



DIVISION OF
CORPORATION FINANCE

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

March 28, 2021

Pierluigi Paracchi
Chief Executive Officer
Genenta Science S.r.l.
Via Olgettina No. 58
20132 Milan, Italy

Re: Genenta Science S.r.l.
Draft Registration Statement on Form F-1
Submitted March 1, 2021
CIK No. 0001838716

Dear Mr. Paracchi:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1 submitted March 1, 2021

Prospectus Summary, page 1

1. We note references to preclinical and preliminary data that treatment with Temferon resulted in an "anti-tumor effect," "changes in the immune system" and similar statements indicating findings of efficacy. Additionally, we also note your statement on page 4 that you believe that the addition of your product candidates to other cancer therapies "will enhance the durability and efficacy of the existing therapies...." Please revise to remove any statements that suggest the efficacy of your product candidates, as these determinations are the exclusive authority of the FDA or other regulators. Also, please limit the prospectus summary discussion of preclinical studies and trial results to an objective description of the endpoints of your studies and trials and whether they were

met. For example, rather than stating that Temferon triggered an anti-tumor effect, present your trial observations without concluding that Temferon caused the observations. Similarly revise the disclosure throughout your filing.

Research and Development Pipeline, page 3

2. Please revise your product pipeline table on pages 3 and 90 to clearly break out each stage or phase of clinical development and include a column for Phase 3. In addition, it appears that the asterisked footnote that appears in your pipeline table on page 90 is missing from the table on page 3. Finally, we note that you have included in your pipeline table various TEMs immuno-gene therapy programs that are in pre-clinical development. Given the early-stage development of these programs, please explain why these programs are sufficiently material to your business to warrant inclusion in your pipeline table. If they are material, please expand your disclosure in the Business section to provide a more fulsome discussion of these programs, including a description of preclinical studies or other development activities conducted. Alternatively, remove any programs that are not currently material from your pipeline table.

Company History and Management Team, page 6

3. Please remove the reference to "first-in-class" as this statement implies an expectation of regulatory approval and is inappropriate given the length of time and uncertainty with respect to securing marketing approval.

Risk Factors

Our gene therapy product candidates and the process for administering our product candidates may cause undesirable side effects...., page 16

4. We note your statement that two recent cases of myelodysplastic syndrome and acute myeloid leukemia relating to a third-party's product "are unlikely related to the LVV...." Please revise to provide the basis for this statement.

We may need to license intellectual property from third parties...., page 45

5. We note that you may need to license intellectual property from third parties. Discuss, if known, whether there are existing intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of your product candidates that could prevent or negatively impact commercialization.

Use of Proceeds, page 70

6. Please revise to specify how far in the development of Temferon, for each indication, you expect to reach with the proceeds of the offering. If any material amounts of other funds are necessary to accomplish the specified purposes for which the proceeds are to be obtained, state the amounts and sources of such other funds needed for each such specified purpose and the sources thereof. Refer to Instruction 3 of Item 504 of Regulation S-K.

Critical Accounting Policies

Share-based Compensation, page 85

7. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the quota underlying your equity issuances and the reasons for any differences between the recent valuations of your quota leading up to the IPO and the estimated offering price with consideration of the conversion of quotas into ordinary shares. This information will help facilitate our review of your accounting for equity issuances including compensation.

Business

Clinical Development of Temferon in GBM

Preliminary Interim Results, page 105

8. Please revise here and throughout to remove conclusory statements regarding the preliminary interim results of your phase 1/2a clinical trial, and provide detailed disclosure regarding the tests conducted, including the number of tests conducted, an explanation of the analysis performed, the range of results observed in each, whether the results were statistically significant and the p-value used to determine statistical significance. For example, we note your disclosure on page 106 that you "analyzed the peripheral blood of the patients from cohorts 1 and 2. In these patients, the peripheral blood showed a change in the T cell immune repertoire post treatment, revealing expansion of tumor-associated clones, which suggested that changes in the immune system are occurring."

Business

Intellectual Property, page 111

9. We note "it is [your] understanding" that Telethon granted OSR a worldwide exclusive license, with the right to sublicense, its rights in the patent families. Please revise to clarify whether Telethon granted OSR a worldwide exclusive license with the right to sublicense or advise.
10. Please revise your intellectual property disclosure to describe on an individual basis the type of patent protection granted for each technology (composition of matter, use, or process).
11. Please revise here to disclose the type of intellectual property right protection applicable to your "proprietary platform." In your revised disclosure, please clarify the source of protection for your "proprietary" platform, explain why the platform is "proprietary," and disclose the applicable jurisdictions and the duration of the underlying intellectual property protection.

License Agreement with Ospedale San Raffaele, page 112

12. With respect to the OSR License Agreement and applicable amendments, please clearly disclose the duration of the agreement and the royalty term, the aggregate amounts paid to date under the agreement and additional amounts that you are subject to pay in the future, including aggregate future potential milestone payments. Please also clarify, if accurate, that under the agreement you are required to file an IND regarding Temferon for GBM prior to February 2022. In addition, with respect to the Sponsored Research Agreement with OSR, please disclose the duration of the agreement and the aggregate amounts paid to date under the agreement.

Know-How License Agreement with Fondazione Telethon, page 114

13. Please file the Telethon License Agreement and the Sponsored Research Agreement with OSR as exhibits or provide your analysis identifying how you determined that the agreements did not need to be filed. Please refer to Item 601(b)(10) of Regulation S-K.

Related Party Transactions

Employment, Consulting and Services Agreements, page 143

14. We note that there are several service, consulting, directorship, and employment agreements discussed in this section. Please file these agreements as exhibits or provide your analysis identifying how you determined that the agreements did not need to be filed. Please refer to Item 601(b)(10) of Regulation S-K.

Statement of Operations and Comprehensive Loss, page F-3, page F-3

15. Please present the historical earnings per quota information as well as provide related disclosures pursuant to ASC 260.

Note 11. Related parties

OSR - San Raffaele Hospital, page F-21

16. In regards to your Agreements with OSR, please address the following:
- We note the various disclosures in the filing related to your OSR License Agreements, which include multiple amendments. Please clearly state the amounts paid since inception under the license agreements, the amounts currently due, and additional amounts that you are subject to pay in the future. Please clearly state the total milestone and other payments you are currently subject to based on current indications;
 - We note that OSR is a co-founder of the Company. Please also clarify in your disclosures whether OSR has any current ownership interests in your company and if so, the extent to which it does; and
 - Please help us reconcile the disclosures provided in the notes to the financial statements to those provided on page 143. The disclosures in the notes to the

financial statements indicate that OSR provided certain services free of charge; whereas, on page 143, it appears you paid OSR amounts for these services. We also remind you that all costs of doing business should be reflected in your historical financial statements.

Note 12. Commitments and Contingencies
Legal Proceedings, page F-24

17. We note your disclosures on page 132 state that you are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on your business and have not been notified of any claims in respect thereof, other than a possible infringement matter. The audited financial statements for the year ended December 31, 2019 indicate that you are not currently party to any material legal proceedings. It is not clear if you gave consideration to this possible infringement matter disclosed on page 132 in making this determination and determining additional disclosures pursuant to ASC 450 do not need to be provided. Please advise or provide additional disclosures related to this matter pursuant to ASC 450-20-50.

General

18. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Nudrat Salik at 202-551-3692 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Kasey Robinson at 202-551-5880 or Jeffrey Gabor at 202-551-2544 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Mitchell S. Nussbaum, Esq.