



DIVISION OF  
CORPORATION FINANCE

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

June 11, 2020

Howard J. Weisman  
Chief Executive Officer  
PaxMedica, Inc.  
50 Tice Boulevard, Suite A26  
Woodcliff Lake, NJ 07677

**Re: PaxMedica, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted May 15, 2020**  
**CIK No. 0001811623**

Dear Mr. Weisman:

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

Prospectus Summary

Our Development Strategy, page 1

1. We note statements here and elsewhere in the prospectus that you believe an approval of PAX-101 in HAT could confer upon you the potential receipt of a priority review voucher (PRV) by the FDA and that you will leverage such approval to facilitate an accelerated development program for the approval in ASD, FXTAS and other indications using the FDA's 505(b)(2) regulatory pathway. Given that you have not yet secured marketing approval for PAX-101, it is inappropriate to state or imply that your clinical development plans will be successful. Please revise to make it clear here and throughout the prospectus that you (i) may be unable to secure a PRV; and (ii) may be required to complete

additional clinical trials for PAX-101 for the treatment of ASD and FXTAS. Please also revise to remove any implication that you will be able to develop your product candidates in a rapid or accelerated manner as such statements are speculative.

2. Please reconcile your disclosure that you believe you will receive approval of PAX-101 for the treatment of HAT without conducting prospective clinical trials with your disclosure on page 2 that you intend to complete additional preclinical and clinical work to support a new drug application (NDA) for the treatment of early stage East African sleeping sickness.
3. We note your disclosure on page 27 regarding PCT international patent application PCT/US2018/017674. We note also your discussion of the clinical trial conducted of suramin for the management of ASD at the University of California, San Diego. We note also that UCSD intends to conduct a Phase II clinical trial assessing suramin as a treatment for autism in the spring of 2021. Please provide disclosure in the Risk Factors and Summary Risk Factors sections highlighting the risks related to competition in commercialization of your product candidate and the effect potential competing patent claims may have on your patent portfolio and your business.

Market for HAT, page 2

4. Please remove the statement regarding the sale prices of recent PRVs as it is not appropriate disclosure for the Prospectus Summary where full and proper context is not provided. We will not object to disclosure in the Business section.

PAX-102, page 3

5. We note your disclosure that you have developed proprietary intranasal formulations and methods of delivering suramin to mammals that have been shown, in in vivo preclinical studies, to safely and effectively deliver suramin to the brain while dramatically reducing systemic exposure. Efficacy and safety are determinations that are solely within the authority of the FDA or similar foreign regulators. You may present clinical trial end points and objective data resulting from trials without concluding efficacy, and you may state that your product candidates are well tolerated if true. Please revise your disclosure to remove statements that present your conclusion with respect to the safety or efficacy of your product candidates.

Our Status as an Emerging Growth Company, page 5

6. 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.

Use of Proceeds, page 40

7. We note your disclosure that you intend to use the proceeds of the offering for product development activities, including clinical and regulatory research and development for your product candidates. Please specifically disclose how far you expect the proceeds from the offering to allow you to proceed in the development of each of your product candidates.

Management's Discussion and Analysis of Financial Condition and Results of Operations, page 45

8. 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, such as the stock options granted in May 2020, and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price.

Results of Operations, page 46

9. Please disclose the costs incurred during each period presented for each of your key research and development projects. If you do not track your research and development costs by project, please disclose that fact and explain why you do not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that provides more transparency as to the type of research and development expenses incurred (i.e. by nature or type of expense) which should reconcile to total research and development expense on the Statements of Operations.

In addition, revise your disclosure to quantify the reasons for the change in general and administrative expenses.

Business

Current Clinical Development Plan, page 53

10. We note your disclosure on pages 2 and 58 that you intend to complete additional preclinical and clinical work for PAX-101 for the treatment of HAT over the next 18 months with the intention of filing an NDA in the second half of 2021 yet your pipeline table indicates that PAX-101 for the treatment of HAT is at the end of Phase 3. Please revise the table accordingly. We also note that you have not included any disclosure regarding the most recent clinical trials that have been completed or that are ongoing for PAX-101 for the treatment of HAT. Please expand your disclosure to discuss specific trial results for your product candidate on which you intend to rely, including the duration of the trial, the number of subjects or patients in such trials, how the product candidate was administered, who conducted the trials, the dosage used, any serious adverse events experienced and the number of patients who experienced them, the primary and secondary endpoints and whether they were met. Also, please be sure to identify the year or years

when referenced trials were conducted or commenced.

11. We note that your pipeline table indicates that you have three programs in the preclinical phase but there is brief discussion of models or results. We also note your disclosure on page 59 that your selective anti-purinergic therapy program is in the discovery phase. Please revise your table to reflect this stage of development and provide us with your analysis as to why these programs are material to your business and appropriate for inclusion in the pipeline table.

Market for HAT, page 55

12. Please revise to disclose how much funding you would need to support the later stage development and commercialization of PAX-101 and PAX-102 in the treatment of ASD and FXTAS and whether a potential sale of a priority review voucher would be able to fully fund the development of both product candidates. Please revise to disclose how you intend to raise those funds if you are unable to receive a priority review voucher from the FDA and sell it.

Clinical Trial of Suramin for Management of ASD, page 56

13. Please revise the statement on page 66 that suramin was found to have profound positive impact on core symptoms of ASD to remove any conclusion regarding efficacy.

Intellectual Property, page 61

14. Please disclose the specific products, product groups and technologies to which your patent applications relate, the type of patent protection you are seeking, the applicable jurisdictions and whether there are any contested proceedings or third-party claims.

The Priority Review Voucher Program, page 66

15. Please revise your disclosure to clarify that priority review does not provide a guarantee the FDA will review an application within six months.

License Agreements, page 68

16. Please disclose the maximum aggregate future payments that you may be required to make to each of the licensors based on the level of each licensor's participation.

Howard J. Weisman  
PaxMedica, Inc.  
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You may contact Ameen Hamady at 202-551-3891 or Sasha Parikh at 202-551-3627 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmiento at 202-551-3798 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Steven M. Skolnick, Esq.