Company accrued €847,255 as the fair value of stock options granted as per the Plan. (See Note 15. Share-based compensation for more details.)

At December 31, 2024, the Company had 18,289,866 common shares issued and outstanding with approximately 1.8 million ordinary shares reserved for the Plan.

In March 2025, 856,602 new ordinary shares were issued pursuant to the ATM, and the Company recorded an increase in common stock no par value of €2,977,060.

In October 2025, 4,285,715 new ordinary shares were issued pursuant to the Registered Direct Offering, and the Company recorded an increase in common stock, no par value of €11,810,398.

For the year ended December 31, 2025, the Company accrued €1,009,738 as the fair value of stock options granted as per the Plan. (See Note 15. Share-based compensation for more details.)

At December 31, 2025, the Company had 23,432,183 ordinary shares issued and outstanding with approximately 2.3 million ordinary shares reserved for the Plan.

Weighted average shares

The calculation was performed by taking the number of shares outstanding during each period and weighting them by the number of days such shares were outstanding. For the years ended December 31, 2025, 2024 and 2023, the weighted average number of the Company's ordinary shares, no par value, was 19,710,187, 18,273,490 and 18,216,907 respectively.

15. Share-based compensation

To reward the efforts of employees, officers, directors, and certain consultants, and to promote the Company's growth and development, the Board may approve, upon occasion, various share-based awards.

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

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

In July 2024, the Company's board of directors, as administrator of the Plan, awarded NSOs on 587,650 shares to certain of the Company's officers and employees. The NSOs vested monthly over three years with a 10-year term, expiring on July 1, 2034. A cliff vesting period is provided for those employees with less than one (1) year of service at the time of grant, until the first anniversary of employment is completed. The exercise price of the NSOs is $3.083 per share, corresponding to the market price at the date of grant. In addition, each new Board member received equity compensation in the form of an initial stock option equity grant of $50,000 (based on the Black Scholes model) that vested immediately.

In the second half of 2024, two employees and a consultant left the Company. As per the applicable rules, the options already granted to the aforementioned employees and consultant but not yet vested as of the termination date of their respective employment or consultancy contracts have been returned to the stock option pool for a total of 56,482. Combined with those already returned to the pool in April 2024, a total of 204,265 options were returned to the pool in 2024.

At December 31, 2024, there were 970,308 granted stock options and 858,678 stock options remaining available for grant.

In June 2025, the Board, as the administrator of the Equity Incentive Plan 2021–2035, awarded NSOs on 495,507 shares to the Company's directors, officers, and employees. For the Chairman and CEO, the NSOs vest monthly over three (3) years and have a 10-year term. For the other two directors of the Company, the NSOs vest monthly over one (1) year, also with a 10-year term. The NSOs granted to officers and employees also have a 10-year term and vest monthly over three (3) years, except for employees with less than one (1) year of service, whose options include a one-year cliff vesting from the date of hire, followed by monthly vesting thereafter.

In June 2025, the CFO was awarded 23,007 NSOs instead of a portion of his 2023 and 2024 performance cash bonus. These options vested immediately and have a 10-year term.

All options were granted with an exercise price of $4.36 per share, reflecting the stock price on the date of grant.

In December 2025, the Board, acting as the administrator of the Equity Incentive Plan 2021-2035, approved the grant, with vesting beginning on November 1, 2025, of 27,110 NSOs to Dr. Francesco Galimi, a member of the Company's Board of Directors and its acting Chief Medical Officer and Head of Development, as part of his compensation package. The options vest monthly over three months and have a 10-year term, expiring on November 1, 2035.

All options were granted with an exercise price of $2.57 per share, reflecting the stock price on the date of grant.

In December 2025, the Company's Board, acting as administrator of the Plan, granted NSOs on 545,000 shares to certain directors, officers, employees, and consultants of the Company. The NSOs vest monthly over three years, except for those granted to one director, which vest monthly over a one (1) year period. All options have a ten-year term and expire on December 18, 2035.

All options were granted with an exercise price of $1.48 per share, reflecting the stock price on the date of grant.

In the second half of 2025, three employees including the Company's Chief Medical Officer and Head of Development left the Company. In line with and according to the applicable plan provisions, the options previously granted to these employees that were unvested as of the respective employment termination dates were forfeited and returned to the stock option pool. Therefore, 68,671 options granted in July 2024 and 78,525 options granted in June 2025, totaling options on 147,196 shares, were returned to the pool as of December 31, 2025. When combined with options forfeited or expired and returned to the pool, a cumulative total of 351,461 options have been returned to the Company's stock option pool.

At December 31, 2025, there were 1.9 million granted stock options and 452,490 stock options remaining available for grant.

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2023	540,523	€ 4.99	7.30	272,480
Granted	46,400	5.30	9.17	-
Vested and exercised	-	-	-	-
Cancelled or forfeited	-	-	-	-
Outstanding as of December 31, 2023	586,923	€ 4.84	6.53	€ 67,596
Exercisable as of December 31, 2023	382,785	€ 5.11	5.44	€ 33,796
Outstanding, expected to vest as of December 31, 2023	**204,138**	**€ 4.34**	**8.58**	**€ 33,800**
Outstanding as of January 1, 2024	586,923	€ 4.84	6.53	€ 67,596
Granted	587,650	2.87	9.50	-
Vested and exercised	-	-	-	-
Cancelled or forfeited	(204,265)	5.94	-	-
Outstanding as of December 31, 2024	970,308	€ 3.65	8.75	€ 706,366
Exercisable as of December 31, 2024	514,210	€ 4.13	8.23	€ 199,667
Outstanding, expected to vest as of December 31, 2024	**456,098**	**€ 3.10**	**9.33**	**€ 506,699**
Outstanding as of January 1, 2025	970,308	€ 3.65	8.75	€ 706,366
Granted	1,067,617	2.32	9.73	-
Vested and exercised	-	-	-	-
Cancelled or forfeited	(147,196)	3.21	-	-
Outstanding as of December 31, 2025	1,890,729	€ 2.78	8.76	€ 4,643
Exercisable as of December 31, 2025	845,607	€ 3.44	7.84	€ 57
Outstanding, expected to vest as of December 31, 2025	**1,045,122**	**€ 2.24**	**9.50**	**€ 4,585**

The Company calculates the fair value of stock option awards granted to employees and non-employees using the Black-Scholes option-pricing method. The Company chose this method because it is considered easier to apply, and it is a defined equation that incorporates only one set of inputs. As a result, it is the model most commonly in use.

