



Chrysler Center
666 Third Avenue
New York, NY 10017
212 935 3000
mintz.com

May 10, 2021

CONFIDENTIAL – VIA EDGAR

Securities and Exchange Commission
Division of Corporation Finance
Office of Consumer Products
100 F Street, N.E.
Washington, D.C. 20549

Attention: Tracie Mariner
Brian Cascio
Jane Park
Celeste Murphy

Re: Acurx Pharmaceuticals, LLC
Draft Registration Statement on Form S-1
Submitted April 5, 2021
CIK No. 0001736243

Ladies and Gentlemen:

This letter sets forth the response of Acurx Pharmaceuticals, LLC (the “Company”) to the comment letter, dated April 30, 2021, of the staff of the Division of Corporation Finance (the “Staff”) of the Securities and Exchange Commission (the “Commission”) with respect to the Company’s Draft Registration Statement on Form S-1 confidentially submitted to the Commission on April 5, 2021 for confidential non-public review pursuant to the Jumpstart Our Business Startups Act, as amended. Concurrently, the Company is confidentially submitting an amendment Draft Registration Statement on Form S-1 (the “Amendment”). Defined terms used but not otherwise defined herein have the meanings ascribed to such terms in the Amendment.

In order to facilitate your review, we have repeated each comment in its entirety in italicized text in the original numbered sequence and followed by the Company’s response. When indicated, the responses below are contained in the Amendment. References to page numbers in this letter refer to the pagination of the Amendment.

1. *We note your statement on page 1 and elsewhere that ibezapolstat is a first-in-class product candidate. The term “first-in-class” suggests that the product candidate is effective and likely to be approved as a new class of antibiotic candidates. Given the early stage of development of ibezapolstat, it is not appropriate to suggest that this product is likely to be effective or receive regulatory approval. Please delete these references throughout your registration statement. If your use of the term was intended to convey your belief that the product is based on a novel technology or approach, you may discuss how your technology differs from technology used by competitors.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised the Amendment to remove references to “first-in-class” on pages 1 and 55 of the Amendment.

BOSTON LONDON LOS ANGELES NEW YORK SAN DIEGO SAN FRANCISCO WASHINGTON
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.

MINTZ

May 10, 2021
Page 2



2. *Please revise your disclosure in the Summary and the Business section to provide clear descriptions of the Clinical Cure, primary and secondary endpoints for your Phase 1 and Phase 2a trials, as applicable.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of the Clinical Cure, primary and secondary endpoints for its Phase 1 and Phase 2a trials, as applicable, on pages 1, 55 and 67 of the Amendment.

3. *We note your disclosure on page 2 that your second antibiotic candidate is currently in the lead-optimization stage. Please revise your disclosure in the Summary to clarify that this candidate is also in the preclinical stage of development.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of “lead-optimization” and to clarify that its second antibiotic candidate is in the preclinical stage of development on page 3 of the Amendment.

4. *You disclose on page 2 and elsewhere in the prospectus that you terminated your Phase 2a clinical trial early based upon the recommendation of your Scientific Advisory Board. Please revise your disclosure to include the specific reasons and analysis that your scientific and medical advisors provided in support of its recommendation, including the references on pages 2 and 64. If material, please file the written consent of the scientific experts as an exhibit to the registration statement or explain to us why you do not believe you are required to do so. Refer to Rule 436 of Regulation S-K.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion regarding the early termination of its Phase 2a clinical trial on pages 1 and 55 of the Amendment.

Further, Rule 436 of the Securities Act requires that a consent be filed if any portion of a report or opinion of an “expert” is quoted or summarized as such in a

registration statement. Section 7 of the Securities Act provides that an expert is “any accountant, engineer, or appraiser, or any person whose profession gives authority to a statement made by him.”

The Scientific Advisory Board, or SAB, is composed of non-employee scientists and clinicians who serve at the pleasure of management and are consulted by the Company in connection with its design of preclinical and clinical trials as well as in the process of analyzing data generated from such trials. The Company submits that the SAB’s recommendations do not reflect the opinion or judgment of an “expert.” Accordingly, the Company believes that the members of the SAB are not among the class of persons subject to Section 7 and Rule 436 of the Securities Act as “experts” unless the Company expressly identifies them as an expert or the statements are purported to be made on the authority of such provider as an “expert.” The Company has neither expressly identified any member of the SAB as an “expert” in the Amendment nor purported to make statements in the Amendment on the authority of any member of the SAB as an “expert.” Accordingly, the Company believes the members of the SAB should not be considered “experts” within the meaning of U.S. federal securities laws.

