



DIVISION OF
CORPORATION FINANCE

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

February 26, 2024

Erik Emerson
Chief Executive Officer
Apimeds Pharmaceuticals US, Inc.
2 East Broad Street 2nd Floor
Hopewell, NJ 08425

**Re: Apimeds Pharmaceuticals US, Inc.
Draft Registration Statement on Form S-1
Submitted January 29, 2024
CIK No. 0001894525**

Dear Erik Emerson:

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

Prospectus Summary

Overview, page 1

1. The disclosure in the Summary should be a balanced presentation of your business. Please revise this section to balance the description of the company's product candidate and related market with equally prominent disclosure of the company's lack of revenue, history of net losses and accumulated deficit, and the regulatory and competitive challenges applicable to the company's business and operations.
2. Please revise your disclosure both here and throughout the prospectus to clarify, if true, that all previously completed clinical trials referenced and discussed in the prospectus were conducted by Apimeds Korea, which is an entity separate and apart from the company, and that Apimeds Korea transferred sponsorship of IND 122804 to the company in October 2020. Please also clarify that the company has not yet initiated its planned

Phase III trials based on IND 122804. We note your disclosure on page 66 in this regard. Please also clarify how the agreements in place between the company and Apimeds Korea provide the company with the right to use the clinical data previously collected by Apimeds Korea in support of the company's ongoing clinical efforts.

3. Please revise to remove the statement on page 1 and elsewhere in your Prospectus that you are “in the process of commercializing Apitox” as you have yet to obtain FDA approval for Apitox and it appears your current commercialization efforts are limited to preliminary discussions with third-parties.
4. Please revise page 1 where you state Apimeds Korea “completed a Phase III trial with Apitoxin for the treatment of pain associated with osteoarthritis ('OA') in 2018” to disclose whether the trial met its primary and secondary endpoints and why you are pursuing additional Phase III clinical trials as opposed to filing a BLA with the FDA. Please also revise to consistently state the indication for clinical trials throughout your Prospectus. For example only, we note on page 1 you disclose Apimeds Korea’s Phase III clinical trial was “for the treatment of pain associated with osteoarthritis” and also “to treat OA in the knee.”
5. Please revise page 1 to identify “the most appropriate population” for which you will advance your Phase III trials in OA. To this point, we note your disclosure on page 63 that the purpose of your Phase III trials in OA “will be to evaluate the effectiveness of Apitox in the treatment of grade 3 and 4 OA of the knee.”

Our Lead Candidate, page 1

6. Please revise page 1 where you state “[b]ee venom has traditionally been used to treat painful inflammatory diseases” to state whether the FDA has approved the use of bee venom in any indication and to provide additional support for this statement.
7. We note the following statement on page 2: "Apitoxin was approved by the South Korean regulatory authorities for use in the reduction of pain associated with OA in 2003." Please revise your disclosure to clarify that the company does not market and sell Apitoxin in South Korea and that Apitoxin has not been approved in the US by the FDA for use in the reduction of pain associated with OA to date, if true.

Our Market, page 2

8. Please revise page 2 to disclose the “other future indicia” you will pursue in the second quarter of 2024 or remove the reference.

Our Strategy, page 3

9. Please revise to remove your statement on page 3 that you will determine the best path to “rapid clinical Phase III success” as the pace of clinical development and successful achievement of designated endpoints is not entirely within the company's control.
10. Please remove the reference to a “previously successful” Phase III trial, as it appears from your disclosure elsewhere that additional trials are required.

Controlled Company, page 4

11. We note your disclosure that the company has applied to list on the NYSE American. Please reconcile this with your reference to the “controlled company” exemption under the Nasdaq listing rules on page 4.

Risk Factors Summary, page 4

12. We note the two summarized risk factors on page 5 relating to obtaining and maintaining patent protection for the company's technology and products. However, your disclosure elsewhere states that the API relied on for your product candidate is a natural, non-synthetic compound that is not patentable. Please reconcile or remove these two bullet points from page 5.

Risk Factors, page 9

13. Please revise this section to include a risk factor regarding the fact that the company's chief executive officer, Erik Emerson, also serves as the company's principal financial officer. Please also discuss Mr. Emerson's qualifications to serve as PFO and whether the company's internal controls have been designed with this in mind.

