

April 26, 2024

**VIA EDGAR AND FEDERAL EXPRESS**

United States Securities and Exchange Commission  
Division of Corporation Finance  
Office of Life Sciences  
100 F. Street, N.E.  
Washington, D.C. 20549  
Attention: Christine Torney, Angela Connell, Jimmy McNamara, Alan Campbell

**Re: MBX Biosciences, Inc.  
Draft Registration Statement on Form S-1  
Submitted March 22, 2024  
CIK 0001776111**

Dear Ladies and Gentlemen:

This letter is confidentially submitted on behalf of MBX Biosciences, Inc. (the “**Company**”), in response to the comments of the staff of the Division of Corporation Finance (the “**Staff**”) of the U.S. Securities and Exchange Commission (the “**Commission**”) with respect to the Company’s Draft Registration Statement on Form S-1, originally confidentially submitted on March 22, 2024 (the “**Draft Registration Statement**”), as set forth in the Staff’s letter, dated April 17, 2024, addressed to P. Kent Hawryluk (the “**Comment Letter**”). The Company is concurrently confidentially submitting Amendment No. 1 to the Draft Registration Statement (“**Amendment No. 1**”), which includes changes to reflect responses to the Staff’s comments and other updates.

For reference purposes, the text of the Comment Letter has been reproduced herein with responses below each numbered comment. For your convenience, we have italicized the reproduced Staff comments from the Comment Letter. Unless otherwise indicated, page references in the descriptions of the Staff’s comments refer to the Draft Registration Statement, and page references in the responses refer to Amendment No. 1. All capitalized terms used and not otherwise defined herein shall have the meanings set forth in Amendment No. 1.

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.*

**RESPONSE:** The Company acknowledges the Staff’s comment and respectfully advises the Staff that it has revised the disclosure on the cover page, pages 13, 201 and 212 of Amendment No. 1 in response to the Staff’s comment.

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*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 1, 4, 5, 120, 123 and 124 of Amendment No. 1 to define or briefly explain scientific or technical terms in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 1, 3, 104, 120, 122, 126, 128 and 130 of Amendment No. 1 as it relates to the phrases "defined regulatory pathways" and "large market opportunities" in response to the Staff's comment by revising the disclosure to "established endpoints for regulatory approval" so as to not suggest that the Company itself has defined regulatory pathways and revising the disclosure to reflect that the market opportunities are "potential." The Company also respectfully advises the staff that it has revised the disclosure on page 8 in the prospectus summary to incorporate explicit risks to balance the presentation of the Company's business and further disclose the risks it faces, including regulatory challenges and prevalence estimates in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment relating to references to "best-in-class" and "first-in-class" and respectfully advises the Staff that it has revised the disclosure on pages 1-7, 94, 120-126, 128, 130, 136 and 140 of Amendment No. 1 to remove references to "best-in-class," and "first-in-class" in response to the Staff's comment. Additionally, the Company acknowledges the Staff's comment relating to claims regarding its platform and respectfully advises the Staff that it has revised the disclosure on pages 2, 3, 5, 120, 121, 124, 128 and 140 of Amendment No. 1 to clarify its intent is to design and develop novel peptide therapeutics with the goal of achieving certain attributes, including potency and tolerability, which may lead to greater potential efficacy. Finally, the Company acknowledges the Staff's comment relating to similar disclosures relating to the potency or efficacy of its product candidates and respectfully advises the Staff that it has revised the disclosure on pages 2, 121, 128, 140 and 145 of Amendment No. 1 to clarify its intent as it relates to efficacy and potency of the Company's product candidates. The Company respectfully advises the Staff that it believes the remaining references to efficacy or potency are appropriate as they speak to the Company's goals to develop efficacious and potent product candidates.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 2, 6, 120, 124, 126, 140 and 142 of Amendment No. 1 to remove references to efficacy that would fall within the authority of the U.S. Food and Drug Administration and instead provide a comparison of preclinical activity and a direct comparison of outcome in response to the Staff's comment. The Company also respectfully advises the Staff that it has clarified disclosure on page 8 to clarify that MBX 4291's results in clinical trials may not reflect the Company's findings in preclinical studies in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on page 9 of Amendment No. 1 to include a reference to the TransCon PTH marketing authorization included elsewhere in the document and pages 9 and 145 of Amendment No. 1 to include disclosure on the NDA for TransCon PTH in response to the Staff's comment.

