

March 12, 2021

VIA EDGAR AND ELECTRONIC MAIL

U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549
Attn.: Division of Corporation Finance,
Office of Life Sciences

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

Ladies and Gentlemen:

On behalf of Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), we hereby submit through EDGAR for confidential non-public review under Section 6(e) of the Securities Act of 1933, as amended, one complete copy of Confidential Draft Submission No. 2 of the Company's Registration Statement on Form S-1 (the "Draft Registration Statement"), for the registration of shares of the Company's common stock, including one complete copy of the exhibits listed as filed therewith.

The Draft Registration Statement responds to the comments received from the staff of the U.S. Securities and Exchange Commission (the "SEC") in its comment letter dated February 26, 2021 with respect to the Company's original Draft Registration Statement on Form S-1 (CIK No. 0001815974) submitted confidentially to the Division of Corporation Finance by the Company on January 29, 2021, as discussed below.

Courtesy copies of this letter and the Draft Registration Statement (as marked to reflect changes), together with all exhibits, are being provided by email directly to the staff for its convenience (attention: Margaret Schwartz, Esq.) in the review of the foregoing documents.

To facilitate the staff's review, the SEC's comments are reproduced before each of the Company's responses thereto. All page numbers referred to in the responses to the staff's comments correspond to the page numbers of the Draft Registration Statement.

Draft Registration Statement on Form S-1, Submitted January 29, 2021**Prospectus Summary**
Our Company, page 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 you and your employees or whether that work was performed by Vernalis (R&D) Limited or another third-party.*

March 12, 2021
Page 2

Response: In response to the staff's comment, the Company has added the following language to page 1: "Vernalis has been the sponsor of all prior preclinical and clinical studies."

The Company has also clarified on page 1 its own contribution of work, stating: "Since the in-licensing with Vernalis we have assembled an executive team and started preparations for a Phase 2 proof-of-concept trial, including the synthesis of a new active pharmaceutical ingredient ("API") and the development and filing of a clinical trial protocol with regulatory agencies in Europe. We are in the process of obtaining patents intended to cover our product, composition and methods of use that are important to the development of our business. We have filed two patent applications for various methods of use of the ANEB-001 compound and delivery systems, which applications are currently pending before the U.S. Patent and Trademark Office."

- 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.*

Response: In addition to the Company's response to Comment No. 1 above with regard to Vernalis' clinical studies, the Company believes its drug development program is in the clinical stage, as (i) all preclinical work has been completed for the Company's lead indication and the Company is in possession of all such data, (ii) the drug has successfully been through Phase 1, even if those studies were sponsored by the licensor, and (iii) the Company has filed the study protocol and all supporting documentation for its Phase 2 study with European regulators and expects to receive a decision allowing the Company to proceed in the Phase 2 study in the first quarter of 2021.

- 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.*

Response: In response to this comment, the Company has replaced "first-in-class therapeutic" with "If approved by the U.S. Food and Drug Administration (the "FDA"), we believe ANEB-001 has the potential to be the first FDA approved treatment of its kind on the market for reversing the effects of tetrahydrocannabinol ("THC"), the principal psychoactive constituent of cannabis." See pages 1, 52 and 64. The Company believes that this statement is factual as there currently is no other approved antidote for the treatment of THC overdose, and since there is a clear pharmacologic rationale and existing preclinical data to support that potential. The Company has removed the language "As the first treatment of its kind, we believe ANEB-001 has the potential to be a first-in-class therapeutic" on page 1 and elsewhere in the Draft Registration Statement.

The Company is not making any statements regarding the likelihood of regulatory approval.

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.*

Response: In response to the staff’s comment, the Company has removed its ANEB-002 program from the Draft Registration Statement due to the early stage of this product candidate. The Company plans to make more detailed disclosures when appropriate as a public company.

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.*

Response: In response to this comment, the Company has replaced the “marketed” column with “NDA submission” to clarify the need for FDA approval. The Company has also removed the “potential for second commercial product” reference and shortened the arrow for ANEB-001 on page 2.

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.*

Response: As noted, the Company has removed the ANEB-002 program from the Draft Registration Statement due to the early stage of this drug candidate.

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.*

Response: As noted above, the Company has removed the ANEB-002 program from the Draft Registration Statement due to the early stage of this product candidate.

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.*

Response: In response to this comment, the reference to Guidepoint Global by name has been removed.

