United States securities and exchange commission logo

October 22, 2021

Eric Easom
Chief Executive Officer
AN2 Therapeutics, Inc.
1800 El Camino Real, Suite D
Menlo Park, CA 94027

Re: AN2 Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted September 24, 2021
CIK No. 0001880438

Dear Mr. Easom:

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 September 24, 2021

Prospectus Summary
Overview, page 1

1. Please revise the disclosure in your Summary to make clear that your clinical development of epetraborole is limited to the ongoing Phase 1b trial being conducted in healthy volunteers in Australia. Address in your revisions that you anticipate enrolling 56 volunteers, as referenced on page 108, and include the number of volunteers enrolled to date. Please also expand your discussion to substantiate your statement that you believe your planned Phase 2/3 trial will be sufficient to proceed to a marketing application for epetraborole. In this regard, we note your disclosure on page 17 that differences with prior clinical trials, including differences in patient populations, targeted indication, formulation and trial design will limit the use of prior clinical data for epetraborole. Please also balance your disclosure with discussion of the following:

Earlier clinical trials were not conducted in patients with non-tuberculous

mycobacterial (NTM) lung disease, as referenced on page 17; and
That clinical resistance was observed in a Phase 2 clinical trial and three other
clinical trials were terminated as a result of these observations, as disclosed on pages
102-103.

Given the current stage of development, please revise your statement concerning the
potential for epetraborole to become the backbone of a multi-drug treatment regimen for
patients suffering from NTM lung disease as such statements are premature and
speculative.

2. We note you cite a "substantial pharmacokinetic and safety data package [that is] expected
to reduce risk in the development program" as a reason why epetraborole is an attractive
opportunity. Please revise to remove any implication that you will successfully mitigate
clinical development risk.

3. On page 3, when describing epetraborole, you discuss results from a "previous Phase 1
clinical trial." Please clarify whether this clinical trial was conducted by a third party or
whether you are referring to your ongoing Phase 1b trial.

Our Pipeline, page 1

4. Please revise your presentation to shorten the arrow corresponding to your Phase 1 trial
for the treatment of treatment-refractory MAC to make clear the current status. In this
regard we note that enrollment is ongoing. As written, your presentation implies that you
are half way to completion. Your presentation should not imply that earlier trials were
conducted in your target indications.

5. It appears your development of epetraborole for the treatment of meliodidosis and
tuberculosis is limited to preclinical research discussed on pages 110-111 and that you
have not secured funding for these programs. Please provide us with your analysis
supporting the materiality of these programs to your business such that inclusion in your
pipeline table is appropriate. Alternatively, please remove these programs from the table.

Our Solution, page 3

6. We note your statement that in previous clinical trials epetraborole was generally safe
and well-tolerated. Please revise these and any similar statements throughout your
registration statement that imply your product candidate is safe or effective as such
determinations are made solely by the FDA or comparable regulatory bodies. As a non-
exhaustive list of examples only, we note the following disclosures:

Epetraborole has demonstrated broad antimycobacterial activity against MAC ; and

Based on the potent in vivo efficacy seen in preclinical mouse models .

7. We note your disclosure that you intend to conduct trials and pursue marketing
authorizations with epetraborole in additional geographies outside of the United States and
Europe, with an initial focus in Japan. Please discuss regulatory approval requirements in
Europe and Japan under an appropriate heading in the Business section.

Risks Associated with our Business, page 5

8. Please add a bullet point highlighting the risks associated with your licensing arrangements, including that you are dependent on your license agreement with Anacor and that a breach by Brii Biosciences of your out-license agreement could result in a breach under your in-license agreement with Anacor, as referenced on page 39.

Implications of Being an Emerging Growth Company, page 6

9. 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

10. Please revise this section to relocate any generic risk factors you present to the end of the section under the caption "General Risk Factors." Refer to Item 105(a) of Regulation S-K.

Risks Related to Regulatory Approval of Epetraborole..., page 49

11. Please revise your discussion of the FDA s limited-population antibacterial drug (LPAD) pathway to remove any implication that the FDA s approval of Insmed s Arikayce under this pathway makes it more likely that you will secure marketing approval for epetraborole. Please also revise to disclose the labeling requirements applicable under this pathway.

Risks Related to this Offering...

