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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

For the month of May 2023

Commission File Number: 001-41115

GENENTA SCIENCE S.P.A.

(Translation of registrant's name into English)

**Via Olgettina No. 58
20132 Milan, Italy**

(Address of Principal Executive Offices)

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

Form 20-F Form 40-F

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

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

Other Events

Effectiveness of the Amended and Restated OSR License Agreement

As previously disclosed in the Annual Report on Form 20-F for the fiscal year ended December 31, 2022 of Genenta Science S.p.A. (“we,” “us” or “our”), we entered into an amended and restated license agreement with Ospedale San Raffaele S.r.l. (“OSR,” and such amended and restated license agreement, the “A&R OSR License Agreement”) in March 2023, which amended and restated the license agreement we 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 A&R OSR License Agreement was subject to Italy’s Law Decree No. 21 of March 15, 2012 (the so-called Italian “Golden Power” regulations), as subsequently amended and supplemented, and would not become effective until the applicable Italian governmental authority consented to the A&R OSR License Agreement. On April 20, 2023, such consent was received and the A&R OSR License Agreement became effective.

Pursuant to the terms of the A&R OSR License Agreement, 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 A&R OSR License Agreement, we have an exclusive option exercisable until April 20, 2026 (the “OPI Option Period”) 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 “OPI Option”). 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 (the “LHI Option”). We have 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 A&R OSR License Agreement, we paid OSR an upfront fee in amount equal to €250,000 pursuant to the Original OSR License Agreement. Pursuant to the A&R OSR License Agreement, as consideration, we 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 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, 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 EU countries, and achievement of certain net sales levels.

As part of the license, we 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 sufficient level of resources. In particular, consistent with the terms of the Original OSR License Agreement, the A&R OSR License Agreement 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 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 us 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 us and OSR, on a 50% - 50% basis.

The A&R OSR License Agreement 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 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) 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.

The foregoing description of the A&R OSR License Agreement does not purport to be complete and is qualified in its entirety by reference of the complete text thereof, a copy of which is filed as exhibit 10.1 to this report on Form 6-K.

Exhibits

Exhibit No.	Description
10.1	<u>Amended and Restated License Agreement between Genenta Science, S.p.A. and Ospedale San Raffaele dated March 23, 2023, which was filed as Exhibit 10.17 to the annual report on Form 20-F of the registrant filed on April 21, 2023. †</u>

† Portions of this exhibit (indicated with markouts) have been redacted in accordance with Item 601(b)(10)(iv).

SIGNATURES

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

GENENTA SCIENCE S.P.A.

By: /s/ Richard B. Slansky

Name: Richard B. Slansky

Title: Chief Financial Officer

Dated: May 1, 2023
