

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

DIVISION OF CORPORATION FINANCE

August 26, 2021

Ron Bentsur, M.B.A. Chairman and Chief Executive Officer Nuvectis Pharma, Inc. 1 Bridge Plaza Suite 275 Fort Lee, NJ 07024

> Re: Nuvectis Pharma, Inc. Draft Registration Statement on Form S-1 Submitted July 30, 2021 CIK No. 0001875558

Dear Mr. Bentsur:

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 S-1 submitted July 30, 2021

### Prospectus Summary, page 1

- 1. Please revise the opening paragraph to clarify that your operations are preclinical.
- 2. Please balance the following statements on page 1 with disclosure highlighting the risk that you may not obtain FDA approval for any product candidates: "The ICR's drug discovery unit has discovered several successful clinical drug candidates, the most notable of which is Zytiga, a leading drug for metastatic prostate cancer" and "Our three co-founders have a proven track record of successful drug development and capability to raise the capital necessary to support the development of product candidates."

- 3. We note your references to your product candidate as "first-in-class" on page 2 and throughout the registration statement. This term suggests that the product candidate is effective and likely to be approved. Please delete these references throughout your registration statement. If your use of these terms was intended to convey your belief that the product is based on a novel technology or approach and/or is further along in the development process, you may discuss how your technology differs from technology used by competitors and, if applicable, that you are not aware of competing products that are further along in the development process. Statements such as these should be accompanied by cautionary language that the statements are not intended to give any indication that the product candidates have been proven effective or that they will receive regulatory approval.
- 4. On page 4 you state that the studies required for a CTA to the MHRA have been completed. However, on page 16, you state that NXP800 will require additional preclinical studies. Please reconcile your disclosure or advise.
- 5. On page 4 you state that you plan to submit a CTA in the fourth quarter of 2021 and an IND in the first half of 2022, and that you plan to initiate a Phase 1 dose escalation in the fourth quarter of 2021. Please revise to state whether this is a U.K.-based trial and include cautionary language that this timeline may be delayed as a result of MHRA review given you have not submitted a CTA yet and plan to do so in the fourth quarter of 2021 at the earliest.
- 6. On page 6 we note your disclosure that you plan to explore NXP800's potential in several additional tumor types, such as gastric, hepatocellular, esophageal, urothelial carcinoma and others. Please state whether your product will require modification to treat these other indications and whether you will need FDA approval for any other these potential applications.

## Shares Eligible for Future Sale, page 104

7. Please revise page 105 to state the number of shares that will be entitled to registration rights and the types of registration rights afforded. To the extent this will be memorialized in an agreement, please file such agreement pursuant to Item 601(b)(10) of Regulation S-K.

# Summary Financial Data, page 11

8. Please revise to present the pro forma as adjusted balance sheet data based on the latest balance sheet when available. Refer to Rule 11-02(c) of Regulation S-X. In addition, revise the December 31, 2020 financial data to agree with your financial statements.

### Capitalization, page 44

- 9. Please revise to double underline cash balance to clarify that such amounts are not included in your total capitalization.
- 10. Here you stated that your capitalization does not include 128,250 preferred A shares. Please revise to present the issuance and conversion of the preferred A shares using a separate pro forma column, and thus eventually include their effect in your pro forma as adjusted column, to properly capture your full capitalization. The same comment applies to your dilution table at page 46.

### **Business**

## The Nuvectis Approach, page 53

11. Given it appears you only have one product candidate in development, please revise the following statement on page 53 and all similar statements that imply you have multiple product candidates in development, or clarify your development program: "We analyze clinical trial data to assess the response signals of a product candidate in development, in order to identify candidates that show promise and favorable pharmacologic properties based on absorption, distribution, and/or side effect profile."

### Our Leadership Team, page 53

12. On page 54 you state that you received "several Orphan Drug (U.S. and EU) and Fast Track Designations." Please revise to state the exact number of Orphan Drug and Fast Track Designations and the indications for the product candidates that received such designations.

## NXP800 - Our Lead Product Candidate, page 55

13. Please clarify whether you or the ICR conducted each of the preclinical pharmacology, pharmacokinetic, and toxicological and other safety studies described in the registration statement, and the extent to which you depend on the ICR for running additional preclinical or clinical trials, as referenced on pages 64 and 67, where you mention the ICR performing additional studies.

## NXP800 Patient Enrichment Strategies, page 58

14. On page 58 you state: "Tumor samples from seven different ovarian cancer xenograft model studies were split into two groups based on their response to NXP800 treatment, with probes required to express at least a two-fold differential in the responsive groups." Please clarify the portion of samples that did not respond to NXP800 treatment or did not express at least a two-fold differential.

#### Intellectual Property, page 65

15. Please revise to state whether the E.U. and Japanese patents are composition of matter patents. With respect to the patents related to HSF1, please state the number of patents, type of patent protection afforded and whether they are patents or patent applications. For the patent family that has a statutory expiration in October of 2037, please provide the jurisdiction(s) covered.

### Clinical Development Plan, page 66

16. Please revise to provide more information concerning your first Phase I trial, including the primary and secondary endpoints, how many subjects you intend to enroll and the planned duration and dosing.

### NXP800 License Agreement, page 66

17. We note your statement that the royalty term under the NXP800 License Agreement may in part expire on a country-by-country basis as to each licensed product until expiry of the last to expire patent in such country. Please revise to clarify when these claims are expected to expire. Please also revise to state the term of the agreement and grounds for termination of the agreement.

### Preclinical Drug Discovery and Validation, page 66

18. Please revise page 66 or elsewhere to more fully describe each preclinical study that has been performed with respect to NXP800, including, with respect to any animal studies, the number of subjects, dosage, duration of the study, results and any serious adverse effects. Please also clarify the scope of preclinical studies conducted thus far.

### Executive Compensation, page 89

19. Please provide the information required by Item 402(r) of Regulation S-K concerning director compensation.

### Principal Shareholders, page 97

20. Please revise your disclosure to identify the natural person or persons who have voting and/or investment control of the shares held by Pontifax VI LP on page 98.

### **Exhibits**

21. We note your reference to entering indemnification agreements with your directors and officers. Please file such agreements as exhibits pursuant to Item 601(b)(10) of Regulation S-K.

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

22. 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 Li Xiao at 202-551-4391 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Margaret Schwartz at 202-551-7153 or Jeffrey Gabor at 202-551-2544 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Matthew W. Mamak, Esq.