



DIVISION OF
CORPORATION FINANCE

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

February 26, 2021

Daniel Schneeberger, M.D.
Chief Executive Officer
Anebulo Pharmaceuticals, Inc.
1415 Ranch Road 620 South, Suite 201
Lakeway, TX 78734

**Re: Anebulo Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted January 29, 2021
CIK No. 0001815974**

Dear Dr. Schneeberger:

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, Submitted January 29, 2021

Prospectus Summary

Our Company, page 1

1. Please revise the Summary and Business sections to clarify what work you and your employees have conducted to date. For instance, it should be clear whether clinical and pre-clinical work was performed by you and your employees or whether that work was performed by Vernalis (R&D) Limited or another third-party.
2. We note your disclosure in the first sentence on page 1 that you are a "clinical-stage biotechnology company developing novel solutions for people suffering from cannabinoid overdose and substance abuse." Please balance your Summary disclosure to clearly state

upfront, if true, that you have not conducted any clinical trials for any of your product candidates.

3. On page 1 and elsewhere you state that ANEB-001 has the potential to be a "first-in-class" therapeutic. This implies the likelihood of regulatory approval and comparisons to other products and product candidates. This statement is speculative in light of its regulatory status, please remove the "first-in-class" references.

Our Product Candidates, page 2

4. Please revise page 2 to (i) disclose more information about the rimonabant data you reviewed, such as the number of subjects and duration of the trial(s), (ii) clarify the meaning of "no clear sign of increased depression and suicide risk" and state how such determination compares to the FDA findings on this topic, and (iii) state why you believe ANEB-002 may be less likely to cause psychiatric side effects than rimonabant. Please also revise your statement referring to rimonabant as efficacious, as determinations as to efficacy are solely within the authority of the FDA and comparable regulatory bodies.
5. In your pipeline table, please visually clarify the need for FDA approval. For instance, remove the "marketed" column as it implies that once you complete Phase 3 trials your product candidates will be marketed. Also clarify the "potential for second commercial product" in your pipeline chart so as to not suggest you will have at least one product approved. Separately, please shorten the arrow for ANEB-001 as it has not begun Phase 2 trials yet.
6. We note the inclusion of ANEB-002 in the table on pages 2 and 62 indicating, for instance, that your ANEB-002 is in the midst of a preclinical development for substance abuse. Please revise your disclosure on page 68 to provide a more fulsome discussion of this program. In your revised disclosure, please ensure to discuss preclinical studies or other development activities conducted. Alternatively, remove ANEB-002 from your pipeline table.
7. We note your statement referencing the Journal of Pharmacology and Experimental Therapeutics on page 2. Please revise to remove any implication that preclinical trials can establish efficacy.

Our Market Opportunity, page 4

8. We note your reference to data from a commissioned market research report from Guidepoint Global, LLC. Please file such party's consent as an exhibit to the registration statement. Refer to Securities Act Rule 436.

Our Clinical Trials and Development Plan, page 5

9. Please revise page 5 to provide the basis for the statement that ANEB-001 was able to significantly reverse the action of THC.

10. We note that two Phase 1 studies were conducted by Vernalis for ANEB-001 from 2006 to 2007. Please revise to provide the program name and target indication. To the extent that Vernalis was targeting a different indication, please revise the charts on page 2 and 62 to indicate that ANEB-001 is still in the preclinical stage for cannabinoid overdose. Similarly, please revise the chart to clarify, if true, that you have not yet filed an IND for cannabinoid overdose. Please include similar disclosure with respect to the EMA or any other drug regulatory authorities.
11. On page 8 you state that the Phase 2 study will lay the foundation for you to conduct a more extensive clinical trial to establish ANEB-001's quality, safety and efficacy with a larger subject population. Please revise this statement as safety and efficacy are determinations within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies.

