



DIVISION OF
CORPORATION FINANCE

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

October 28, 2021

Christer Rosén
Chief Executive Officer
Jupiter Neurosciences, Inc.
1001 North US HWY 1, Suite 504
Jupiter, Florida 33477

Re: Jupiter Neurosciences, Inc.
Registration Statement on Form S-1
Filed on October 12, 2021
File No. 333-260183

Dear Mr. Rosén:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form S-1, Filed on October 12, 2021

Market, Industry and Other Data, page 5

1. We note your statement that investors are "cautioned not to give undue weight to any such information, projections and estimates." Such statement may imply an inappropriate disclaimer of liability for such third-party information. Please revise to remove any implication that investors are not entitled to rely on information in your registration statement.

Prospectus Summary

Business Overview, page 6

2. We note your disclosure that you believe JOTROL™ is the first and only resveratrol product in the world that delivers a therapeutically effective dose of resveratrol in the

blood stream without causing gastrointestinal (GI) side effects and that JOTROL™ is a safe oral medication. Please revise these statements and similar statements throughout your prospectus that state or imply that your product candidates are safe or effective as these determinations are solely within the authority of the U.S. Food and Drug Administration ("FDA") and comparable regulatory bodies. As a non-exhaustive list for illustrative purposes only, we note the following disclosures:

- Page 97: “Overall, the oral administration of JOTROL (resveratrol) as single ascending doses ranging from 200 mg up to 700 mg was safe and well tolerated in healthy adult subjects.”
 - Page 103: “Studies in mice show that a high dose of resveratrol is effective in treating MPS I.”
 - Page 106: “These are targets that a high dose of resveratrol has shown efficacy both in pre-clinical work as well as in the well published Turner et al. trial.”
 - Pages 109-110: “We believe JOTROL™ will be demonstrated to be very safe based upon the very mild adverse events seen in our Phase I study....Resveratrol is a natural well-known product with a well-documented safety profile with only gastro-intestinal adverse side effects that we believe we have resolved with our product JOTROL™.”
3. We note your statement on page 6: “JOTROL™, based on our pre-clinical and Phase I study results, delivers resveratrol into the blood plasma with significantly greater bioavailability than conventional resveratrol and has the ability to cross the blood-brain barrier.” This comparison appears to be based on literature, like the comparison on page 97 to the MCR Friedreich’s Ataxia study and Turner et al. Alzheimer disease study. Please remove such comparison and any other comparisons that are not head-to-head trials as comparisons to available products and other product candidates are not appropriate unless you have conducted head-to-head trials. You may generally discuss the literature on the topic in the "Description of Business" section without comparing it to the results of your trials. Additionally, on page 9 you state: “Pre-clinical testing showed that patented technology (JOTROL™) delivered 17X higher maximum level in plasma (“C-Max”) and 4X higher area under the curve (“AUC”).” Please revise to clarify what this is a comparison to and provide more details on this study.
4. We note your statement on page 6: “We plan to continue pursuing grant funding opportunities in all areas where they are available, such as Phase II and Phase III trials in Alzheimer’s disease (up to \$75 Million available per project through NIA /NIH) as well as the opportunity in receiving at least 50% of the cost of Phase II and Phase III trials in rare (“orphan”) diseases.” Please revise the last sentence of the paragraph in which this sentence appears to reflect that you may never receive any future grants or cost savings.

JOTROL, page 8

5. On page 8 you say that your Phase 1 pharmacokinetic study will be cross-referenced for all indications where JOTROL™ will be used in Phase II and Phase III clinical trials. Similarly, in your pipeline table you state: “A successful Phase II trial may lead to direct

Phase II/III trial in other mitochondrial rare disease since data can be referenced.” Please revise to state whether you have discussed the use of cross referencing in this manner with the FDA or other comparable regulatory authorities.

Resveratrol, page 8

6. Given that resveratrol has never been approved by the FDA or comparable regulators to treat any of the indications shown, this presentation is speculative and without context. Please revise to remove this graphic.

Product Development, page 9

7. We note your statement on page 9: “There are often opportunities to get accelerated FDA approval for a rare disease indication if a product shows efficacy and has a good safety profile.” Please revise to describe the FDA pathways you are referencing in more detail and remove the word “often.” Address in your revisions that any accelerated approval pathway designation does not guarantee accelerated FDA review. Alternatively, delete this statement.