In addition, the Company notes that the consent requirements of Rule 436 of the Securities Act are generally directed at circumstances in which an issuer has engaged a third-party expert or counsel to prepare a valuation, opinion or other report specifically for use in connection with or incorporated into a registration statement. The Company respectfully advises the Staff that the SAB has acted solely in an advisory capacity since 2018 to assist the Company in the design of its preclinical and clinical trials and to assist in the analysis of data generated from such trials. The SAB has not prepared any data for the Company nor has it prepared any report for purposes of the Amendment. The SAB’s recommendations are based upon the Company’s own research. As such, the SAB’s recommendations were not prepared specifically in connection with or for the purpose of inclusion in the Amendment or to otherwise satisfy any specific disclosure requirement.

MINTZ

May 10, 2021
Page 3



As a result of the foregoing, the Company advises that the members of the SAB are not experts within the meaning of Section 7 of the Securities Act and for purposes of Rule 436 and thus consents from such members are not required to be filed as an exhibit.

5. *Please expand your disclosure in the Summary regarding the impact the COVID-19 pandemic on your business to include the Paycheck Protection Program loan you received in 2020 under the CARES Act. We note your disclosure on page F-10.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of the impact of the COVID-19 pandemic to include the Paycheck Protection Program loan on pages 7 and 50 of the Amendment.

6. *We note your risk factor disclosure that certain of your materials are only available from a single-source supplier. Please expand your disclosure here to discuss your sources, the availability of raw materials and the names of any principal suppliers. See Item 101(h)(4)(v) of Regulation S-K.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of raw materials and suppliers on page 23 of the Amendment.

7. *To the extent known, please revise to identify the specific product candidates for which you intend to use the proceeds of the offering. Please also disclose the approximate amount of proceeds you intend to allocate toward each of your programs and how far the proceeds from the offering will allow you to proceed with the continued development of each of your programs. Refer to Instruction 3 to Item 504 of Regulation S-K.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of the use of proceeds on pages 8 and 40 of the Amendment.

8. *We refer to your disclosure that a major vendor accounted for approximately 40% of your research and development expenditures for the year ending December 31, 2020 and that you expect to maintain this relationship. Please expand your disclosure to discuss the material terms of the agreement and file the agreement with this vendor as an exhibit to the registration statement, or tell us why it is not material.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of the major vendor on page 54 of the Amendment. In addition, the Company has filed the Master Services Agreement with this vendor as an exhibit to the Amendment.

9. *Please clarify the meaning of scientific or technical terms the first time they are used in the Business section in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by NOAEL, PAE, time-kill kinetics and non-inferiority clinical trial in your discussion.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of scientific or technical terms in the Business section of the Amendment.

10. *We note your disclosure of your Scientific Advisory Board on page 53, in the Summary and on your website. If material, please include disclosure that describes the role or function of your Scientific Advisors, whether there are any rules of procedures governing this board as well as how the Scientific Advisors are compensated.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of the Scientific Advisory Board on pages 1, 2, 55 and 67 of the Amendment.

MINTZ

May 10, 2021
Page 4



11. *Please expand your disclosure in the Business section with respect to the log kill times and log differences and how they relate to the FDA’s evidentiary standards of efficacy. For example, we note your discussion on pages 59 and 60.*

Response: The Company respectfully acknowledges the Staff’s comment and has revised its discussion of log kill times and log differences and relation to FDA evidentiary standards of efficacy on pages 61, 62 and 63 of the Amendment.

12. *We note your disclosure of the asset purchase agreement you entered in to with GLSynthesis, Inc. for the acquisition of ibezapolstat. Please revise your disclosure to include any up-front payments made, the royalty term, when the last-to-expire patent is scheduled to expire and jurisdiction of the patent acquired. Please also file the purchase agreement as required by 601(b)(10) of Regulation S-K or explain to us why it is not material.*

Response: The Company respectfully acknowledges the Staff's comment and has revised its discussion of the asset purchase agreement with GLSynthesis, Inc. on page 57 of the Amendment. In addition, the Company has filed the purchase agreement as an exhibit to the Amendment.