Our Growth Strategy, page 8

12. Please revise your statement on page 8 and elsewhere that you intend to rapidly develop and commercialize ANEB-001. Clinical development is a lengthy process and indications that you will be successful in developing and commercializing your product candidate in a rapid or accelerated manner are speculative.

Private Placement and Recapitalization, page 9

13. Please revise page 9 to state whether you have a written agreement pursuant to which each of 22NW, LP and Mr. English has agreed to purchase the milestone warrants and exercise them on a net-exercise basis into Series A preferred stock in connection with the closing of this offering. If so, please also file such agreement as an exhibit.

Risk Factors

Risks Related to Ownership of Our Common Stock and this Offering, page 37

14. We note your exclusive forum provision on page 2 says that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act unless you consent to an alternative forum. In that regard, we note that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act. Please include a risk factor discussing any uncertainty regarding enforceability of this provision and clearly describe any risks or other impacts on investors. Risks may include, but are not limited to, increased costs to bring a claim and that these provisions can discourage claims or limit investors' ability to bring a claim in a judicial forum that they find favorable.

Use of Proceeds, page 45

15. Please revise to disclose an estimate of how far in your development and commercialization of ANEB-001 and ANEB-002 the proceeds from this offering will

allow you to reach with respect to each product candidate, including specific phases of preclinical and clinical trials. Also, please disclose the total estimated cost of each of the specified purposes for which the net proceeds are intended to be used, and, if material amounts of other funds are necessary to accomplish the specified purposes, provide an estimate of the amounts of such other funds and the sources thereof. Additionally, on page 54 you mention that you may use a portion of the proceeds to repay certain debt. If any material part of the proceeds is to be used to discharge indebtedness, set forth the interest rate and maturity of such indebtedness. If the indebtedness to be discharged was incurred within one year, describe the use of the proceeds of such indebtedness other than short-term borrowings used for working capital. Refer to Item 504 of Regulation S-K.

Capitalization, page 47

16. Please revise the table to only include long-term indebtedness, convertible preferred stock, and stockholders' equity in the total capitalization line item. If you present a cash and cash equivalents line item, please include a double line underneath that line so as to distinguish it from the capitalization line items.

Dilution, page 48

17. Please revise the presentation to disclose historical net tangible book value prior to the presentation of pro forma net tangible book value.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Contractual Obligations and Commitments, page 56

18. Please revise to include a description of your contractual obligations under the Vernalis license agreement considering its significance in your operations.

Business

Our Clinical Trials and Milestones, page 65

19. We note that the preclinical trials discussed in this section provide results without providing proper context for such results. For each of the pre-clinical trials discussed in this section, please disclose the date(s) of the trials, the sponsor and the location; scope and size; dosage and duration; and actual results observed.
20. Please provide p-values for both Phase 1 studies and explain how statistical significance relates to FDA standards of efficacy. Please also state the number of subjects in your Phase 1b study.

Protection of Intellectual Property, page 76

21. With respect to all of your patents and patent applications, including those licensed from Vernalis to the extent not described elsewhere, please revise your discussion on page 76 to state (i) the specific products, product groups and technologies to which such patents

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relate, (ii) whether the patents are owned or licensed, (iii) the type of patent protection (composition of matter, use or process), (iv) patent expiration dates and (v) identify the jurisdiction(s) covered.

22. Please revise page 76 to explain the requirements that must be met to achieve the cited regulatory periods of exclusivity.

Management, page 77

23. Please revise page 84 to state whether you compensated your directors in 2020, and if so, provide the information required by Item 402(r) of Regulation S-K.

Exhibits

24. Please file the Investors' Rights Agreement and Consultancy Agreement with Traxeus Pharma Services Limited as an exhibit pursuant to Item 601 of Regulation S-K, or advise.

General

25. 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 Li Xiao at 202-551-4391 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Margaret Schwartz at 202-551-7153 or Jeffrey Gabor at 202-551-2544 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Spencer G. Feldman, Esq.