

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

DIVISION OF CORPORATION FINANCE

September 3, 2021

Alon Ben-Noon Chief Executive Officer NeuroSense Therapeutics Ltd. Medinat ha-Yehudim Street 85 Herzliya 4676670 Israel

> Re: NeuroSense Therapeutics Ltd. Draft Registration Statement on Form F-1 Submitted August 10, 2021 CIK No. 0001875091

Dear Mr. Ben-Noon:

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 August 10, 2021

# Prospectus Summary Overview, page 1

- 1. We refer to your disclosure that your product candidates utilize a combination of FDAapproved drugs with well-established safety and efficacy profiles, specifically ciprofloxacin and celecoxib. Please revise to clarify in the Summary that both are generic drugs. Where appropriate, please also provide a brief overview of the FDA approved uses of ciproflaxacin and celecoxib.
- 2. Please expand your disclosure to provide a brief overview of the treatment emergent adverse events that were observed in your Phase IIa NST002 trial of PrimeC in ALS

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patients in Israel in the Summary. We refer to your disclosure on page 70.

- 3. We note your disclosure on page 37 that you have received initial agreement from the FDA for your development to continue under the 505(b)(2) pathway. Please expand your disclosure in the Summary to provide such information and specify when you received this initial agreement from the FDA.
- 4. We note your disclosure that all patients who completed the NST002 trial elected to continue into an extension study with PrimeC. Please expand your disclosure to indicate the number of patients who completed the NST002 trial.

## Risks Associated with Our Business, page 3

5. Please revise the Summary to highlight your belief that you were a PFIC in the preceding taxable year and that you expect you will be a PFIC for the current taxable year. Please disclose the adverse tax consequences to investors resulting from a PFIC classification in any given tax year, including additional reporting requirements.

# **Risk Factors**

# We have not applied for regulatory approvals to market..., page 15

6. We note that you have "financed the pharmaceutical compounding of the two FDAapproved drugs that comprise PrimeC" and provided the relevant information to two ALS clinicians treating eight ALS patients under a CDA without discussing such provision with the FDA. Please expand your disclosure to specify whether the patients were being treated in the United States, describe the effects of the treatment on the patients, and discuss the reporting requirements relevant to compassionate use and the risks resulting from not discussing such provision with the FDA.

## Cautionary Note Regarding Forward-Looking Statements, page 50

7. You state on page 51 that investors are "cautioned not to unduly rely upon" statements that reflect your beliefs and opinions. Please note that you are responsible for the disclosure contained in your registration statement and you may not use language that could be interpreted as a disclaimer of information contained in your filing. Please revise.

## **Business**

## Clinical Results - NST002 Phase IIa Trial in ALS, page 70

- 8. We note your disclosure that most of the TEAEs were assessed as related to study drug were gastrointestinal disorders. Please expand your disclosure to identify the TEAEs that were assessed as related to the study drug, the number of times the TEAE was reported, and whether they were classified as serious adverse events.
- 9. We refer to your discussion of PrimeC's potential efficacy using two accepted ALS clinical endpoints, the ALSFRS-R and FVC on pages 71 and 72. Please expand your disclosure to address related statistical significance and/or p-values.

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10. We note your disclosure on page 72 relating to the analysis of blood samples and additional ALS-associated pathological markers such as markers of autophagy and lysosomal trafficking. Please expand your disclosure to include the design and scope of your study and to discuss the data from the results to support the conclusions drawn.

## Clinical Results - NST001 Phase I Trial in ALS, page 72

11. We refer to your disclosure on page 72 that the Phase I NST001 trial of PrimeC for the treatment of ALS has not yet been completed and that you plan to complete the trial in the third quarter of 2021. Based on clinicaltrials.gov, it appears that you are conducting these trials in the United States, but based on your disclosure elsewhere in the prospectus, it appears that you have not yet filed an IND for PrimeC. Please revise your disclosure to identify the location of the NST001 trial and to explain this discrepancy. In addition, please clarify your timeline for the development of PrimeC, including addressing your completion of the Phase IIa NST002 trial in February 2021 prior to completion of the Phase I NST001 trial, and how this factored into your discussions with the FDA regarding approval of your trial design.

## Preclinical Pipeline, page 73

12. We note the inclusion of your CogniC and StabiliC product candidates for the treatment of Alzheimer's and Parkinson's disease in your pipeline table on pages 1 and 66. You also disclose on page 3 that you are currently conducting a robust in-vitro study of CogniC, with plans to conduct a patient-derived cell study and an in-vivo study thereafter. If they are material, please expand your disclosure in this section to provide a more fulsome discussion of these programs, including a description of preclinical studies or development activities conducted. Alternatively, please remove any programs that are not currently material from your pipeline tables.

## Competition, page 73

13. We refer to your disclosure on pages 2 and 67 identifying Exservan as an FDA-approved treatment for ALS that is delivered orally, which minimizes disruption to patients' quality of life. Please expand your disclosure to identify competition from FDA-approved treatments. Please also disclose the types of modifying therapeutics that each of the listed competitors are developing and where they are in the development process.

## Intellectual Property, page 74

14. We note your disclosure that your patent portfolio includes a U.S. patent application that is currently pending. Please amend your disclosure to clarify the type of patent protection and expected expiration date. While you disclose that your U.S. provisional application is directed to the composition of ciprofloxacin and celecoxib, please also specify the expected expiration date.

## Compensation of Executive Officers and Directors, page 87

15. Please disclose the total amounts set aside or accrued by the company to provide pension, retirement or similar benefits, as required by Item 6.B.2 of Form 20-F.

#### Management

Executive Management and Directors, page 87

16. Please tell us what consideration you gave to including information required by Item 6 of Form 20-F for Dr. Oron Yacoby-Zeevi.

## **Related Party Transactions**

#### IP Transactions, page 106

17. We refer to your disclosure relating to the assignment of the exclusive rights to an invention related to the methods and compositions of anti-inflammatory drug and dicer activator for treatment of neuronal diseases. Please tell us whether this invention relates to your lead product candidate.

#### Principal Shareholders, page 108

18. Please revise footnote 2 to identify the natural persons who are the beneficial owners of the shares held by E Europe Limited.

<u>Financial Statements</u> <u>Note 2- Basis of Presentation</u> <u>F. Use of estimates and judgment</u> Share-based payment transactions, page F-9

19. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances. Please discuss with the staff how to submit your response.

#### <u>General</u>

20. Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

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You may contact Tracie Mariner at 202-551-3744 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Irene Paik at 202-551-6553 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Brian K. Rosenzweig, Esq.