If the Company determined that other methods were more reasonable, or other methods for calculating these assumptions were prescribed by regulators, the fair value calculated for the Company's stock options could change significantly. Higher volatility and longer expected lives would result in an increase in share-based compensation expense to non-employees determined at the date of grant. Share-based compensation expense to non-employees affects the Company's general and administrative expenses and research and development expenses, depending on the non-employee's function.

The Company calculated the stock-based compensation expense for the granted options using the Black-Scholes method, applying the following inputs for each stock grant:

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

The Company's share-based compensation expense for the years ended December 31, 2025, 2024, and 2023 is represented by the following table:

	Year ended December 31		
	2025	**2024**	**2023**
(in Euros)			
Research & development expense	€ 218,664	€ 116,532	€ 73,392
Research & development expense - related party	108,455	39,800	-
General & administrative expense	242,903	436,877	505,828
General & administrative expense - related party	367,719	254,045	160,664
Total	€ 937,742	€ 847,254	739,884
Unrecognized expense	€ 2,271,990	€ 1,404,415	€ 907,683

For the years ended December 31, 2025, 2024 and 2023 the Company recorded €937,742, €847,255 and €739,884 respectively, as the fair value of the stock options granted.

The amount of unrecognized expense at December 31, 2025, 2024 and 2023 was €2,271,990, €1,404,415 and €907,683 respectively.

The weighted average fair value of the options granted during the period ended December 31, 2025, 2024 and 2023 was €2.32, €2.87 and €5.30 per share, respectively.

The amount of stock option expenses recognized in the Consolidated Statements of Operations and Comprehensive Loss, totaling €937,742, differs from the €1,009,738 reported in the Consolidated Statements of Changes in Shareholders' Equity. The difference of €71,996 is explained by the partial offset of provisions previously accrued in the Consolidated Balance Sheets for 2023 and 2024 performance bonuses.

16. Accumulated other comprehensive income

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

	Changes in Accumulated Other Comprehensive Income For the year ended December 31, 2025		
	Unrealized gains and losses on available-for-sale debt securities	Foreign currency translation adjustments	Total
Beginning Balance	€ 96,234	€ (7,288)	€ 88,946
Adjustment for net (gain) loss on marketable securities	(96,234)	-	(96,234)
Change in fair value of marketable securities	103,439	-	103,439
Cumulative translation adjustment	-	70,360	70,360
Total	€ 103,439	€ 63,072	€ 166,511

The unrealized net gain on marketable securities not matured at December 31, 2025, was approximately €0.1 million. Translation adjustments on investment transactions expressed in U.S. dollars were not material. The cumulative translation adjustments reserve mainly includes the effect of the translation of U.S. dollars held by the U.S. Subsidiary into Euros as the consolidated financial statements' currency.

17. Related parties

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

	For the Year Ended December 31, 2025		
	Third Parties	Related Parties	Total
(in Euros)			
Consultants & other third parties	€ 145,071	€ 150,811	€ 295,882
Materials & supplies	1,456,243	-	1,456,244
Compensation (including share-based)	721,095	191,170	912,264
Travel & entertainment	17,976	-	17,976
Other	16,976	-	16,976
Total	€ 2,357,361	€ 341,981	€ 2,699,342

	For the Year Ended December 31, 2024		
	Third Parties	Related Parties	Total
(In Euros)			
Consultants & other third parties	€ 262,229	€ 753,679	€ 1,015,908
Materials & supplies	2,301,038	-	2,301,038
Compensation (including share-based)	744,959	695,764	1,440,723
Travel & entertainment	29,137	-	29,137
Other	26,048	-	26,048
Total	€ 3,363,410	€ 1,449,443	€ 4,812,854

	For the Year Ended December 31, 2023		
	Third Parties	Related Parties	Total
(in Euros)			
Consultants & other third parties	€ 305,289	€ 1,331,166	€ 1,636,455
Materials & supplies	3,639,920	-	3,639,920
Compensation (including share-based)	467,557	645,932	1,113,489
Travel & entertainment	44,243	-	44,243
Other	39,965	369	40,334
Total	€ 4,496,974	€ 1,977,467	€ 6,474,441

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

The Company recorded research and development expenses of approximately €2.7 million in 2025, €4.8 million in 2024 and €6.5 million in 2023. The tax credit compensation effect was approximately €2.2 million in 2025, €0.5 million in 2024 and €0.4 million in 2023.

The decrease in R&D expenses of approximately €2.1 million was mainly due to several factors as explained above under the section *Results of Operations Comparison of Year Ended December 31, 2025 to Year Ended December 31, 2024*. The overall decrease of €2.1 million was primarily driven by decreased manufacturing and clinical activities, including fewer drug product batch productions, reduced CRO engagement, lower patient enrollment, and the absence of certain trial-related activities previously associated with the TEM-GBM program. The Company's strategic focus shifted predominantly to the TEM-GU study, which was in an earlier clinical phase and required a comparatively lower level of exploratory analyses and oversight activities. The decrease was further supported by contractual amendments, consulting cost reductions, management compensation adjustments, and the impact of R&D tax credits. These reductions were partially offset by increased manufacturing associated activities related to the implementation of an Exclusive GMP Suite agreement, although such increase was mitigated by the tax credit benefit.

The decrease in R&D expenses of approximately €1.7 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, was mainly due to several factors as explained above under the section *Results of Operations Comparison of Year Ended December 31, 2024 to Year Ended December 31, 2023*. The overall decrease was primarily attributable to lower manufacturing and scale-up costs related to lentiviral vector production, reduced technology transfer activities, and decreased fees to OSR in line with contractual payment schedules. These reductions were partially offset by increased clinical trial expenses associated with the commencement of the TEM-GU study in October 2024.

