



DIVISION OF
CORPORATION FINANCE

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

September 4, 2020

Anthony Mack
Chief Executive Officer
Virpax Pharmaceuticals, Inc.
1554 Paoli Pike #279
West Chester, PA 19380

Re: Virpax Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted August 10, 2020
CIK No. 0001708331

Dear Mr. Mack:

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 August 10, 2020

Cover page

1. We note your disclosure that no assurance can be given that your application to list your common shares on the Nasdaq Capital Market will be approved. Please tell us whether the offering is contingent upon securing Nasdaq listing approval and if it is not, please revise the cover page to clarify this fact.

Prospectus Summary
Our Portfolio, page 1

2. It appears that each of your product candidates are still in pre-clinical development with

INDs expected to be filed in 2021. However, your pipeline table suggests that you have already completed Pre-IND related activities. Please shorten the arrow for each product candidate, as appropriate, to illustrate how far along you are in the Pre-IND process. Given that you have not yet initiated clinical trials for any of your product candidates, please also revise your statement throughout the prospectus that you are a clinical stage biopharmaceutical company and your statement that you have three clinical-stage product candidates.

3. Please revise your statement here and repeated throughout your registration statement that the U.S. Food and Drug Administration (FDA) has acknowledged your intention to pursue the regulatory pathway under Section 505(b)(2) of the FDCA to remove any implication you will be successful in securing regulatory approval under this pathway or that you have successfully mitigated risks associated with clinical development of your product candidates. Additionally, please remove the column illustrating your anticipated timeline on page 2 and similar timelines throughout your registration statement, including in your pipeline table on page 1 and in the Business section, as these timelines are premature and speculative. We will not object to a discussion of your planned development activities. Please also revise your reference to six product candidates on page 5 to make it clear that you are developing product candidates for multiple indications.

Diclofenac Epolamine Metered-Dose Spray Film (Epoladerm™), page 2

4. We note your disclosure here and in the Business section that you believe Epoladerm has a "first-in-class" metered dose film. 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 this term 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 candidate has been proven effective or that it will receive regulatory approval.

Long-acting Bupivacaine Liposomal-gel 3.0% (LBL100 or Probudur) , page 2

5. We note your disclosure that early animal studies indicate that Probudur may provide pain control for up to 96 hours. We note also your statement on page 3 that NES100 has demonstrated comparable preclinical activity to morphine in all animal pain models without the drug seeking, respiratory depression and tolerance associated with opioids. Please revise these and similar statements throughout your registration statement that state or imply that your product candidates are safe or effective as these determinations are solely within the authority of the FDA and comparable foreign regulators.

Our Strengths, page 4

6. We note your discussion of opioid-related deaths and that the HEAL initiative and recent FDA guidance has made it more efficient to bring novel non-opioid medication to market. Your prospectus should provide a balanced and factual presentation of your business. Given your limited preclinical data available to date, it is inappropriate for you to state or imply your product candidates may mitigate abuse-related deaths, or that a projected increase in abuse-related deaths operates as a competitive advantage. Please revise your disclosure accordingly.
7. Please revise your disclosure to clarify that the FDA's accelerated approval pathway may not lead to a faster development process or regulatory review and does not increase the likelihood that a product candidate will receive approval.

Implications of Being an Emerging Growth Company, page 6

8. Please 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.

Summary of Risks Associated with Our Business , page 6

9. Please add a bullet point highlighting the risk that you are dependent upon intellectual property licensed from third parties, as discussed on page 29. Please also add a bullet point highlighting the risks related to your concentrated share ownership, as discussed on page 39.

Summary Selected Financial Data, page 8

10. Please tell us the existing conditions that permit you to present pro forma balance sheet information for periods other than the most recently presented balance sheet date. Please refer to Article 11-02(c) of Regulation S-X for guidance.

Use of Proceeds, page 46

11. Please expand your disclosure to state how far the allocated net proceeds are expected to allow you to continue in the development for each of your product candidates.

