



DIVISION OF
CORPORATION FINANCE

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

August 18, 2020

Marcio Souza
Chief Executive Officer
Praxis Precision Medicines, Inc.
One Broadway, 16th Floor
Cambridge, MA 02142

Re: Praxis Precision Medicines, Inc.
Draft Registration Statement on Form S-1
Submitted July 22, 2020
CIK No. 0001689548

Dear Mr. Souza:

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 on Form S-1

Prospectus Summary

Company Overview, page 1

1. We note your statements indicating that your therapeutics are potentially "best-in-class" or "first-in-class." These terms suggest that your product candidates are effective, likely to be approved and favorable, as compared to competitive products and product candidates. Given the status of development, it is premature for you to make such statements or implications at this time. Accordingly, please delete all references in your registration statement to your product candidates being potentially "best-in-class" or "first-in-class." If your use of these terms was intended to convey your belief that the products are 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 candidates have been proven effective or that they will receive regulatory approval.

2. Please revise your statement that you own global commercialization rights for all of your product candidates with reference to your financial obligations under your license and collaboration agreements as discussed on pages 154-156.
3. We note your disclosure that you intend to initiate the first of two registrational trials, Phase 2/3, in the United States and Australia. Your characterization of two trials as registrational is not appropriate given that you must complete multiple trials prior to submitting the related New Drug Application (NDA). Please revise your disclosure to remove this characterization here and throughout your prospectus.

PRAX-114, page 2

4. We note your disclosure that you have an ongoing three-part Phase 2a clinical trial ongoing in Australia, with Part A having demonstrated rapid and marked improvements in depression scores in MDD patients. As efficacy determinations are solely within the authority of the U.S. Food and Drug Administration (FDA) and comparable regulatory bodies, it is inappropriate to state or imply that your product candidates are effective. Please revise this statement and similar statements here and throughout your prospectus, including, but not limited to, in your Business section. We will not object to a discussion of objective data resulting from your trials without including conclusions related to efficacy. As a non-exhaustive list of illustrative examples only, we note the following disclosures:
 - To date, PRAX-562 has demonstrated efficacy in in vivo models...
 - Based on clinical data showing a rapid, pronounced and durable antidepressant effect in MDD patients...
 - We plan to initiate a Phase 2 trial for Short-lasting Unilateral Neuralgiform headache with Conjunctival injection and Tearing, or SUNCT, and Short-lasting Unilateral Neuralgiform headache attacks with Autonomic symptoms, or SUNA, to demonstrate rapid clinical proof-of-concept and then subsequently expand into severe pediatric epilepsies.
 - Because the doses at which EEG changes observed in rats are similar to those that demonstrated efficacy in a preclinical model of essential tumor....
 - We have evaluated the safety and tolerability of PRAX-944 in over 100 healthy volunteers in four separate clinical trials and demonstrated pharmacodynamic effects in humans using EEG.

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Page 3

Our Strategy, page 4

5. We note that you state your strategy is to "efficiently advance" your product candidates towards regulatory approval and commercialization. Please revise your disclosure to remove any implication that you may be able to accelerate the FDA review process.

Risks Associated with Our Business, page 5

6. Please expand your disclosure in the fourth bulletpoint to highlight the risk that your clinical trials to date have been conducted outside the U.S. and that if the FDA or comparable regulators do not accept earlier preclinical and clinical data you may need to conduct additional clinical trials, as referenced on pages 16 and 24. Please also add a bullet point highlighting the risks related to concentration of ownership of your common stock, as referenced on page 73.

Use of Proceeds, page 82

7. It appears from your disclosure that the proceeds from the offering will not be sufficient to fund development of your product candidates through regulatory approval and commercialization. Please disclose the sources of other funds needed to reach regulatory approval and commercialization for each product candidate. Refer to Instruction 3 to Item 504 of Regulation S-K.

Business

Our Approach, page 116

8. Please expand your disclosure to explain briefly what you mean by "validated" target-specific EEG endpoints. Additionally, please define "CHO cells" used on page 122.

Broad Psychiatry and Neurology Programs

PRAX-114

Phase 2a trial in patients with depression

Part A results, page 127

9. We note your comparison of the results of PRAX-114 observed in your Phase 2a Part A trial to published reports on changes in HAM-D scale in clinical trials of approved antidepressants. As these comparisons are not based on head-to-head studies, please tell us why you believe it is appropriate to include them. Address in your response whether you expect to be able to rely on such comparisons to support an application for marketing approval.

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License Agreement with RogCon, page 154

10. We note your disclosure that the \$3.0 million milestone payment will become due to RogCon when the first profit share payment has become due and certain certain contingent payments become due to Ionis. Please expand your disclosure to specify the triggers for these payments.

Ionis Collaboration Agreement, page 155

11. Please expand your disclosure to include the financial terms related to the option exercise provisions, including the royalty rate or range not to exceed ten percentage points.

License Agreement with Purdue, page 155

12. Please expand your disclosure to include the period of time relevant to the royalty term.

General

13. 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.

You may contact Gary Newberry at 202-551-3761 or Kate Tillan at 202-551-3604 if you have questions regarding comments on the financial statements and related matters. Please contact Courtney Lindsay at 202-551-7237 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: William D. Collins, Esq.