Product Pipeline, page 9

8. Please remove the text descriptions under each indication in the pipeline table on page 9 and elsewhere. Each one sentence description requires more context that is not appropriate for a pipeline table, but can be described outside of the table. For example, for JNS101, describe in the “Description of Business” section what “positive outcomes” means and additional detail such as number of subjects and duration. Additionally, please tell us why you believe JNS109, JNS110 and JNS120 are sufficiently material to be included in the pipeline table considering the early stage of such programs. We note, for example, your statement on page 106 concerning JNS109 where you state: “Our Co-Chairman of the SAB, Professor Rudolph Tanzi, Ph.D., has expertise in this field and suggested that we shall investigate how JOTROL™ can have a positive impact for ALS patients.” To the extent you have taken any concrete actions in the development of these programs please describe them to us in your response.

You state in the Use of Proceeds section that you intend to use a portion of the proceeds of the offering to “fund IND submissions for Friedreich's ataxia, MELAS and MCI/early Alzheimer's Disease.” Where applicable, make clear in the table the extent to which you expect to rely on data from clinical trials conducted by third parties. Address in the narrative the basis for your expectations in this regard.

Selected Historical Financial Data, page 14

9. Please explain the usefulness of a Gross Profit subtotal when you have not reported any sales or cost of goods sold in any of the periods presented. Alternatively, please remove this subtotal from your Statement of Operations Data.

Risk Factors

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies, page 54

10. Please revise page 54 to highlight your reliance on the Acquanova AG license agreement specifically, including the consequences of the loss of such license.

Use of Proceeds, page 81

11. We note your statement on page 150: “We intend to pay a portion of the outstanding license fee due to Aquanova AG with our cash balance as of the date of this filing. We project to payout the remaining accrued license fee with proceeds from this offering.” Please revise the Use of Proceeds to reflect this use of proceeds.

Dilution, page 89

12. Please explain to us how you determined your net tangible book value per share to be (\$0.15) at June 30, 2021.

Description of Business

Business Overview, page 90

13. Please describe the material terms of the grant with the National Institute on Aging. Additionally, file such agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K or advise.
14. Please describe the agreements with each of your key partners listed on page 128-129 and file such agreements pursuant to Item 601(b)(10) of Regulation S-K, or advise.

JOTROL Intellectual Property, page 93

15. With respect to your material patents and patent applications, please revise to specify (i) the specific products, product groups and technologies to which such patents relate, (ii) whether the patents are owned or licensed, (iii) the type of patent protection, (iv) the patent expiration dates and (v) the jurisdiction. Please also explain the meaning of the following sentence on page 93, and, if applicable, the extent to which your patent protection for JOTROL™ is incomplete: “The patent application was assigned to Aquanova AG, as Aquanova AG has other patents on their micellar formulation technology that was utilized in creating JOTROL™.”
16. Please revise to describe the material terms of all material license agreements, including the Aquanova AG License Agreement and the MCRI agreement, such as: (i) the nature and scope of intellectual property transferred, (ii) each parties’ rights and obligations, (iii) the duration of the agreement and royalty term, (iv) the termination provisions, (v) any up-front or execution payments, (vi) the aggregate amounts paid to date, (vii) the aggregate

future potential milestone payments segregated by development, regulatory and commercial sales milestones, and (viii) the royalty rates or a royalty range not to exceed ten percentage points per tier. Additionally, please file the Aquanova AG License Agreement and any other material license agreement as an exhibit pursuant to Item 601(b)(10) of Regulation S-K.

JOTROL Pre-clinical studies, page 94

17. With respect to your preclinical studies, please provide additional detail such as the number of studies performed and the number of subjects in each study.
18. We note the p-values on page 96. Please revise to provide p-values for all statements of statistical significance and explain how statistical significance relates to FDA standards of efficacy.

JOTROL Phase I Pharmacokinetic ("PK") and Safety Study, page 96

19. Please revise page 97 to clarify the different arms of the PK study (Treatment A through D).

Market Overview, page 98

20. We note your statement on page 98: "The tables below illustrate how lucrative just one approval in an orphan indication can be. With JNS's position of multiple possible approval in orphan diseases as well as for Alzheimer's disease the Company feels that there are many scenarios for generating meaningful treatments for patients which ultimately will lead to financial success." Please remove these statements and the associated table as they imply you have an increased chance of obtaining an orphan drug designation and approval for at least one candidate, which you then imply would be lucrative. You may describe what an orphan drug designation means and state that you intend to pursue multiple orphan drug designations, but also state that you may not achieve regulatory approval of any of your product candidates.
21. We note the bar graph on page 99. Given your statement that the average price for a product treating an orphan drug is higher than for a product treating a non-orphan drug, the number of approved orphan drugs generating these sales is smaller than for non-orphan drugs, which is not explained in the graphic. Please revise the graphic to include the number of different types of drugs sold in each year shown. Alternatively, please remove this graphic.

