



DIVISION OF
CORPORATION FINANCE

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

February 19, 2023

Paul A. Romness, MPH
President and Chief Executive Officer
OS Therapies Incorporated
15825 Shady Grove Road, Suite 135
Rockville, Maryland 20850

Re: OS Therapies Inc
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted January 20, 2023
CIK No. 0001795091

Dear Paul A. Romness:

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.

Amendment No. 1 to Draft Registration Statement on Form S-1

Cover page

1. We note your reference to an expected price. Please confirm that in a future amendment you will disclose the actual price to the public or, as applicable, include a bona fide estimate of the price range.
2. Please revise the second paragraph of the Public Offering Prospectus cover page to disclose the conversion price applicable to the convertible promissory notes. Please also revise the cover page of the Resale Prospectus, where appropriate, to include this same information.

3. With reference to page Alt-4 of the Resale Prospectus, please revise the cover of the Public Offering Prospectus to highlight that the selling stockholders have represented to you that they will not offer or sell shares prior to the closing of the primary offering. Also, revise the third paragraph of the cover page to the Resale Prospectus so that it is consistent with the representations disclosed on page Alt-4. In this regard, the Resale Prospectus cover page appears to indicate that the selling stockholders could commence offers and sales prior to the IPO closing.

About This Prospectus, page ii

4. Please tell us the authority on which you rely to qualify your disclosure by reference to actual documents as you do in the second paragraph on this page.

Prospectus Summary, page 1

5. Please revise to disclose industry terms at first use. As examples and without limitation, we refer to the following terms:
 - Tunable,
 - Antibody drug conjugate,
 - Minimal residual disease, and
 - exatecan-silanols.
6. We note your disclosure that the ADC technology is "(y)our proprietary" technology. Please tell us, and revise your disclosure on page 61, to clarify whether the BlinkBio license is an exclusive license without restrictions as to fields of use.
7. We refer to your disclosure on page 2 concerning the canine Osteosarcoma "Phase 1" trial. Please tell us your basis for presenting this veterinary trial as a "Phase I" trial. Cite to relevant USDA or other applicable regulatory guidance. Additionally, please revise to clarify that this trial constitutes preclinical work as it relates to your development of OST31-164 to treat Osteosarcoma in humans.
8. We note your disclosure on Page 2 and elsewhere that OST31-164 was awarded rare pediatric disease designation, fast track designation, and orphan drug status which "may allow for a speedier review process." Please revise your disclosure to clarify that such designations do not convey any advantage in, or shorten the duration of, the regulatory review or approval process. In this regard, we note your risk factor disclosure on page 18 that a Fast Track Designation by the FDA may not actually lead to a faster development or regulatory review or approval process.
9. In reference to your Pipeline table on page 2, please address the following:
 - Please revise to remove the OST-HER-2 Canine Osteosarcoma candidate from the table. In this regard, your prospectus does not describe any plans to commercialize a veterinary product candidate.
 - The bar for OST-HER-2 (Human Osteosarcoma) extends to the end of the Phase II column, which suggests that that you have completed this phase. Shorten this bar to

- reflect that you are still conducting a Phase IIb clinical trial.
 - Please tell us whether any preclinical work must be conducted prior to submission of IND applications for the third, fourth and fifth candidates reflected in the table. If so, then revise to shorten the bar for each such candidate.
 - Delete the “Novel TDC Programs” for which you have not identified any indication.
10. We refer to your disclosure on page 1 highlighting that your OST-TDC platform can "carry various types of payloads, and features tunable pH sensitive silicone linkers." Given your disclosure on page 2 indicating that the OST-TDC platform remains in preclinical development, it appears premature for you to make these performance claims. Please revise or advise.

Summary Financial Data, page 10

11. It appears that some of the numbers in the Statement of Operations Data are presented in thousands while others, for example, net loss available to common shareholders, are presented as whole numbers. Please revise to present all items with the Statement of Operations Data on the same basis.

In light of the large population of patients with Osteosarcoma who reside in foreign countries..., page 23

12. Please revise the first sentence of the risk factor to clarify whether you are addressing incidence or prevalence. In light of the global figure you present, please revise the risk factor heading which references a "large" patient population. Please note that we would not object to a reference to a "larger" patient population.