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.*

Response: In response to the staff’s comment, the Company has changed “We demonstrated that orally administered ANEB-001 was able to significantly reverse the action of THC” to read: “As part of the preclinical characterization of ANEB-001, Vernalis demonstrated that oral administration of ANEB-001 reduced hyperlocomotion in mice after 30 minutes, effectively reversing the actions of THC.” This change clarifies the statement to refer to the mouse experiment described in the two prior sentences. See page 5.

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.*

Response: In response to this comment, the Company notes that Vernalis was developing ANEB-001 for the target indication of obesity. The Company has added that information (“In 2006 and 2007, two Phase 1 studies for the treatment of obesity were conducted by Vernalis for ANEB-001,” on page 5), and disclosed the trial codes for both trials.

However, the design and goals of Phase 1 trials would not differ materially between the indications of obesity and THC overdose. Usually, the goals of Phase 1 trials are to establish safety and tolerability, characterize the pharmacokinetics and potentially deliver pharmacodynamic signals. Those goals have all been achieved and the Company plans to directly proceed with its Phase 2 trial later this year. It is the Company’s belief that no additional preclinical or clinical data will be required to move forward – it would, therefore, be inaccurate to say that ANEB-001 is in preclinical stage for cannabinoid overdose.

The Company has finalized the design of its Phase 2 trial and submitted the protocol to European regulators. The Company does not currently have an open IND in the United States and has clarified this with the following additional disclosure:

“We believe this study will lay the foundation for us to engage with the FDA and/or comparable foreign regulatory authorities, file for an Investigational New Drug Application (“IND”) with the FDA in the United States and conduct more extensive clinical trials with the goal of generating additional clinical data that will ultimately enable us to file a marketing application with the FDA.” See pages 8 and 71.

The Company has also edited this section to make clear that the studies have been performed by Vernalis.

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.*

Response: As noted above, the Company has revised this statement on page 8 as follows:

“We believe this study will lay the foundation for us to engage with the FDA and/or comparable foreign regulatory authorities, file for an Investigational New Drug Application (“IND”) with the FDA in the United States and conduct more extensive clinical trials with the goal of generating additional clinical data that will ultimately enable us to file a marketing application with the FDA.”

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.*

Response: In response to the staff’s comment, the Company has removed all language describing *arapid* development or a *rapid* path to commercialization.

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.*

Response: In response to this comment, the Company has removed the sentence regarding the purchase of the milestone warrant. The Company expects to definitively set forth this arrangement in the next SEC filing.

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.*

Response: As requested by the staff, an appropriate risk factor addressing the exclusive forum provision has been added on page 43.

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.*

Response: In response to this comment, the Company has disclosed that for ANEB-001 it believes that the Company will have sufficient net proceeds from the offering to generate the P2 proof-of-concept data, advance regulatory discussions and prepare for pivotal trials. The Company will require additional capital to run the pivotal trials and file a marketing application. The Company will also have to raise additional funds if it decides to commercialize ANEB-001 without any third-party collaborative arrangements. References to ANEB-002 and the repayment of certain outstanding debt have been removed. See the fourth paragraph under Use of Proceeds on page 47 for this added disclosure.

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.*

Response: As noted, the Capitalization chart has been updated to properly reflect that cash (as well as current liabilities) is not calculated within the capitalization line item. See page 49.

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.*

Response: As revised, the historical net tangible book value is disclosed prior to the presentation of pro forma net tangible book value. See updated chart on page 50.

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.*

Response: As requested by the staff, the contractual obligations under the Vernalis license agreement are disclosed beginning on page 58.

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.*

Response:

In response to this comment, the Company notes that ANEB-001 is a competitive CB1 antagonist with a high affinity for the human CB1 receptor (0.6 nM) (1). In vitro testing showed ANEB-001 had >1000x selectivity with the human CB1 receptor over all other tested receptors. (2) As part of the preclinical characterization of ANEB-001, Vernalis demonstrated that oral administration of ANEB-001 reduced hypolocomotion in mice after 30 minutes, effectively reversing the action of THC. (3)