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

	For the Year Ended December 31, 2025		
	Third Parties	**Related Parties**	**Total**
(In Euros)			
Compensation (including share-based)	€ 749,515	€ 1,232,384	€ 1,981,899
Accounting, legal & other professional	722,836	-	722,836
Communication & IT - related	172,690	-	172,690
Facility & insurance - related	4,556	16,260	20,816
Consultants & others	270,122	36,400	306,522
Others	695,193	4,442	699,635
Total	€ 2,614,912	€ 1,289,486	€ 3,904,398

	For the Year Ended December 31, 2024		
	Third Parties	**Related Parties**	**Total**
(In Euros)			
Compensation (including share-based)	€ 1,019,056	€ 1,459,302	€ 2,478,358
Accounting, legal & other professional	828,592	-	828,592
Communication & IT - related	188,951		188,951
Facility & insurance - related	3,348	14,795	18,143
Consultants & others	561,458	-	561,458
Other	874,165	1,789	875,954
Total	€ 3,475,570	€ 1,475,886	€ 4,951,456

	For the Year Ended December 31, 2023		
	Third Parties	**Related Parties**	**Total**
(In Euros)			
Compensation (including share-based)	€ 1,218,299	€ 1,317,068	€ 2,535,367
Accounting, legal & other professional	1,026,534	-	1,026,534
Communication & IT related Facility	166,416		166,416
Facility & insurance related	6,180	15,731	21,911
Consultants & other third parties	610,103	-	610,103
Other	896,018	2,152	898,170
Total	€ 3,923,550	€ 1,334,951	€ 5,258,501

General and administrative expenses were approximately €3.9 million for the year ended December 31, 2025, as compared to approximately €5.0 million for the year ended December 31, 2024. The decrease of approximately €1.1 million was primarily due to the combined effect of:

1) a decrease in compensation, (approximately €0.5 million) primarily due to: (1) the reversal of bonus accruals recorded during 2023 and 2024 for the CMO and CFO, which were not subsequently confirmed in part and therefore were not paid in during 2025; (2) the absence of any bonus accruals for 2025, following a change in the Company's bonus recognition policy;

2) a net decrease in accounting, legal and other professional (approximately €0.1 million) mainly related to a decrease in external audit expenses;

3) a net decrease in consultants and other third-party costs (approximately €0.3 million) primarily driven by cost-saving contract amendments and reduced consulting activity. Additionally, certain consultant contracts were not renewed in 2025;

4) a net decrease in other general and administrative costs (approximately €0.2 million), primarily driven by a decrease in patent maintenance costs (approximately €0.1 million).

General and administrative expenses were approximately €5.0 million for the year ended December 31, 2024, as compared to approximately €5.3 million for the year ended December 31, 2023. The decrease of approximately €0.3 million was primarily attributable to lower professional fees, reduced consultancy expenses, and decreased insurance costs, partially offset by higher legal expenses, increased IT and cybersecurity-related costs, and higher patent maintenance expenses.

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

	At December 31,		
	2025	**2024**	**2023**
		(in Euros)	
San Raffaele Hospital (OSR)	€ 300,328	€ 180,116	€ 170,888
Total	€ 300,328	€ 180,116	€ 170,888

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

	At December 31,		
	2025	**2024**	**2023**
		(in Euros)	
San Raffaele Hospital (OSR)	€ 4,415	€ 128,188	€ 413,935
Richard Slansky	10,043	243,101	116,738
Pierluigi Paracchi	46,678	336,000	175,254
Francesco Galimi	17,036	-	-
Carlo Russo	-	324,055	155,651
Total	€ 78,172	€ 1,031,345	€ 861,578

The Company has identified the following related parties as of December 31,2025:

- Pierluigi Paracchi (director, CEO, and co-founder of the Company);
- Luigi Naldini (co-founder of the Company and chair of the scientific advisory board, until December 31, 2025);
- Bernhard Rudolph Gentner (co- founder of the Company and member of the scientific advisory board, until December 31, 2025);
- Richard Slansky (Chief Financial Officer);
- Francesco Galimi (Acting Chief Medical Officer and Head of Development and advises the Chief Executive Officer);
- Giacomoantonio Paracchi (member of the Company's Board of Directors);
- San Raffaele Hospital (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).

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

Pierluigi Paracchi

Mr. Pierluigi Paracchi is the Company's Chief Executive Officer, Chairman, General Manager, and co-founder. His current employment arrangement with the Company, effective April 1, 2025, provides an annual gross salary of €451,560 plus a 40% annual bonus subject to Board approval. Mr. Paracchi also has use of a Company car.

Effective from May 2025, Mr. Pierluigi Paracchi also receives an annual compensation of €45,000 for his role as the Company's Chairman of the Board of Directors.

For the year ended December 31, 2025, 2024 and 2023 the Company expensed approximately €550,430 (including (€91,105 of social contributions and TFR), €688,000 (including €87,738 of social contributions and TFR) and €692,000 respectively, related to Mr. Pierluigi Paracchi's compensation.

As of December 31, 2025, Mr. Pierluigi Paracchi received NSOs on a total of 260,000 of the Company's ADSs, with 80,000 received in June 2025, and 180,000 in December 2025.

As of December 31, 2025, the Company did not accrue any bonus in respect of Mr. Pierluigi Paracchi's activities performed in 2025, while a bonus of €168,000 was accrued as of December 31, 2024, and December 31, 2023, in respect of his activities performed in 2024 and 2023.

In June 2025, previously accrued performance bonuses for the years 2024 (€168,000) and 2023 (€168,000) were paid, for a total gross amount of €336,000.

Luigi Naldini/Bernhard Rudolph Gentner

Drs. Naldini and Gentner are co-founders of the Company and were an instrumental part of the Company's SAB – Scientific Advisory Board, with Dr. Naldini as Chairman, and Dr. Gentner as a member. The Company had consulting agreements with each of Drs. Naldini and Gentner.

Dr. Naldini had an advisory agreement approved by the Board of Directors whereby he and his staff performed pre-clinical studies for the Company.

The latest consulting agreement with Dr. Naldini was signed on June 20, 2022, which included an annual fee of €100,000 starting July 1, 2022.

On May 12, 2025, the consulting agreement originally dated October 1, 2015, and subsequently amended on June 20, 2022, was further amended to extend its validity for an additional 12 months, from July 1, 2025, to June 30, 2026. The contract was altered so that it would not be automatically renewed. Additionally, the annual fee for the extended term was reduced to €50,000, effective July 1, 2025.

On October 12, 2025, the consulting agreement, amended on May 12, 2025, was further amended to shorten its term to December 31, 2025, without automatic renewal, for a fixed fee of €6,250.

At December 31, 2025, 2024 and 2023, Dr. Naldini billed €68,750, €100,000 and €100,000 respectively, and all invoices issued were paid before December 31st of each respective year.

