



DIVISION OF  
CORPORATION FINANCE

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

April 17, 2024

P. Kent Hawryluk  
President and Chief Executive Officer  
MBX Biosciences, Inc.  
11711 N. Meridian Street, Suite 300  
Carmel, Indiana 46032

**Re: MBX Biosciences, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted March 22, 2024**  
**CIK No. 0001776111**

Dear P. Kent Hawryluk:

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 S-1

Cover Page

1. Please disclose, if accurate, that the closing of this offering is contingent upon a Nasdaq listing, or otherwise advise. Please ensure the disclosure is consistent with your underwriting agreement.

Prospectus Summary

Overview, page 1

2. Please revise your Prospectus Summary to define or explain briefly scientific or technical terms. By way of example, we note the following terms:
  - Peak-to-trough
  - Prodrug
  - Receptor antagonist
  - Fatty acylation

- Hypercalcemic
  - Hypocalcemic
3. We note your disclosure regarding your pipeline of novel candidates with "defined regulatory pathways" and "large market opportunities." Please revise to reflect your statements (i) on page 17 that developing product candidates is an "uncertain process", (ii) on page 16 that you have not yet demonstrated an ability to obtain regulatory approvals and (iii) on page 30 that your estimates as to prevalence may not be accurate and that published literature includes estimates which are lower than your estimates.
  4. Please remove references throughout your prospectus to potential "best-in-class" and "first-in-class" when describing your product candidates as these descriptions imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing such approval. In addition, please remove claims that you are able to design and develop novel peptide therapeutics that have high or enhanced "potency" and you can improve efficacy and tolerability. Please also remove any similar disclosures regarding the current potency or efficacy of your product candidates as these statements appear to be premature given your current stage of development.
  5. We note your disclosure here and elsewhere stating that preclinical studies demonstrated that MBX 4291 showed a "similar efficacy profile" as tirzepatide. As safety and efficacy determinations are solely within the FDA's authority, please remove these references to efficacy. You may compare the performances of MBX 4291 and tirzepatide in preclinical studies without concluding as to efficacy. Please also clarify that MBX 4291's results in clinical trials may not reflect your findings in preclinical studies.
  6. Please revise your Prospectus Summary, where appropriate, to reflect your disclosure elsewhere in the prospectus that TransCon PTH was granted a marketing authorization in the EU in November 2023 and that you could potentially be precluded from gaining approval for MBX 2109 in the EU until 2035. Please also revise to reflect that an NDA for TransCon PTH is currently under review by the FDA.

Our Platform, page 2

7. We note that you characterize your PEP platform as "leading" and "world-class." Please revise to provide the basis for these statements.
8. We note your disclosure here, and elsewhere, regarding your co-founder Dr. DiMarchi's global recognition. Please revise to clarify, if true, Dr. DiMarchi is not a director or employee of your company. Please also disclose the number of hours per week, if any, that Dr. DiMarchi is required to devote to your company. With reference to your disclosure on page 22, please also revise to state whether you have any independent discovery capabilities or whether you are reliant on Dr. DiMarchi's discovery capabilities.

MBX 2109: Potential best-in-class treatment for chronic hypoparathyroidism, page 3

9. We note your disclosure on page 4 that the FDA has granted Orphan Drug Designation to MBX 2109 for the treatment of HP. Please briefly describe the significance of having obtained orphan drug designation. In addition, please revise your reference to orphan drug designation to clarify that such a designation neither shortens the development time or regulatory review time of a product candidate, nor does it provide any guarantee of approval in the regulatory review or approval process.

Our Pipeline, page 3

10. We note your inclusion of a row in your pipeline table for "Additional Obesity Programs." However, none of these programs appear to be discussed in your prospectus. Accordingly, please remove this row from your pipeline table.

Our company and team, page 6

11. We note your disclosure regarding raising funding from "leading" healthcare investors. Please clarify that prospective investors should not rely on the named investors' investment decisions, that these investors may have different risk tolerances and, if true, that the shares purchased by these investors were acquired at a discount to the IPO price.

Our Strategy, page 7

12. We note your disclosure here, and elsewhere, regarding your strategy to "rapidly advance" MBX 2109 and MBX 1416 through clinical development. Please revise these statements and any other similar statements to remove any implication that you will be successful in advancing your product candidates in a rapid or accelerated manner, as such statements are speculative. In this regard, we note your disclosure on page 17 that developing product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete.

Critical Accounting Policies and Significant Judgments and Estimates

Determination of the Fair Value of Common Stock, page 114

13. Please revise disclosures to explain the specific event(s) or factor(s) that resulted in an increase in the initial valuation of the common stock fair value from \$0.27 per share to \$0.34 per share.
14. 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 IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. Please discuss with the staff how to submit your response.

Business

Ongoing Avail Phase 2 clinical trial, page 134

15. Please revise this section to reflect your disclosure on pages 29-30 indicating that you have added new sites to this trial following slow enrollment at the originally selected sites and that you were unable to enroll sites in the EU.

Our solution: MBX 4291

Preclinical studies, page 141

16. Please define CPS in the graphic on page 141.
17. Please revise to clarify the number of mice dosed with the MBX 4291 active drug and tirzepatide, as well as the number of non-human primates used to assess the conversion of MBX 4191. We also note your claims here and throughout the prospectus indicating that MBX 4291 demonstrated extended duration as compared to tirzepatide in a preclinical study that may support once-monthly dosing. However, the preclinical study on page 142 appears to indicate that observation of the concentration of tirzepatide ceased after one week. In addition, it appears that you are relying on the results of MBX 4291 active drug to support your claim that the decline in exposure is flatter than the more rapid reduction in tirzepatide exposure. However, your disclosure elsewhere in the prospectus indicates that you are developing MBX 4291 as a prodrug and the prodrug decline in exposure appears to track tirzepatide's. Please advise and revise your disclosure accordingly. To the extent observation of tirzepatide ceased after one week, please remove or revise your claims that MBX 4291 has demonstrated an extended duration as compared to tirzepatide.

License agreement

Indiana University Research and Technology Corporation Exclusive License Agreement, page 145

18. Please revise to provide the percentage of the sublicensing revenue, or a range not exceeding 10 percentage points.

Exhibits

19. Please revise to either (i) clearly disclose that Exhibit 10.6 also contains amendments to the original agreement or (ii) separately number the amendments to the license agreement.
20. When available, please file the Senior Executive Cash Incentive Bonus Plan as an exhibit to your registration statement.

General

21. Please ensure the writing is legible in the visual depictions throughout your draft registration statement. For example only, certain text on the y-axis on pages 127 and 133 is not legible.

P. Kent Hawryluk  
MBX Biosciences, Inc.  
April 17, 2024  
Page 5

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.

Please contact Christine Torney at 202-551-3652 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at 202-551-7349 or Alan Campbell at 202-551-4224 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Edwin O'Connor