There may be conflicts of interest amongst our directors and officers and Apimeds Korea., page 11

14. Please revise this risk factor to clarify which officers and directors hold positions with both the company and Apimeds Korea.

We or the third parties upon whom we depend on may be adversely affected by natural disasters..., page 23

15. We note your mention of the potential impact of the wars in Ukraine and Israel in the risk factor on page 23. Please revise this risk factor to concisely explain how this risk affects the company or the securities being offered, pursuant to Item 105 of Regulation S-K.

We are controlled by our principal stockholders and management..., page 38

16. We note your statement on page 38 that Inscobee, including through its wholly-owned subsidiary, Apimeds Korea, beneficially owns 91.35% of the company's common stock. Please reconcile this statement with your disclosure on the cover page and pages 4 and 100 that Inscobee holds approximately 86.1% of the company's common stock.

Use of Proceeds, page 47

17. We note your statement on page 47 that it is difficult to estimate with certainty the exact amount of the net proceeds from the offering that may be used for each purpose mentioned in the third paragraph of this section. However, per Item 504 of Regulation S-K, this section should quantify the approximate amount intended to be used for each listed purpose. In addition, if any material amounts of other funds are necessary to accomplish the specified purposes of which the proceeds are to be obtained, disclosure of the amounts of such other funds needed for each such specified purpose and the sources thereof should be included. Please revise your disclosure accordingly.

Capitalization, page 49

18. Please double underline the cash amount to highlight that cash is not included in total capitalization.
19. We note that your pro forma capitalization table gives effect to the conversion of an aggregate of \$660,000 principal amount of convertible notes. Please revise to clearly disclose the event(s) that trigger conversion of your convertible notes and explain why you believe the current IPO transaction would result in conversion.

Business

Our Product Candidate, page 64

20. Please revise page 64 to disclose and discuss the data supporting your statements that “Apitox has both anti-inflammatory and analgesic effects as well as hormone-stimulating and immune-modulating effects” and that “the components in Apitox may ameliorate immune-inflammatory responses associated with MS.”

Clinical Development History, page 64

21. Please revise your description of the clinical development of Apitoxin to disclose details regarding the trial designs, including the following information:
- the primary and secondary endpoints of each trial;
 - whether the designated endpoints were met;
 - whether the trials were powered for statistical significance and if so, whether the results were statistically significant;
 - the resulting data from each trial.

Additionally, provide the same disclosure for the “formal Phase I and Phase II publications specific to MS” Apimeds Korea relied on in submitting its 2014 IND, as discussed on page 65.

Apitox Preliminary Phase III Trials On MS, page 65

22. Please revise to disclose the new primary efficacy endpoint you will implement for your Phase III clinical trial in MS in response to the FDA recommendations, as disclosed on page 66.

Competition, page 69

23. Please revise page 69 to remove the statement that Apitox is a "highly safe and effective option to patients experiencing debilitating pain." You may state that Apitox was determined to be safe and effective for the indications approved by The Korean Ministry of Food and Drug Safety in South Korea, if true, but should make clear that the FDA has not determined Apitox to be safe or effective in the US.

Executive Compensation

Director Compensation Table, page 95

24. We note your statement that none of your directors received any form of compensation for the years ended December 31, 2022 and 2021. Please revise this disclosure to also address the company's last completed fiscal year. Refer to item 402(r) of Regulation S-K.

Financial Statements

Unaudited Condensed Balance Sheets, page F-2

25. We note the significant increase in your prepaid expenses at September 30, 2023. Please address the following:
- Disclose the significant terms of the underlying agreements that comprise your prepaid expenses.
 - Separately disclose any significant elements of your prepaid expenses balance.

License Agreement, page F-21

26. Please revise to disclose all significant terms of the License Agreement with Apimeds Korea, including the estimated term of the agreement and any potential future payments required under the agreement.

Exhibits

27. Please ensure each exhibit is in the proper text-searchable format. See Item 301 of Regulation S-T.

Erik Emerson
Apimeds Pharmaceuticals US, Inc.
February 26, 2024
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28. Please file the Consulting Agreement with Murdock Capital Partners Corp. as an exhibit to the registration statement. See Item 601(b)(10) of Regulation S-K.

General

29. 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 Eric Atallah at 202-551-3663 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: David Mannheim