Dr. Gentner, like Dr. Naldini, oversaw pre-clinical research related to the Company's platform technology. In addition, he analyzed clinical biological data. The consulting agreement with Dr. Gentner started on July 1, 2022, and provided fees for an amount of €45,000 per year.

On July 1, 2025, the consulting agreement originally dated April 1, 2016, and subsequently amended on July 1, 2022, was further amended to reduce the annual compensation for Dr. Gentner from €45,000 to €22,500, effective July 1, 2025. The agreement was to remain in effect for a fixed term of one (1) year, from July 1, 2025, through June 30, 2026.

On October 1, 2025, the consulting agreement amended on July 1, 2025, was further amended to shorten its term to December 31, 2025, without automatic renewal, for a fixed fee of €2,814.

In February 2024, Dr. Gentner entered into an addendum to the consulting agreement in which the Company agreed to pay a total one-time fee of up to €15,000 to conduct research, write and submit a scientific research paper. The agreement stipulated the fees that were to be billed progressively, if and when the expected research steps were met.

At December 31, 2025, the second step was achieved, billed and paid for €5,000.

At December 31, 2024, the first step was achieved, billed, and paid for €5,000.

At December 31, 2025, 2024 and 2023 Dr. Gentner billed €35,939, €45,000 and €45,000 respectively, and all invoices issued were paid before December 31st of each respective year.

Richard Slansky

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

For the years ended December 31, 2025, 2024 and 2023 the Company expensed approximately €320,277, €458,000 and €456,000 respectively, related to compensation for Mr. Slansky. At December 31, 2025, the Company did not accrue any bonus in respect of Mr. Slansky's activities performed in 2025, while a bonus of approximately €108,000 and €116,000 was accrued as of December 31, 2024 and December 31, 2023, in respect of his activities performed in 2024 and 2023.

In June 2025, Mr. Slansky was awarded a bonus of approximately €98,832 (gross amount), related to the activity performed in 2023, and €49,416 (gross amount), related to the activity performed in 2024, and accrued in the respective periods.

The 2023 bonus was allocated as follows:

- 15,338 fully vested NSOs with an exercise price of $4.36 based on the Black-Scholes pricing model in place of €47,997 cash as a portion of the 2023 bonus;
- €45,902 paid in cash to Mr. Slansky;
- €2,196 and €1,318, respectively, allocated from Mr. Slansky's bonus to two (2) finance employees and paid in cash.

The original 2024 bonus amount accrued was approximately €108,000; however, this was reduced by 50% and allocated as follows:

- 7,669 fully vested NSOs with an exercise price of $4.36 based on the Black-Scholes pricing model in place of €23,998 cash as a portion of the 2024 bonus;
- €18,531 paid in cash to Mr. Slansky;
- €3,089, €1,853, and €1,235, respectively, allocated from Mr. Slansky's bonus to three (3) finance employees and paid in cash.

As of December 31, 2025, Mr. Slansky received NSOs on a total of 180,000 of the Company's ADSs, with 60,000 received in June 2025 with an exercise price of $4.36, and 120,000 in December 2025 with an exercise price of $1.48.

Francesco Galimi

On October 1, 2025, the Company entered into a consulting agreement with FG Consulting Inc., an entity controlled by Francesco Galimi, the Company's Acting Chief Medical Officer and Head of Development. Under the agreement, ongoing scientific and strategic advisory services are provided by Dr. Galimi and invoiced to the Company through FG Consulting Inc.

The consulting agreement originally dated October 1, 2025, was subsequently amended on October 20, 2025, to extend the term of the agreement from December 31, 2025, to January 31, 2026, and to modify the compensation terms, effective November 1, 2025.

For the year ended December 31, 2025, Dr. Galimi invoiced the Company, through FG Consulting Inc., €25,869 for services provided in his capacity as Acting Chief Medical Officer and Head of Development, and accrued expenses of €17,037 were recognized in relation to such services. In addition, the agreement provided compensation in the form of stock options. A total of 27,110 stock options were granted to the consultant, vesting over the period from November 2025 to January 2026. As of December 31, 2025, the value of the vested options amounted to €33,839.

For the year ended December 31, 2025, Dr. Galimi also invoiced the Company €19,453 for his services as a member of the Board.

Giacomoantonio Paracchi

Mr. Giacomoantonio Paracchi is a member of the Company's Board of Directors. His annual gross compensation amounts to €30,000, pro-rated for the period from November 2025 through the next shareholders' meeting.

As of December 31, 2025, Mr. Giacomoantonio Paracchi received compensation of €5,000 for his services as a member of the Board.

OSR – San Raffaele Hospital

OSR - San Raffaele Hospital is a co-founder of the Company, and the Company is a corporate and research spin-off of OSR. OSR is one of the leading biomedical research institutions in Italy and Europe, with a 45-year history of developing innovative therapies and procedures. The Company has agreements to license technology, to perform research, pre-clinical and clinical activities, as well as to lease facilities and obtain certain other support functions. The Company's headquarters is currently in an OSR facility.

Amended and Restated OSR License Agreement

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

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

Pursuant to the terms of the ARLA, OSR has granted the Company an exclusive, royalty-bearing, non-transferrable (except with the prior written consent of OSR), sublicensable, worldwide license, subject to certain retained rights, to (1) certain patents, patent applications and existing know-how for the use in the field(s) of Interferon ("IFN") gene therapy by lentiviral based-hematopoietic stem and progenitor cells ("HSPC") gene transfer with respect to any solid cancer indication (including glioblastoma and solid liver cancer) and/or (b) any lympho-hematopoietic indication for which the Company exercises an option (described below); and (2) certain gene therapy products (subject to certain specified exceptions related to replication competent viruses) developed during the license term for use in the aforementioned field(s) consisting of any lentivirals or other viral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter. Lympho-hematopoietic indication means any indication related to lympho-hematopoietic malignancies and solid cancer indication means any solid cancer indication (e.g., without limitation, breast, pancreas, colon cancer), with each affected human organ counting as a specific solid cancer indication.

