



DIVISION OF
CORPORATION FINANCE

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

May 10, 2021

Tiago Reis Marques
Chief Executive Officer
Pasishea Therapeutics Corp.
1111 Lincoln Road
Suite 500
Miami Beach, FL 33139

Re: Pasishea Therapeutics Corp.
Registration Statement on Form S-1
Filed April 13, 2021
File No. 333-255205

Dear Dr. Marques:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form S-1

Cover Page

1. Your disclosure on pages 10 and 101 indicates that you have agreed to issue warrants to Kingswood Capital Markets ("Kingswood") as part of the underwriter compensation for the offering. Please revise the cover page to disclose your agreement to issue the warrants to Kingswood, including the number of warrants to be issued and the exercise price. Your disclosure further indicates that this registration statement is intended to cover the warrants to be issued to Kingswood. Please revise the registration statement fee table to reflect the warrants and file a form of the warrant to be issued to Kingswood as an exhibit.

Prospectus Summary
Business Overview, page 1

2. We note that you have not discussed any activities related to drug development, e.g. activities related to drug discovery or identifying compounds to develop or acquire. Please revise your prospectus throughout to make clear the current status of your operations including your heading entitled “Development Pipeline.” Remove the reference to your company as a “clinical stage biotechnology company” on page 11 and explain the reference on page 65 to your "ketamine drug candidate" and on page 70 to “COMP360.” Please also briefly explain what you mean by “cross talk” between the immune system and brain disorders. Additionally, revise your statement that you have not commenced “core” operations to make it clear that you have not yet entered into any agreements with independent professional services companies, as referenced on page 29.
3. Please revise here and in the Business section to provide the basis for your claim that current therapies for Major Depressive Disorder (MDD) and bipolar depression (BDep) have a distinct lag of onset that can generate further distress and impairment in patients.
4. With respect to your plans to establish anti-depression clinics across the UK and provide business support services and administer intravenous infusions of ketamine using psychiatric assessment combined with physician medical providers, revise your disclosure throughout to make clear which services you plan to provide, your plans for doing so and which services are to be performed by third parties. Be sure to clearly explain how you plan to earn revenue and describe the material terms of your “partnership” arrangements. As an example only, your disclosure here and throughout refers to your partnership with The IV Doc to provide private intravenous infusions of ketamine. However, the terms of your agreement with The IV Doc state that The IV Doc intends to only provide non-professional administrative, back office and business support services and that The IV Doc will not assume responsibility for the care of patients. Please revise the disclosure in your registration statement, including in the second paragraphs of the Prospectus Summary and the Business section and the first paragraph on page 4, to clarify that The IV Doc will be providing administrative services as a subcontractor, rather than clinical care.
5. Please revise your disclosure here and in the Business section to discuss the study or trial in which a single subanesthetic dose infusion of ketamine was shown to have potential antidepressant effects in treatment-resistant MDD and PTSD.
6. We note your statement that ketamine's potential safety and effectiveness have been demonstrated in multiple research studies. Safety and efficacy are determinations are solely within the authority of the U.S. Food and Drug Administration (FDA) or similar foreign regulators. Please revise your disclosure to remove any implication that IV ketamine has been determined to be safe or effective for the treatment of MDD or BDep.

We further note your claim that as many as 70% of those who receive ketamine infusions show a response, typically after the first session. Please revise to describe the studies that provide the basis for this claim, including who performed the studies, when they were conducted, the indications that were treated, the length of the studies and the number of participants, dosages used and what is meant by the phrase "show a response." Disclose also all serious adverse events and the number of patients who experienced them.

Clinical Services, page 3

7. Please revise this section to clearly describe the regulatory landscape applicable to your business model in this area in the UK and the United States including applicable government regulations and laws concerning the corporate practice of medicine and fee-splitting, along with any associated risks and liabilities that you may become subject to by entering into management agreements with independent professional services companies. Additionally, indicate in each diagram on pages 3 and 5 which party will perform the relevant services so that your role is clear. Identify what entities will be responsible for obtaining, administering and storing ketamine, including the ownership and maintenance of applicable controlled substances licenses and compliance with DEA requirements. Please also revise to clarify how you anticipate recruiting individual clinicians and independent professional services companies in the United States to enter into agreements with you and disclose the challenges you may face in doing so. Discuss also the significance of establishing insurance reimbursement for ketamine treatments, which party will be responsible for establishing reimbursement and any challenges in doing so. Revise your discussion on page 62 in your Business section to explain why the formation process to establish an independent professional services company in New York and California is material to an understanding of your business. Additionally, revise your Business section to disclose the material terms of your planned management agreements with independent professional services companies.
8. Please revise your disclosure in this section and in the Business section to indicate whether you have commenced the process to obtain applicable regulatory approvals in the UK and in the United States. Please also revise to discuss FDA regulation of off-label promotion and the impact such regulation may have on your business. Additionally, please balance your disclosure with reference to competition you face from approved products, as referenced on page 65.