Capitalization, page 48

12. Please expand the table to include your short-term and long-term debt instruments.
13. Please expand your description of the Pro Forma column to include what specifically in the amended and restated certificate of incorporation will impact your capital structure upon effectiveness.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Use of Estimates
Fair Value of Common Stock and Stock-Based Compensation, page 53

14. Once you have an estimated offering price, please provide us with an analysis explaining how you determined the fair value of the common stock underlying your equity issuances along with the reasons for any differences between recent valuations of your common stock leading up to your offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances.

Future Capital Requirements, page 55

15. We note your disclosure that you expect the net proceeds of the offering and existing cash will be sufficient to fund your operations, future research and development and general working capital for at least a specified time. Please revise your disclosure to specify such time. Please also discuss your auditor's going concern opinion in the Liquidity discussion in your MD&A, addressing your financial condition, the uncertainties you face, such as your need to obtain additional financing, and the consequences for your business if you are unable to obtain additional financing.

JOBS Act, page 57

16. We note your disclosure here and on page 41 that you have elected not to take advantage of the extended transition period for the implementation of new or revised accounting standards. Please reconcile these disclosures with the cover sheet and your disclosure on page 6.

Business

Diclofenac Epolamine Metered-Dose Spray Film (Epoladerm), page 58

17. We note that you have not included any disclosure about the preclinical trials you reference. For example, you state that Epoladerm and OSF200 are being studied in early animal trials. You also state that Probudur has completed IND enabling studies and that early clinical data from animal studies indicate that Probudur can provide pain control for up to 96 hours. Similarly, you state on page 60 that the Molecular Envelope Technology (MET) nanoparticles are well tolerated, that NES100 demonstrated comparable preclinical activity to morphine and that there is pharmacological evidence of activity of MET enabled enkephalin in morphine-tolerant animals. Please revise your disclosure to remove your conclusions that your product candidates are safe or effective. Additionally, for each of these product candidates, please expand your disclosure to explain how the trials were conducted, the number of animal models used, the number of trials conducted and the objective results observed.

High-Density Molecular Masking Spray Formulation for the Prevention of Respiratory Viruses (MMS019), page 60

18. We note your disclosure that MMS019 has completed IND-enabling toxicology studies. Please expand your disclosure to describe how the studies were conducted and the objective results observed.

Intellectual Property, page 63

19. Please expand your disclosure to identify the specific product candidates to which the patents relate, the type of protection covered by each patent, the expiration date for each patent and the foreign countries where you have been issued patents.

LipoCureRx, Ltd., page 64

20. Please disclose the amount of the upfront fee that was required upon signing. Please also disclose the royalty term.

Material Agreements

MedPharm Limited, page 64

21. We note your disclosure that under the MedPharm License Agreement, royalty payments must be paid to MedPharm in an amount equal to a single-digit percentage of net sales of all MedPharm Product sold by us during the royalty term in the territory. Please disclose the royalty term.

Nanomerics Ltd., page 64

22. Please disclose the royalty term under the Nanomerics License Agreement and the Nanomerics Collaboration Agreement.
23. We note that under the Nanomerics License Agreement you are required to make royalty payments equal to a low double digit percentage of annual net sales of royalty qualifying products. Please revise your description of the royalty rate to provide a range that does not exceed ten percent (e.g., 5% to 15%, single digit to mid-teens).

Yissum, page 65

24. Please revise to quantify the annual license maintenance fee. Please also disclose the royalty term.

Description of Indebtedness, page 93

25. We note your disclosure at the top of page 93 that the agreements and related documents summarized in this section have been filed as exhibits to the registration statement. However, such such agreements do not appear to be filed. Please file these agreements and update your exhibit index accordingly. Additionally, please expand your disclosure to

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Page 6

include the events of default under your Paycheck Protection Program loan.

Note 7. Stockholders' Equity, page F-11

26. We note that you issued shares of common stock during fiscal years 2018 and 2019 pursuant to subscription agreements. Please disclose the material terms of these subscription agreements and whether any of the agreements are with related parties.

You may contact Tracey Houser at 202-551-3736 or Terence O'Brien at 202-551-3355 if you have questions regarding comments on the financial statements and related matters. Please contact Deanna Virginio at 202-551-4530 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Steven Skolnick, Esq.