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

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

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

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

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

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

Pursuant to the ARLA, as consideration, the Company agreed to pay OSR additional license fees equal to up to €875,000 in total, which are payable on April 20, 2023, December 31, 2023, and upon our entering into a sublicense agreement with a third party sublicensee (pursuant to which the Company is entitled to receive an upfront payment in an amount exceeding a specified threshold from such sublicensee) during the period between September 30, 2022 and April 20, 2028 (with most of these additional license fees being triggered upon our entering into such a sublicense agreement). In addition, the Company has agreed to pay OSR royalties and on a single digit percentage of the net sales of each licensed product. The royalty may be reduced upon the introduction of generic competition or patent stacking, but in no event would the royalty be less than half of what it would have otherwise been, but for the generic competition or patent stacking. The Company also agreed to pay OSR a royalty of our net sublicensing income for each licensed product and to pay OSR certain milestone payments upon the achievement of certain milestone events, such as the initiation of different phases of clinical trials of a licensed product, market authorization application ("MAA") approval by a major market country, MAA approval in the United States, the first commercial sale of a licensed product in the United States and certain E.U. countries, and achievement of certain net sales levels.

As part of the ARLA, the Company has agreed to use reasonable efforts to involve OSR in Phase I clinical trials for licensed products in the field of use, subject to OSR maintaining any required quality standards and providing its services on customary and reasonable terms and consistent with then-applicable market standards. The Company is also obligated to carry out its development activities using qualified and experienced professionals and sufficient level of resources. In particular, consistent with the terms of the Original OSR License Agreement, the ARLA continues to require the Company to invest (a) at least €5,425,000 with respect to the development of the licensed products, and (b) at least €2,420,000 with respect to the manufacturing of such licensed products (subject to certain adjustments). (See Note 18. Commitments and contingencies.)

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

The ARLA expires upon the expiry of the "Royalty Term" for all licensed products and all countries, unless terminated earlier. The Royalty Term begins on the first commercial sale of a licensed product in each country, on a country by country basis, and ends upon the later of the (a) expiration of the commercial exclusivity for such product in that country (wherein the commercial exclusivity refers to any remaining valid licensed patent claims covering such licensed product, any remaining regulatory exclusivity to market and sell such licensed product or any remaining regulatory data exclusivity for such licensed product), and (b) 10 years from the first commercial sale of such licensed product in such country.

The parties may terminate the agreement in the event the other party breaches its obligations therein, which termination shall become effective 60 business days following written notice thereof to the breaching party. The breaching party shall have the right to cure such breach or default during such 60 business days. OSR may terminate the agreement for failure to pay in the event that the Company fail to pay any of the upfront payment, additional license fees, sublicensing income or milestone payments within 30 days of due dates for each. In addition, OSR may terminate (with a 60-business-day prior written notice) the Company's rights as to certain fields of use for the Company's failure to achieve certain development milestones for specified licensed products within certain time periods, which may be subject to extension. In addition, OSR may terminate the agreement in the event that commercialization of a licensed product is not started within 24 months from the grant of both (i) the MAA approval and (ii) the pricing approval of such licensed product, provided that such termination will relate solely to such licensed product and to such country or region to which both such MAA approval and pricing approval were granted.

Amendment to OSR Amended and Restated License Agreement

On September 28, 2023, the Company and OSR entered into an amendment to the ARLA, whereby the Company and OSR agreed that the Company had fulfilled the obligations as set forth in the ARLA specific to Candidate Products 1 pursuant to the CP1 SRA. Furthermore, the amendment provides that the Company and OSR have no further obligations to negotiate and execute a sponsored research agreement for the performance of feasibility studies related to certain gene therapy products consisting of any lentiviral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of cytokines and their variants (other than IFN or in addition to IFN) under the control of a Tie2 promoter, either alone or in combination with any immunotherapy ("Candidate Products 2"). Notwithstanding the removal of the obligation to enter into a sponsored research agreement with regards to Candidate Products 2, OSR granted the Company an exclusive option, to be exercised by sending written notice to OSR on or before September 30, 2025, to include certain intellectual property related to Candidate Products 2 and Candidate Products 2 as part of the licensed patents and licensed products under the ARLA. The option fee and the Company's fee to extend the option period, if necessary, remain consistent with the prior fees to those costs reflected in the ARLA specific to Candidate Products 2. OSR will also have the right to prepare, file and prosecute patents and patent applications with respect to the results of Candidate Products 2. The amendment provides that the costs of the foregoing activities will be borne by the Company.

At December 31, 2025, the cumulative total amount of expense for the OSR clinical trial activity from inception amounted to approximately €12.0 million and including the cost for the exercise of the first and the second solid cancer indication option fee of €1.0 million, as well as the cost for ARLA fees of approximately €0.4 million.

At December 31, 2025, there were no pending activities with OSR related to any agreement in place prior to the ARLA effective date, except for the project called "TEM-MM unspent budget reallocated to the TEM-GBM study", for which the last tranche of activities corresponding to the 20% of the total project of approximately €0.2 million still pending completion.

OSR Sponsored Research Agreement

On August 1, 2023, the Company entered into a Sponsored Research Agreement ("CP1 SRA"), which was contemplated under the ARLA, pursuant to which the Company will fund feasibility studies for certain gene therapy products consisting of any lentiviral vectors regulated by miR126 and/or miR130 and/or other miRs with the same expression pattern as miR126 and miR130 in hematopoietic cells for the expression of IFN under the control of a Tie2 promoter, in combination with any immunotherapy ("Candidate Products 1"), along with three additional research projects, to be conducted at OSR. If OSR determines that additional funds are needed, OSR will inform the Company and provide an estimate for completing the research.

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

As of December 31, 2025, the Company recorded and paid approximately €0.5 million for the CP1 SRA studies.

Operating leases

The Company entered into a non-cancelable lease agreement for office space in December 2020, effective since December 2019.

On February 5, 2026, the Company provided formal notice to OSR of its intention to terminate the office lease agreement. The Company has indicated its availability to vacate the premises prior to the contractual expiration date. As of the date of issuance of these financial statements, the Company is awaiting confirmation from OSR regarding the effective termination date and any related financial implications. (see Note 18 Commitments and contingencies below).

Carlo Russo

Dr. Carlo Russo served the Company as Chief Medical Officer and Head of Development until September 30, 2025. He was responsible for the clinical development of Temferon™, the Company's gene therapy platform.

His employment arrangement was with the U.S. subsidiary and provided for an annual gross salary of $500,000, plus a 30% bonus, subject to Board approval.

In June 2025, previously accrued performance bonuses for the years 2023 and 2024 were reversed for a total amount of approximately €260,000. No bonuses were accrued for the six months ended June 30, 2025.