Our amended and restated certificate of incorporation will provide that the Court of Chancery..., page 61

12. We note your disclosure on page 160 that your choice of forum provision would not apply to claims brought to enforce any duty or liability created by the Securities Exchange Act. Please revise your risk factor disclosure to so state and ensure that the exclusive forum provision in your governing documents states this clearly. Please also disclose that your forum selection provisions may increase costs for an investors to bring a claim. Please also revise your disclosure concerning your federal forum selection provision to disclose that there is uncertainty as to whether a court would enforce such provision. In this 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 or the rules and regulations thereunder.

Management's Discussion and Analysis

Stock-Based Compensation

Common Stock Valuations, page 83

13. Please disclose the specific methodology used to determine your enterprise value and the nature of any significant assumptions used.

Business

Prior Clinical Experience with Epetraborole, page 102

14. We note that your disclosure that previous epetraborole studies were discontinued in 2010 due to "clinical resistance." Please explain the term "clinical

resistance" and provide
specific examples.
15. We note your statement on page 104 that in the SAD/MAD Phase 1 study, there were no
deaths, serious adverse events (SAEs) or any adverse events leading to withdrawal from
the study. Throughout this section, ensure that you disclose all SAEs and the number of
patients who experienced them for all SAEs that were determined to be treatment related
or that the investigator could not determine were not treatment related.

Our Global Health Initiatives, page 110

16. Please expand your disclosure to discuss the preclinical mouse model and in vitro studies
referenced in this section, including when they were conducted. Please revise statements
that present your conclusions regarding efficacy, such as "Epetraborole has demonstrated
effectiveness [in] in vitro and in vivo mouse models of melioidosis." You may present
results from your study but may not conclude that the data establishes efficacy.
Additionally, given the early stage of development for these indications, please revise
your disclosure concerning the potential of epetraborole to have a significant impact on
the global health system as such statements are premature and speculative.

Adjuvant Global Health Agreement, page 111

17. We note your disclosure that you have obligations under the Adjuvant Global Health
Agreement to, among others, use reasonably diligent efforts to develop epetraborole for
melioidosis and tuberculosis and to develop regulatory strategies and pursue necessary
product registrations and actively seek funding from governmental grants and other
granting sources. You state that if you do not maintain compliance with these and other
program-related investment commitments, Adjuvant may be entitled to repayment of any
portion of its investment that is not used for the purposes outlined in the agreement. Please
revise to clearly explain the terms under which Adjuvant would be entitled to repayment.
To the extent your activities to date pursuant to your obligations are limited to preclinical
research referenced on pages 110-111, please revise to so state. Alternatively, please

describe your activities to date. Additionally, please file the agreement as an exhibit to
your registration statement. Refer to Item 601(b)(10) of Regulation S-K.

Licensing Agreements
License Agreement with Anacor Pharmaceuticals, Inc., page 112

18. Please revise this section to disclose aggregate potential milestone payments segregated
by development, regulatory and commercial sales milestones. Where applicable, disclose
the royalty rate or range not to exceed ten percentage points per tier. Additionally, please
provide the number of years related to the royalty term and the anticipated expiry of
exclusivity and the last-to-expire patent licensed under the agreement. Please also clarify
the financial terms triggered by your out-license agreement with Brii Biosciences Limited.

License Agreement with Brii Biosciences Limited , page 113

19. Please revise this section to disclose aggregate potential milestone payments segregated
by development, regulatory and commercial sales milestones. Where applicable, disclose
the royalty rate or range not to exceed ten percentage points per tier.

Additionally, please
disclose the royalty term, duration of the agreement and termination
provisions.
6. Commitments and Contingencies
Adjuvant Global Health Agreement, page F-16

20. Describe and quantify the covenants you are required to maintain
governing your
contingent obligation to repay Adjuvant for "any portion of its
investment that is not used
for purposes outlined in the Global Health Agreement." Tell us
supplementally why you
believe repayment will not be required.

You may contact Franklin Wyman at 202-551-3660 or Mary Mast at
202-551-3613 if
you have questions regarding comments on the financial statements and related
matters. Please
contact Gary Guttenberg at 202-551-6477 or Christine Westbrook at 202-551-5019
with any
other questions.

Sincerely,

FirstName LastNameEric Easom

Division of
Corporation Finance
Comapany NameAN2 Therapeutics, Inc.

Office of Life
Sciences
October 22, 2021 Page 5
cc: Josh Seidenfeld, Esq.
FirstName LastName