



DIVISION OF
CORPORATION FINANCE

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

April 30, 2021

David Luci
Chief Executive Officer
Acurx Pharmaceuticals, LLC
259 Liberty Avenue
Staten Island, NY 10305

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

Dear Mr. Luci:

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 April 5, 2021

Our Technology, page 1

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.

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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.
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.
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.

Effects of the Coronavirus on Our Business, page 6

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.

We contract with third parties for the manufacture of our product candidates..., page 22

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.

Use of Proceeds, page 39

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.

Major Vendor, page 52

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.

Business, page 53

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.
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.
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.

Our Technology, page 53

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.
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.

About QIDP and Fast Track Designations, page 55

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.

In vivo Efficacy Animal Models, page 60

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.

Competition, page 69

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.

Competitive Strengths, page 71

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.

Intellectual Property and Market Exclusivity, page 71

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.
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.

General

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.

You may contact Tracie Mariner at 202-551-3744 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Celeste Murphy at 202-551-3257 with any other questions.

David Luci
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Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Ivan Blumenthal, Esq.