In June 2025, Dr. Russo received NSOs on 65,000 of the Company's ADSs, compared to July 2024, when he received NSOs on 100,000 of the Company's ADSs.

On September 30, 2025, Dr. Carlo Russo resigned and his role was assigned to Dr. Francesco Galimi.

Accordingly, as of the end of the 2025 fiscal year, Dr. Carlo Russo is no longer considered a related party. Any stock options granted to him that had not vested at the time of his resignation were forfeited.

18. Commitments and contingencies

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

The following table summarizes the Company's obligations by contractual maturity at December 31, 2025:

(in Euros)	Payments by Period				
	Total	Less than a year	1 to 3 years	4 to 5 years	More than 5 years
OSR office rent	€ 16,389	€ 16,389	€ -	€ -	€ -
AGC manufacturing	€ 17,000	€ 17,000	€ -	€ -	€ -
Insurance policies	€ 1,166	€ 1,166	€ -	€ -	€ -
Total	€ 34,555	€ 34,555	€ -	€ -	€ -

The commitments with OSR relate to the office rent agreement and the ARLA.

The commitments with AGC Biologics ("AGC") relate to product manufacturing. Please see the following section, *Legal Proceedings,* for more information.

Insurance on operating leases is related to the non-lease insurance component of the Company's auto lease agreement, which was entered into in February 2022 and subsequently terminated in February 2026 with the purchase of the car.

The Company has not included future milestone and royalty payments in the table above because the payment obligations under these agreements are contingent upon future events, such as the Company's achievement of specified milestones or generating product sales, and the amount, timing, and likelihood of such payments are unknown and are not yet considered probable.

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

As part of the ARLA, the Company is obligated to carry out development activities using qualified and experienced professionals and a sufficient level of resources. In particular, consistent with the terms of the Original OSR License Agreement, the ARLA continues to require the Company to invest (a) at least €5,425,000 with respect to the development of the licensed products, and (b) at least €2,420,000 with respect to the manufacturing of such licensed products (subject to certain adjustments).

The Company incurred €2.8 million, €1.8 million and €2.5 million of expenses during the period ended December 31, 2025, 2024 and 2023 respectively. The cumulative expense to date is approximately €13.7 million, therefore, there is no residual commitment for the Company at December 31, 2025.

The Company has agreed to pay OSR royalties for four percent (4%) of the net sales of each licensed product. The royalty may be reduced upon the introduction of generic competition or patent stacking, but in no event would the royalty be less than half of what it would have otherwise been, but for the generic competition or patent stacking. The Company also agreed to pay OSR a royalty of the Company's net sublicensing income for each licensed product and to pay OSR certain milestone payments upon the achievement of certain milestone events, such as the initiation of different phases of clinical trials of a licensed product, market authorization application ("MAA") approval by a major market country, MAA approval in the United States, the first commercial sale of a licensed product in the United States and certain E.U. countries, and achievement of certain net sales levels.

No events have occurred or have been achieved (and none are considered probable) to trigger any contingent payments under the ARLA during the period ended December 31, 2025.

AGC Biologics

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.

During 2024, the Company and AGC reached an agreement to renew the Master Service Agreement (MSA) originally signed in March 2019. Initially, the same agreement was temporarily extended until June 2025 to allow for a better definition of the scope and terms of the new MSA, which was signed with effect from December 24, 2024.

The new MSA was an open-ended agreement with no specific expiration date, as its term is tied to the completion of any service phase, or work statement ("WS"), starting with WS01.

The services provided by AGC included activities of manufacturing, testing, and release of Cell Therapy Drug Product using an Exclusive GMP Suite ("EGS") and a dedicated team ("EGS Team"). The services are remunerated through monthly fees that primarily cover the costs of the suite and the dedicated team, in addition to direct production costs for materials and other accessories if applicable. AGC retains control over both the logistical and organizational aspects of the services, as well as the operational aspects related to the hiring, training, and coordination of personnel. AGC also remains solely responsible for fulfilling any remuneration and social security obligations toward its personnel.

WS01 included two main phases:

1. An initial Ramp-Up Phase with an estimated duration of 6 months, starting on February 1, 2025 (start of activities) and ending on August 1, 2025.

2. A Routine Phase, which began on the first day of the subsequent month after the completion of the Ramp-Up Phase (specifically, after the receipt of authorization from the Regulatory Agency ("AIFA") to use the Exclusive Suite and the successful completion of the training of personnel assigned to the dedicated team).

The Company had the right to terminate this schedule or work statement by providing twelve (12) months' prior written notice to AGC. However, such notice could not be issued before the sixth (6th) month anniversary of the Ramp-Up Phase commencement date (for clarity, the notice was not to be sent before August 1, 2025).

As a result of these contractual provisions, as of December 31, 2024, the Company had a commitment of approximately €3.5 million, and since the agreement was signed in December 2024, the commencement date of this agreement was February 2025. The Company is determining if the agreement qualifies as an operating lease under ASC 842.

On July 1, 2025, AGC and the Company signed the Second Amendment to their original MSA dated 2019, effective on June 30, 2025, to further extend the term of the original MSA, until September 30, 2025, including the possibility of further extension upon mutual written agreement.

On August 1, 2025, the Company issued a formal written notice of termination of Work Statement No. 01 dated December 24, 2024, pursuant to Section 4.1 of the MSA dated December 2024. This notice commenced the twelve-month prior notice period ending on July 31, 2026 (the "Termination Date"), during which AGC will continue to issue quarterly invoices in accordance with the MSA, and the Company will remain responsible for all payment obligations relating to the Exclusive GMP Suite (EGS) and the EGS Team, as specified in Section 3 of Schedule 1A of the Second Amendment to the MSA, until the Termination Date.

On August 27, 2025, the Company received formal notification from AGC, referencing Work Statement 1 dated December 24, 2024, confirming that the Ramp-up phase—which began on February 1, 2025—had been successfully completed. AGC stated that both contractual conditions had been met: the Authorization from AIFA to use the Exclusive Suite was received on July 3, 2025, and the training of the personnel assigned to the Dedicated Team had been finalized. Consequently, the Routine Phase commenced on September 1, 2025.

