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

DIVISION OF
CORPORATION FINANCE

September 27, 2024

Udi Gilboa
Executive Chairman
Nasus Pharma, Ltd.
Igal Alon 65
Tel Aviv, Israel 6744317

Re: Nasus Pharma, Ltd.
Draft Registration Statement on Form F-1
Submitted August 30, 2024
CIK No. 0002029039

Dear Udi Gilboa:

We have reviewed your draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1

Prospectus Summary
Our Company, page 1

1. With reference to your disclosures on page 105 and elsewhere, please revise your Prospectus Summary to disclose that you plan to pursue FDA's 505(b)(2) regulatory pathway for NS001 and NS002. Briefly describe what that pathway entails and identify the reference listed drug/device that you intend to use in your prospective NDA applications. Identify and briefly explain the clinical testing that you plan to conduct prior to submitting NDAs for both candidates. Briefly explain relevant terminology at first use, including, as applicable, "reliability study," "stability program," "phase 2 study" and "pivotal study."
2. Please revise your Our Company section to provide a balanced presentation of your business. In this regard, we note several performance claims concerning your product candidates relative to approved products notwithstanding that you need to perform

additional clinical testing. With reference to your disclosures on pages 16, 21 and elsewhere, please explain that you currently have no FDA approved products, that your products have been tested on relatively small patient populations and the FDA may not agree that your product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval.

3. Please revise your Prospectus to remove statements that your product candidates are safe as safety determinations are within the sole discretion of the FDA and similar foreign regulators. As a non-exhaustive list, we note your disclosure on page 1 that NS001 has a "favorable safety profile," on page 90 that "NS002 was found to be a safe, needle-free treatment" and on page 93 that your pharmacodynamic results "reflect the safety of [y]our intranasal administration."

The Offering, page 5

4. Please revise here and in your Use of Proceeds section to clarify the stages of development you intend to fund using the proceeds from this offering used for the "two additional early-stage indications."

Risk Factors
Risks Related to Our Business and Industry
We manage our business through a small number of employees and key consultants . . . ., page 44

5. Please revise to identify your one-full time employee. With reference to your "Management" disclosure on page 123, please clarify which members of the management team are part-time, independent contractors and/or consultants. To the extent that you do not have a Chief Financial Officer or a full-time Chief Financial Officer, please revise to provide appropriate risk factor disclosure or advise.

Business
The Intranasal Drug Delivery Product Market
Overview, page 79

6. We note your graphics on page 82 appear to have footnotes associated with different countries but there are no accompanying footnote disclosures. We also note "USA" is listed twice in both graphics. Please revise or otherwise advise.

Nasus's Well Differentiated and Diversified Technology Platform - Intranasal Powder, page 87

7. We refer to Figure 5 on page 88. Please identify the third-party particles depicted in the left graphic and the particles depicted in the right graphic.

Aptar UDS and collaboration, page 89

8. Please revise to explain whether the agreement covers use of the Unit Dose Spray product to deliver drug products in addition to Naloxone. In this regard, it is unclear whether your NS002 candidate will be delivered using Aptar's nasal unidose system or another spray system that is covered under a separate agreement.

Our Products, page 89

9. Please revise the Business section to disclose, for each clinical trial, the primary and secondary endpoints, as applicable, whether the trials met these endpoints, whether the trials were powered for statistical significance and if so, whether the results were statistically significant, disclose if there were any significant adverse events and if so, disclose the type and number of each. Regarding statistical significance, we note you indicate some of your data is statistically significant, but we are unable to tell if the data pertains to an endpoint and if so, whether the endpoint is a primary or secondary endpoint.

Our phase 2 dose-finding/safety study - NP006, page 91

10. We note the reference on page 92 to a "PS002 study." Please tell us whether this is the same study as the NP006 study or is an entirely different one.

Intranasal Naloxone (NS001), page 94

11. Please revise your disclosure on page 98 to provide the details of the "scientific advice request from several countries in the European Union." Revise to state the purpose of the "short preclinical study in rats."

Competitors and Market for NS002, page 100

12. Please revise under this heading and elsewhere in your Business section to remove statements that your products are superior to competitors and comparisons that were not the result of head-to-head clinical trials. You may provide and discuss the data from head-to-head clinical trials and state the conclusions supported by the data. Where you make comparisons between your product candidates and approved therapies, revise to add context that your product candidates have only been tested in small patient sample sizes, have not been approved by the FDA or a similar foreign regulator and may never receive such approval.

Intellectual Property, page 102

13. Please revise under this heading to disclose whether you own or license your intellectual property, the expiration dates for your issued patents and expected expiration dates for your pending patents. To the extent your intellectual property is licensed, revise your Risk Factors section to provide appropriate disclosure.

Research and Development, page 105

14. We note your disclosures concerning the steps that you must complete in order to submit the NDA dossier necessary for marketing approval of each product candidate. Please expand your disclosure in this section or elsewhere in the Business section to explain what each step entails. For steps that involve clinical testing, please explain the trial size,

timing, cost and the endpoints or performance measures that will need to be shown relative to the reference drug/device product in order to support an NDA application filed pursuant to the 505(b)(2) pathway.

15. For your NS002 candidate, please tell us whether you will need to conduct clinical testing that involves self-administration by subjects with severe Type I allergies and patients experiencing anaphylaxis. With respect to NS001, please tell us whether you will need to conduct clinical testing for emergency treatment of known or suspected opioid overdose or whether testing will be limited to healthy patients.

16. We note your disclosure on page 106 that you "entered into a non-recurring research and development arrangement with a governmental body." Please revise to state whether you are still performing services pursuant to the agreement and whether the agreement includes future obligations, and if so, disclose the obligations.

Orange Book Listing, page 108

17. Please disclose, if known, whether you will need to challenge patents via a Paragraph IV certification. To the extent that you plan to pursue this certification or there is material uncertainty, then please add a risk factor that discusses the need or potential need for a 30-month stay on future NDA applications that you submit for your lead candidates.

Exclusivity, page 109

18. Please revise to indicate, if known, whether you will pursue non-patent regulatory exclusivity for your candidates. If you do not and/or there is a material risk that you will not be eligible, please add a risk factor, as applicable, that you may face competition from third parties seeking to market generic versions of your products shortly after FDA approval.

Management
Compensation
Services Agreements with Executive Officers, page 125

19. Please revise under this heading where appropriate to disclose the exercise price and expiration dates for the share options granted to Tair Lapidot and Oren Elmaliah under the 2019 Plan. Refer to Item 6.B(1) of Form 20-F.

Related Party Transactions
Formulex License Agreement, page 147

20. Please revise page 148 to disclose how Formulex may terminate the Formulex License Agreement.

Financial Statements
Consolidated Statement of Operations, page F-4

21. Please revise your filing to present the subtotals and totals, such as those for operating loss from continuing operations, net loss, and earnings per share information within parentheses to represent that these are negative numbers.

Signatures, page II-6

22. Please identify your principal executive officer or officers as well as your principal financial officer, controller or principal accounting officer.

Please contact Christine Torney at 202-551-3652 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Eric Victorson, Esq.