13. *We refer to your disclosure on page 54 that your Phase 1 trial data showed that dosages of your lead product candidate were "safe and well tolerated" with an adverse event profile similar to the placebo control group. Please note that determinations of safety and efficacy are solely within the authority of the FDA; therefore, please revise the prospectus to remove all references and/or implications of safety and efficacy, including the reference cited above. Please also clarify your disclosure to specify if any serious adverse events were observed with respect to your Phase 1 trial.*

Response: The Company respectfully acknowledges the Staff's comment and has revised its discussion of safety and efficacy on page 57 of the Amendment.

14. *We note your statement on page 56 that you believe that ACX-375C, which is "currently in pre-clinical development, will also be eligible for FDA's QIDP and fast track designations" based on advice from your scientific advisors. This statement suggests that the product candidate is likely to be approved for QIDP and fast track designations. Please expand your disclosure to specify the reasons that your scientific advisors provided to support its conclusion.*

Response: The Company respectfully acknowledges the Staff's comment and has revised its discussion relating to eligibility for QIDP/Fast Track status on page 58 of the Amendment.

15. *The graphics identified as Table 2 and Figure 2 on page 61 and the table on page 71 contain text that is illegible. Please revise accordingly.*

Response: The Company respectfully acknowledges the Staff's comment and has revised the graphics on pages 63 and 74 of the Amendment.

MINTZ

May 10, 2021
Page 5



16. *We note your statement that no new antibiotics in clinical development have shown improvement in either initial cure rate (ICR) or sustained cure rate (SCR) in comparison to currently marketed antibiotics. Given that you have not identified or conducted head-to-head trials with such new antibiotics, it does not appear appropriate to make these comparisons. Please delete this statement or tell us why you believe it is appropriate and revise accordingly. We also refer to the graphic on page 71. We note that the first two rows provide comparisons of currently marketed antibiotics against the current standard-of-care antibiotic for CDI, vancomycin. Please add a row showing a comparison of ibezapolstat and another standard antibiotic as applicable*

Response: The Company respectfully acknowledges the Staff's comment and has revised its discussion of cure rates for each of the enumerated antibiotics and antibiotic candidates and the comparative effects of ibezapolstat on the microbiome on pages 73 and 74 of the Amendment.

17. *You disclose that you believe there is a "high probability" that your Phase 2b trial will be successful. Please explain the meaning of the "NI" term and the use of p-values and how it relates to the FDA's evidentiary standards of efficacy.*

Response: The Company respectfully acknowledges the Staff's comment and has revised its discussion of the "NI" term referenced above and the use of p-values as they relate to evidentiary standards of efficacy on page 74 of the Amendment.

18. *We note your disclosure of two U.S. patents with claims that cover ibezapolstat and will expire in May 2023 and September 2030. You also disclose a key U.S. composition-of-matter patent that expires in May 2032. Please clarify your disclosure to specify the type of patent protection provided to each of the U.S. patents issued. Please also revise your disclosure on page 72 to specify the number of your non-U.S. composition-of-matter patents in Europe, Japan and Canada and the specific product or technology each of these patents relate to.*

Response: The Company respectfully acknowledges the Staff's comment and has revised its discussion of patent protection provided to each of the U.S. patents issued and the composition-of-matter patents in each of Europe, Japan and Canada on page 75 of the Amendment.

19. *You disclose on page 72 that you have filed a corresponding international patent application with regard to ACX-375C that is currently pending. Please expand your disclosure to include the type of patent protection, expiration date and applicable jurisdiction for this patent.*

Response: The Company respectfully acknowledges the Staff's comment and has revised its discussion of the corresponding international patent application with regard to ACX-375C on page 75 of the Amendment.

20. *Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.*

Response: The Company respectfully acknowledges the Staff's comment and respectfully advises the Staff that the Company has not, nor has anyone on its behalf, presented any written communications, as defined in Rule 405 under the Securities Act to potential investors in reliance on Section 5(d) of the Securities Act. In the event that the Company prepares written communications that it expects to be presented to potential investors in reliance on Section 5(d) of the Securities Act, the Company intends to retain copies of such communications and will provide copies of such communications to the Staff.

If you have any questions or comments in connection with this letter or the Amendment, please contact the undersigned by phone at (212) 692-6784 or via e-mail at ikblumenthal@mintz.com.

Very truly yours,

/s/ Ivan K. Blumenthal

Ivan K. Blumenthal

MINTZ

May 10, 2021
Page 6



cc: David P. Luci, Chief Executive Officer (Acurx Pharmaceuticals, LLC)