On September 24, 2025, the Company filed a civil action before the Court of Milan against AGC Biologics S.p.A., seeking a declaratory judgment of nullity and/or termination, with retroactive effect, of the Master Service Agreement and related amendments executed on December 24, 2024. The claim is based on the failure of an essential underlying assumption—the availability of a minimum number of patients required to initiate and sustain clinical production activities. As a result, the Company believes that the manufacturing agreement with AGC is no longer operative; however, the Company has proposed to continue working with AGC based on the availability of production slots, as in the previous agreement.

The proceedings are ongoing, the first hearing was on March 11, 2026, and the next hearing is scheduled for June 3, 2026. (See Note 19. Subsequent events for more details).

Office operating leases

On December 1, 2019, the Company began a six-year non-cancelable (and renewable for further six (6) years until December 1, 2031) lease agreement for office space with OSR. Withdrawal is allowed from the fourth year with a notice of 12 months. As of December 31, 2025, neither party had communicated any termination of the lease agreement, which is therefore considered renewed until December 2031. On February 5, 2026, the Company provided formal written notice of termination of the lease agreement and expressed its willingness to vacate the premises earlier than the contractual expiration date. As of the date of issuance of these financial statements, the Company is awaiting confirmation from OSR regarding the effective termination date and any related financial implications.

Since the annual rent amounts to approximately €16,000, at December 31, 2025, outstanding minimum payments amount to approximately €16,000.

Legal proceedings

AGC Biologics S.p.A

In September 2025, the Company filed a civil action before the Court of Milan against AGC Biologics S.p.A., seeking a declaratory judgment of nullity and/or termination, with retroactive effect, of the Master Service Agreement and related amendments executed on December 24, 2024. The claim is based on the failure of an essential underlying assumption - the availability of a minimum number of patients required to initiate and sustain clinical production activities. As a result, the Company believes that the manufacturing agreement with AGC is no longer operative; however, the Company has proposed to continue working with AGC based on the availability of production slots, as in the previous agreement.

AGC has asserted claims for alleged unpaid amounts arising under the Amendment and related services, including:

- €1,554,484 claimed in initial proceedings; and
- aggregate invoiced amounts of €2,402,385, including invoice no. 26VIT00003 dated January 29, 2026 for €847,901.

The parties additionally filed their respective third briefs pursuant to Article 171-ter of the Italian Code of Civil Procedure: AGC on February 25, 2026 (Third Brief – AGC v. Genenta), and the Company on February 27, 2026 (Memoria ex art. 171-ter, no. 3 c.p.c.).

In summary, through their respective third briefs, the parties have consolidated their opposing positions: AGC attributes responsibility for the failed patient enrollment to the Company and defends the full validity of the contract and its credit claim, while the Company challenges the very effectiveness of the contractual title, maintains the essential nature of the minimum patient presupposition, and asserts that any breach and resulting damages are attributable to AGC.

The proceedings are ongoing, the first hearing was on March 11, 2026, and the next hearing is scheduled for June 3, 2026. (See Note 19. Subsequent events for more details.)

19. Subsequent events

A.T.C. Acquisition

On January 24, 2026, as part of the Company's strategic transformation, the Company entered into an investment agreement (the "Investment Agreement") with A.T.C. S.r.l. ("A.T.C."), a privately held Italian manufacturer of high-precision tactical rifles, special-forces weapon systems, and competition-grade sporting firearms.

Pursuant to the Investment Agreement, on January 26, 2026, the Company acquired an initial 19.5% equity interest in A.T.C. for €1.3 million, with the opportunity to increase its ownership to up to 51% through multiple closings for an aggregate consideration of €5.1 million. The completion of additional equity acquisitions is subject to A.T.C. achieving specified turnover and EBITDA performance milestones and maintaining the licences required under Italian law to conduct its business activities.

The Investment Agreement also provides the Company with a put option, pursuant to which the Company may require A.T.C.'s existing shareholders to repurchase the Company's entire equity interest if (i) A.T.C.'s required licences are revoked or suspended for a period of at least two months, or (ii) A.T.C. achieves less than 30% of the applicable turnover and EBITDA performance milestones. The consideration payable upon exercise of the put option would equal the Company's total investment at the time of exercise.

Shareholders' Agreement with Fondazione Praexidia

On January 25, 2026, the Company entered into a shareholders' agreement (the "SHA") with Pierluigi Paracchi, the Company's Chief Executive Officer, Chairman of the Board of Directors (the "Board"), General Manager, and co-founder, and Fondazione Praexidia (the "Foundation"). Prior to entering into the SHA, Mr. Pierluigi Paracchi donated 3,000 American Depositary Shares of the Company to the Foundation.

The Foundation is an Italian private foundation that brings together senior figures from Italian government institutions, the defense industry, and the armed forces. The SHA has an initial term of five years and is automatically renewable for additional five-year periods, unless terminated by either party with at least one month's prior written notice.

The SHA provides for mutual commitments and consultation procedures between the Foundation and Mr. Pierluigi Paracchi in connection with transactions subject to the Italian Golden Power regime (the "Significant Transactions"). In the event that a Significant Transaction is included on the agenda of a Board meeting, Mr. Pierluigi Paracchi is required to inform the Foundation, which may provide a non-binding opinion to the Board. Mr. Pierluigi Paracchi will ensure that any such opinion is presented to the Board; however, both the Board and Mr. Pierluigi Paracchi retain full discretion in their respective deliberations, resolutions and votes.

If a Significant Transaction is subject to approval at a shareholders' meeting, Mr. Pierluigi Paracchi and the Foundation will consult with the aim, but not the obligation, of determining common voting indications. In the absence of a common position, each party may vote independently. The SHA does not grant the Foundation any management or decision-making authority over the Company.

The SHA also includes a lock-up in respect of the shares held by Mr. Pierluigi Paracchi and the Foundation, subject to certain customary exceptions, including transfers to affiliates (provided such affiliates adhere to the SHA), transfers required by law, and transfers in connection with a public tender offer for a majority of the Company's share capital. Mr. Paracchi is also permitted to transfer any shares held in excess of the number required to maintain majority voting power at the Company's shareholders' meetings.

Enea Tech Biomedical ("ETB")

On January 27, 2026, the Company initiated legal proceedings before the Court of Milan against Fondazione Enea Tech Biomedical ("ETB"), with which the Company entered into a €20 million convertible bond loan agreement in March 2025 (the "Agreement"). To date, the Company has received €7.5 million under the Agreement.