Paul A. Romness, MPH, and our other executive officers, directors and their affiliates will continue to exercise significant influence..., page 43

13. We note that the other executive officers and directors, excluding Paul A. Romness, beneficially own approximately 5% of your outstanding shares. Please reconcile this disclosure with the beneficial ownership table on page 87, which provides an estimate of approximately 8%, or otherwise advise.

Cautionary Note..., page 47

14. Please revise to remove references Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 given that these provisions do not apply in the context of initial public offerings.

Use of Proceeds, page 48

15. We refer to the final sentence of the third paragraph and note that your disclosure on page 64 indicates that you plan to finish the Phase IIb trial in late 2024. With a view to revised disclosure here and elsewhere, please tell us whether you plan to conduct a Phase III trial

and, if applicable, the expected duration and costs of such a trial. Also, tell us the timeframe necessary for preparing and submitting an NDA.

Pipeline of Our Product Candidates, page 64

16. Your Business section does not describe the preclinical work that has been conducted to date for any of the candidates highlighted in your Oncology Pipeline table. Please revise to present the results of all material preclinical work so that investors can understand why you are pursuing these candidates. In particular, please provide detailed disclosure concerning the OST31-164 canine study that you prominently highlight in the Summary. In this regards, it is unclear what basis there is to claim “significant improvements” in overall survival and metastatic disease progression. To the extent that you have not conducted preclinical work to date for a given candidate, please clarify this status.
17. Please revise the Business section and Summary, where appropriate, to clarify whether you, Advaxis or another party conducted Phase 1 and/or Phase IIa clinical trials for OST31-164 in humans. If so, please revise the Business section to provide a detailed description of the trial or trials, including trial protocols, the number of patients, primary and secondary endpoints, and any serious adverse effects reported. Disclose who conducted the trials, where they were conducted, and when.
18. With respect to the ongoing OST31-164 Phase IIb trial, please revise to present the trial protocols, including the number of patients as well as primary and secondary endpoints. Disclose where the trial is conducted. In terms of status, disclose whether enrollment remains ongoing.

Our Scientific Collaborators, page 67

19. We note your disclosure regarding the use of proprietary technology developed at the University of Pennsylvania under the guidance of Robert G. Petit, your Chief Scientific & Medical Officer. Please clarify the rights and ownership of this proprietary technology, including any rights or ownership of the University of Pennsylvania.

Our Intellectual Property, page 69

20. We note your disclosure here and elsewhere regarding “numerous” pending foreign applications for OST31-164 and OST-TDC. Please specify the number of pending foreign patent applications, the types of patents (e.g., composition of matter, method, or use), the applicable jurisdictions, and dates of expiration for each application.

Management

Executive Officers, page 77

21. We note your disclosure that Christopher P. Acevedo is a part time employee. We also note your disclosure on page 85 that you are contemplating entering into a consulting agreement with him to continue as your Chief Financial Officer for no specified term.

Paul A. Romness, MPH
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Page 5

Please revise to include risk factor disclosure concerning Mr. Acevedo's part-time status and the number of hours of service hours per month he is expected to provide. Please also revise throughout the prospectus to clarify whether Mr. Avecedo is an Interim Chief Financial Officer. In this regard, we note that Mr. Avecedo is disclosed as your Chief Financial Officer in the prospectus summary, but is identified as an Interim Chief Financial Officer on page 77.

Executive Compensation, page 84

22. Please file the employment agreements for Paul A. Romness, Christopher P. Acevedo, Robert G. Petit, and Jutta Wanner as exhibits pursuant to Item 601(b)(10) of Regulation S-K. In this regard, we note your disclosure on page 40 that you have entered into employment letter agreements with your executive officers.

General

23. 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.
24. Please provide us with a copy of your cover graphics. For guidance, please refer to Compliance Disclosure Interpretations, Securities Act Forms, Question 101.02.

You may contact Christine Torney at (202) 551-3652 or Lynn Dicker at (202) 551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at (202) 551-7349 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Spencer G. Feldman