Our Team, page 5

9. Please provide us with the basis for your claim that you are led by a "best-in-class" management team. Alternatively, please remove this disclosure.

Your disclosure also indicates that Professor Steinman currently serves as a professor at Stanford University and that Dr. Marques is a senior clinical fellow at Imperial College London and a lecturer at King's College London. Please disclose if each of Professor Steinman and Dr. Marques will work full-time or part-time for the company and, if less

than full-time, disclose the number of hours per week or month that you plan for each of Professor Steinman and Dr. Marques to work for the company. To the extent that either Professor Steinman or Dr. Marques will be working part-time for the Company, please add related disclosure under an appropriate heading in the Risk Factors section highlighting the risks related to their limited time devoted to your business.

Summary of Risk Factors, page 7

10. Your risk factor summary currently exceeds two pages. Please revise your risk factor summary to be no more than two pages and to discuss the principal factors that make an investment in you or in the offering speculative or risky, rather than listing each heading that appears in the Risk Factors section. For guidance, please refer to Item 105(b) of Regulation S-K.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company, page 9

11. 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.

Risk Factors, page 12

12. Revise and organize the risk factors section to disclose the material risks related to your current status and planned operations with the most significant risks clearly identified. As examples only, we note your disclosure in the first risk factor on page 12 stating that you have devoted substantially all of your resources to building and equipping your research and development laboratories, building and equipping your manufacturing suites, acquiring raw materials for manufacturing and securing related intellectual property rights. However, it appears from your disclosure elsewhere that you have not performed these activities and do not own any intellectual property. Additionally, you state in the risk factor on page 16 that you face increased labor costs due to nationwide nursing shortages. Please explain how these conditions will materially impact your business. Include under an appropriate heading a discussion of risks associated with ketamine use and its status as a Schedule III controlled substance under the Controlled Substances Act. Additionally, relocate risks that could generically apply to any registrant or offering to the end of the section under the caption "General Risk Factors." Refer to Item 105 of Regulation S-K.

Industry and Other Data, page 49

13. Your statements that (i) you have not independently verified third-party publications and studies and (ii) no independent source has verified your internal research and market definitions may imply an inappropriate disclaimer of responsibility with respect to the third party information and your own research. Please either delete these statements or specifically state that you are liable for such information.

Use of Proceeds, page 50

14. We note your disclosure that you intend to use portions of the proceeds of this offering to (i) fund research and development, including clinical trials and product development for your pipeline and (ii) develop your U.S. and UK clinic businesses. Please indicate how far the proceeds of the offering will allow you to proceed with respect to each specified purpose. If any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of other funds needed for each specified purpose and the sources. For guidance, please refer to Item 504 of Regulation S-K.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies, page 57

15. Please provide a description and quantification of the methods and assumptions used to determine the fair value of your common stock, as discussed in Note 5.

Business

License Agreements and Strategic Collaborations, page 65

16. Please revise your disclosure in this section to (i) discuss the termination provisions contained in the agreements with the Zen clinics and (ii) disclose the material terms of the IV Doc agreement, including the respective party's rights and obligations, term and termination provisions.

Executive and Director Compensation, page 82

17. Please revise this section to clearly identify your named executive officers ("NEOs") and to describe the material terms of any employment arrangements that you have with each of your NEOs. In this regard, we note that you have identified in the exhibit index an employment agreement with Dr. Marques.

Certain Relationships and Related Party Transactions

Brio Financial Group, page 86

18. Please file your agreement with Brio Financial Group as an exhibit to your registration statement or explain to us why it is not required to be filed. Refer to Item 601(b)(10) of Regulation S-K.

Item 15. Recent Sales of Unregistered Securities, page II-2

19. Your disclosure here indicates that you sold 395,625 shares of common stock for proceeds of approximately \$633,000 subsequent to December 31, 2020 (implying a price per share of approximately \$1.60) and then an additional 239,969 shares of common stock for proceeds of approximately \$1,200,000 (implying a price per share of approximately \$5.00). However, your disclosure here and on page F-12 indicates that you sold shares at a price of \$0.08 per share and \$0.12 per share. Your disclosure on page F-10 also indicates

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that you raised \$576,000 in Offering 2, rather than \$1.2 million. Please reconcile your disclosure.

Exhibits

20. When available, please file the 2021 Incentive Plan as an exhibit to your registration statement.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Franklin Wyman at 202-551-3660 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at 202-551-4224 or Christine Westbrook at 202-551-5019 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Richard Bass, Esq.