Our Relevant Market Size, page 100

22. With respect to the rare disease market size calculation on page 100, please revise to state the countries included and name the three indications you refer to. Additionally, on page 101 you state: "The Alzheimer's disease market is very large evident by the Aduhelm pricing of \$56,000 per year per patient... We expect our product to be priced significantly

lower if approved for MCI/early AD. We estimate the relevant global market size for our product to be in excess of \$100 billion.” Please revise to explain the basis for your market share calculation of over \$100 billion.

JNS101 Friedreich's ataxia direct to Phase II, page 102

23. Please revise to clarify your relationship with MCRI and state whether you have discussed your ability to reference this data with the FDA. Also revise to provide the p-values for "statistically different positive results" on page 102.

JNS102 Phase II trial for MPS I, page 103

24. On page 103 you state: “IND for Phase I, executed, approved by FDA. Small FDA hurdles to start the Phase II.” Please revise to describe the small hurdles.

JNS108 Mild Cognitive Impairment/early Alzheimer's Disease, page 105

25. Please clarify your relationship with Georgetown and whether you have discussed your ability to rely on and reference the Phase II trial conducted by Georgetown with the FDA.

Competitive Advantages, page 109

26. Please remove the comparison to Celgene on page 109 which could inappropriately imply that you will also be approved for multiple different indications for one technology and generate billions in annual sales.
27. Please remove the statement “We also believe that JOTROL™ can be sold at a very competitive price and thereby have a stronger possibility of support from payors” or revise to detail all the assumptions you are making regarding pricing. For example, explain the current stage of your manufacturing ability and the extent to which you can currently predict cost of manufacturing on a commercial scale and the limitations and assumptions inherent therein, and explain which payors you are referencing, detail the basis on which you believe payors will support you, and if you are referencing reimbursement, explain how reimbursement works including by detailing all steps you will need to complete in order to obtain reimbursement coverage if regulatory approval is granted. We note on page 110 you state you have “no plans to implement the commercialization of our product JOTROL™ but expect to either out-license JOTROL™....”
28. On page 110 you state: “In addition, we were able to receive, from a major pharmaceutical company, a full chronic toxicology study performed on resveratrol saving most likely 1 year in development time and over \$2 million in cost.” Please revise to provide the details of this study in the appropriate subsection of the "Description of Business" section.

Marketing and Commercialization Plan, page 110

29. On page 110 you state: "In cases with no existing available treatment an approval of a breakthrough drug spreads extremely efficient through Key Opinion Leaders (KOL) and patient advocacy groups which may reduce marketing costs." Please revise to state that this is your belief, if true, or provide support. Additionally, revise to state that you have not applied for breakthrough designation by the FDA, if true. Please also clarify the indications you are referring to as indications "with no existing available treatment."

Executive Compensation, page 113

30. Please revise the Summary Compensation Table to include the footnote required by Instruction 1 to Item 402(n)(2)(v) and (n)(2)(vi) of Regulation S-K, and revise the Director Compensation Table to include the footnote required by Instruction to Item 402(r)(2)(iii) and (iv) of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Research and Development Expenses, page 114

31. Please discuss the type of the R&D expense incurred and tell us whether you track your research and development costs by program area. If so, tell us your consideration given for disclosing a breakdown of such information in your filing. If not, tell us your consideration for disclosing the fact you do not track these costs by pipeline program area. In addition, quantify in your narrative discussion of the changes in such expenses the changes due to each program, or if not known, the changes due to clinical vs non-clinical.

Description of Securities, page 160

32. Once you have an estimated offering price range, please explain to us the reasons for any differences between recent valuations of your common shares leading up to the planned initial public offering and the midpoint of your estimated offering price range. This information will help facilitate our review of your accounting for equity issuances, including stock compensation.

General

33. Please provide the undertaking required by Item 512(a)(5) of Regulation S-K.
34. 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.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Christer Rosén
Jupiter Neurosciences, Inc.
October 28, 2021
Page 8

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Christie Wong at 202-551-3684 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Margaret Schwartz at 202-551-7153 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Craig D. Linder, Esq.