- (1) Vernalis Laboratory, United Kingdom, report issued March 30, 2006. The compound was tested as a displacer in established radioligand binding assays for the CB1 receptor. ANEB-001 displaced the antagonist radioligand, [³H]-SR141716A from the human CB1 receptor with high affinity (0.55 nM).
- (2) Vernalis Laboratory, United Kingdom, report issued March 30, 2006. The compound was tested as a displacer in 90 binding assays and 19 enzymes and functional assets. ANEB-001 has a K_i value of greater than 1 micromolar at all the off-target receptors at which it has been tested, except the A3 receptor where it had a K_i value of 737 nM. As ANEB-001 has an affinity of 0.55 nM for the human CB1 receptor, there results indicate that ANEB-001 has a selectivity of at least 1000 fold over all other binding sites tested.
- (3) Vernalis Laboratory, United Kingdom, report issued March 30, 2006. C57 mice administered THC 3 mg/kg ip 10 min pre-test exhibited reduced locomotor activity when placed in automated locomotor activity cages for 15 minutes. V24343 given orally at a dose of 30 mg/kg 30 minutes pre-test significantly reversed the action of THC on the total activity time parameter (p<0.01 by one way ANOVA and Newman Keuls test, n=7 per group).

Responsive disclosure has been added on page 68, as follows:

Preclinical Data

The preclinical characterization of ANEB-001 was performed at Vernalis' internal laboratory in the United Kingdom between 2003 and 2006. The compound was tested as a displacer in established radioligand binding assays for the CB1 receptor. ANEB-001 displaced the antagonist radioligand, [3H]-SR141716A from the human CB1 receptor with high affinity (0.55 nM) and was shown to be a competitive antagonist in cAMP assays. In vitro testing as a displacer in 90 binding assays and 19 enzyme and functional assays, showed that ANEB-001 had >1000x selectivity with the human CB1 receptor over all other tested receptors. Further, Vernalis demonstrated that simultaneous oral administration of ANEB-001 reduced hypolocomotion in mice, effectively reversing the action of THC. C57 mice administered THC 3 mg/kg ip 10 min pre-test exhibited reduced locomotor activity when placed in automated locomotor activity cages for 15 minutes. V24343 given orally at a dose of 30 mg/kg 30 minutes pre-test significantly reversed the action of THC on the total activity time parameter (p<0.01 by one way ANOVA and Newman Keuls test, n=7 per group).

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.*

Response:

In response, p-values typically require a formally tested hypothesis. Vernalis did not calculate p-values for safety or pharmacokinetics. As an exploratory pharmacodynamic endpoint, Vernalis did analyze test meal intake and changes in body weight. The trial was not powered for statistical significance and the Company will be evaluating different endpoints in its Phase 2 trial, but the Company has nevertheless included the p-values as requested by the staff.

The Company has amended the disclosure on page 70 as follows:

With regard to pharmacodynamics, a marked reduction in test meal energy intake was seen even at the lowest dose level in Phase 1a Part B (p<0.01 on Day 14 for OD 100mg, p<0.05 on Day 7 for OD 100mg, not statistically significant for all other cohorts). Further, Vernalis observed statistically significant decreases in body weight (p<0.001 on Day 14 for OD 100mg, p<0.05 for OD 50/5mg and OD 200/50mg, not significant for OD75/15mg) indicating that ANEB-001 was able to cross the blood-brain barrier and antagonize central cannabinoid receptors."

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 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.*

Response: As requested by the staff, the discussion of the Company's patents and patent applications has been expanded. See page 79 under "Patent and patent applications."

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

Response: As requested, the requirements to achieve the three types of regulatory periods of exclusivity are set forth on page 79 under "Regulatory 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.*

Response: In response to this comment, language has been added to state that the Company's directors were not compensated for serving as directors in 2020. See page 87.

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.*

Response: Pursuant to Item 601 of Regulation S-X, the Investors' Rights Agreement with 22NW and Consultancy Agreement with Traxeus Pharma Services Limited are being filed as Exhibits 10.3 and 10.10 to the Draft Registration Statement.

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*

The Company has not provided, nor has it authorized anyone to provide on its behalf, written materials to potential investors in reliance on Section 5(d) of the Securities Act. There have not been, nor does the Company expect there to be, research reports about the Company published or distributed by any broker or dealer that is participating, or is expected to participate, in the offering in reliance upon Section 2(a)(3) of the Securities Act.

* * *

The Company respectfully requests the staff's review of the Draft Registration Statement to coincide with this timing in order to meet the Company's ultimate goal of an early May 2021 initial public offering.

Kindly address any comments or questions that you may have concerning this letter or the enclosed materials to Daniel Schneeberger, M.D., the Chief Executive Officer of the Company (tel.: (857) 500-2017), or me (tel.: (212) 451-2234).

Very truly yours,

/s/ Spencer G. Feldman

Spencer G. Feldman

cc: Margaret Schwartz, Esq.
Dr. Daniel Schneeberger
Mr. David Lachtman
Ben A. Stacke, Esq.