The proceedings seek, among other things, a declaration that the Agreement is null and void and the recovery of damages. The Company's claim is based on its assertion that ETB, following a memorandum of understanding entered into in 2022 and subsequent delays in executing the Agreement through two separate term sheets, modified the amount, number of instalments, and certain other terms of the financing before its execution in March 2025.

The outcome of the proceedings cannot be predicted at this time, and no assurance can be given as to the ultimate resolution of this matter.

Proceeds from ATM

On January 28, 2026, the Company issued 158,837 ADSs through its ATM program pursuant to the existing sales agreement with Rodman & Renshaw and Virtu Capital, generating gross proceeds of approximately €277,047 (or $330,857). Following this transaction, the total number of the Company's outstanding ordinary shares increased to 23,591,020.

Office Operating Lease

In February 2026, the Company provided formal notice of termination of its office lease agreement with OSR. The Company is currently awaiting OSR's response regarding the effective termination date that in any case cannot exceed 12 months. The financial impact, if any, will be assessed once an agreement between the parties is finalized.

AGC Biologics

On March 11, 2026, the parties appeared before the Court and reiterated their respective arguments and objections, in particular regarding the application under art. 186-ter c.p.c. and the admissibility of claims and documents. The case, considered mainly documentary in nature, was not taken under advisement. The Court adjourned the proceedings to the hearing of June 3, 2026.

Statement of Claim

On March 18, 2026, the Company was served with an Italian statement of claim ("atto di citazione") filed before the Tribunal of Milan by certain minority shareholders. The statement of claim challenges the validity of the May 2, 2024 shareholders' resolution related to the Company's loyalty share program that provided multiple votes per share depending on the amount of time an ordinary shareholder has held their shares (up to a maximum of 10 votes per share for ordinary shareholder that have held their shares for 10 years), and the October 29, 2025 shareholders' resolution expanding the corporate purpose to allow Genenta to explore Golden Powers sectors. According to Italian civil procedure law, the Company must file its response by May 15, 2026. Although the Company does not believe these claims hold any merit, the outcome of the proceedings cannot be predicted at this time, and no assurance can be given as to the ultimate resolution of this matter.

Sophia HT S.r.l. acquisition binding offer

On March 23, 2026, the Company entered into a binding offer with Sophia High Tech S.r.l., structured as a phased minority-to-control transaction. The total potential consideration amounts to up to €6.0 million, including primary capital increases, a minor secondary purchase from the founders, and a performance-based earn-out.

The transaction is structured in two phases. At the initial closing, the Company will subscribe to a capital increase of up to €3.25 million, resulting in an equity interest of approximately 30%, secondary acquisition from the founders. A second tranche of up to €1.95 million is contemplated, subject to the achievement of an EBITDA target for FY2026 (with flexibility retained by the investor), which would increase the Company's ownership to 51%, thereby granting control.

The agreement also includes an earn-out component of up to €0.5 million payable to the founders, aimed at aligning incentives and bridging valuation expectations.

This transaction represents a structured growth investment designed to strengthen Sophia High Tech's capital base, while enabling a progressive transfer of control and aligning the interests of the founders and the investor.

Cancellation of Extraordinary Shareholders' Meeting

On March 23, 2026, the Company issued a notice of revocation announcing that its Board of Directors had resolved to revoke the call of the Extraordinary Shareholders' Meeting (the "Meeting"), which had been scheduled to be held on March 25, 2026, on first call, and, if necessary, on March 26, 2026, on second call, and that the Meeting was cancelled. The Meeting had originally been called to seek shareholder approval of a proposed change to the Company's corporate name. Following further evaluation, the Company concluded that its current corporate name, "Genenta," continues to maintain significant recognition and association with the Company's business. In addition, the initiatives underlying the proposed corporate name change remain at an early stage of development.

OSR - ARLA – Development Obligations and Contractual Remedies

On April 20, 2026, the first relevant contractual milestone under the Amended and Restated License Agreement ("ARLA") between the Company and Ospedale San Raffaele, will occur, relating to the assessment of compliance with the minimum development obligations outlined in the agreement. Under the ARLA, failure to meet such obligations may entitle OSR to exercise contractual remedies, including termination of the agreement or conversion of the license from exclusive to non-exclusive. As of the date of approval of the financial statements, assessments regarding the fulfillment of such obligations and discussions with the counterparty are ongoing, and no final determinations have been made.

Exhibit 12.1

Certification of the Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act, as amended

I, Pierluigi Paracchi, certify that:

1. I have reviewed this annual report on Form 20-F of Genenta Science S.p.A. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the board of statutory auditors, acting as the audit committee of the Company's Board of Directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize, and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 31, 2026

By: */s/ Pierluigi Paracchi*
Name: Pierluigi Paracchi
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 12.2

Certification of the Financial Officer (Principal Financial Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act, as amended

I, Richard B. Slansky, certify that:

1. I have reviewed this annual report on Form 20-F of Genenta Science S.p.A. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the board of statutory auditors, acting as the audit committee of the Company's Board of Directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize, and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 31, 2026

By: */s/ Richard B. Slansky*
Name: Richard B. Slansky
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 13.1

Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to U.S.C. Section 1350 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Genenta Science S.p.A. (the "Company"), does hereby certify, to such officer's knowledge, that:

(1) The Annual Report on Form 20-F for the year ended December 31, 2025 of the Company (the "Annual Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

GENENTA SCIENCE S.P.A.

March 31, 2026

By: */s/ Pierluigi Paracchi*
Name: Pierluigi Paracchi
Title: Chief Executive Officer
(Principal Executive Officer)

March 31, 2026

By: */s/ Richard B. Slansky*
Name: Richard B. Slansky
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 23.1

DANNIBLE & McKEE, LLP
Certified Public Accountants and Consultants
Financial Plaza, 221 S. Warren St., Syracuse, New York 13202-1628
(315) 472-9127 Fax (315) 472-0026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

March 31, 2026

We hereby consent to the incorporation by reference in the Registration Statement on Form F-3 (No. 333-271901) and in the Registration Statement on Form S-8 (No. 333-278392) of our report dated March 31, 2026, with respect to the consolidated financial statements of Genenta Science S.p.A included in this Form 20-F of Genenta Science S.p.A for the year ended December 31, 2025.

Dannible & McKee, LLP
Syracuse, New York

GGi
INDEPENDENT MEMBER
Member of Geneva Group International, a worldwide alliance of independent professional firms.