#### 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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 2, 7, 121, 126 and 128 of Amendment No. 1 in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 7, 23 and 125 of Amendment No. 1 to clarify Dr. DiMarchi's current relationship with the Company and revised the disclosure on pages 2, 3, 23, 121 and 128 of Amendment No. 1 to provide more detail on the Company's independent discovery capabilities in response to the Staff's comment.

#### 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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the staff that it has revised the disclosure on pages 4 and 123 of Amendment No. 1 in response to the Staff's comment to briefly describe the significance of Orphan Drug Designation. The Company also respectfully advises the Staff that it has revised disclosure on page 9 to clarify that Orphan Drug Designation does not shorten the development time or regulatory review time of a product candidate and does not 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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 3 and 122 of Amendment No. 1 in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 7 and 125 of Amendment No. 1 in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 7, 34, 126, 129 and 130 of Amendment No. 1 in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on page 117 of Amendment No. 1 to provide more detail on the increase in the initial valuation. In connection with financial reporting for the period ended December 31, 2022, the Company applied the appropriate bifurcation of upside and downside scenarios according to the American Institute of Certified Public Accountants Accounting and Valuation Guide: Valuation of Privately Held Company Equity Securities Issued as Compensation (the Practice Aid). This resulted in a slightly higher fair valuation of common stock than the initial valuation performed for tax purposes.

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.*

**RESPONSE:** The Company respectfully acknowledges the Staff's comment and will supplementally provide the requested information once the estimated offering price or range has been determined.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure in response to the Staff's comment on page 30 to properly refer to the Company's Phase 1 trial of MBX 2109 and remove the erroneous reference to the Company's Phase 2 trial of MBX 2109 and on page 31 to remove the reference to enrollment issues in the European Union as this was erroneously characterized as an inability to enroll patients in the European Union when in fact the Company made a strategic choice to not enroll sites in the European Union.

Our solution: MBX 4291  
Preclinical studies, page 141

16. *Please define CPS in the graphic on page 141.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the graphic on page 142 of Amendment No. 1 in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 2, 6, 120, 124, 126, 140 and 143 of Amendment No. 1 to clarify the number of mice and non-human primates dosed and used to assess the conversion of MBX 4291 and to explain claims regarding the MBX 4291 active drug versus prodrug and the potential dosing schedule of MBX 4291, as compared to tirzepatide, in response to the Staff's comment.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the disclosure on pages 106 and 147 of Amendment No. 1 in response to the Staff's comment.

#### 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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has revised the title of Exhibit 10.6 in response to the Staff's comment.

20. *When available, please file the Senior Executive Cash Incentive Bonus Plan as an exhibit to your registration statement.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that the Senior Executive Cash Incentive Bonus Plan will be included as an exhibit once available.

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.*

**RESPONSE:** The Company acknowledges the Staff's comment and respectfully advises the Staff that it has replaced illegible visual depictions on pages 3, 122, 128, 130 and 134-136 of Amendment No. 1 in response to the Staff's comment.

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.*

**RESPONSE:** The Company respectfully advises the Staff that it will provide the Staff, on a confidential basis under separate cover, copies of all written communications presented to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of such communications.

If you should have any questions concerning the enclosed matters, please contact the undersigned at (212) 813-8853.

Sincerely,

/s/ Edwin M. O'Connor

Edwin M. O'Connor, Esq.

Enclosures

cc:

P. Kent Hawryluk, *MBX Biosciences, Inc.*

Richard Bartram, *MBX Biosciences, Inc.*

Mitchell S. Bloom, Esq., *Goodwin Procter LLP*

Daniel Hughes, Esq., *Goodwin Procter LLP*