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

DIVISION OF
CORPORATION FINANCE

April 19, 2024

Daniel Schmitt
President and Chief Executive Officer
Actuate Therapeutics, Inc.
1751 River Run, Suite 400
Fort Worth, TX 76107

Re: Actuate Therapeutics, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted April 9, 2024
CIK No. 0001652935

Dear Daniel Schmitt:

We have reviewed your amended draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments. Unless we note otherwise, any references to prior comments are to comments in our April 1, 2024 letter.

Amendment No. 1 to Draft Registration Statement on Form S-1, Submitted April 9, 2024

Prospectus Summary
Our Market Opportunity, page 2

1. We note your statement on pages 2 and 92 that, "[s]ubject to [y]our receipt of the proceeds of this offering, the manufacture of Elraglusib Oral Tablet under current Good Manufacturing Practices (cGMP) is expected to be available in the third quarter of 2024...." Please reconcile this statement with your statement on page 108 that "GMP investigational product has already been manufactured...."

Pipeline and Development Timeline, page 2

2. We note that the revised pipeline table now separately depicts Part 1 and 2, Part 3A, and Part 3B of the Actuate-1801 study; Phase 1 and Phase 2 of the Actuate-1902 study; and Phase 1 and Phase 2 of the Actuate-2401 study. Please include footnote disclosure to the table clarifying, if true, that within each study, each subsequent part or phase is successive to the preceding part or phase and not a separate study that will individually proceed through each of phases 1, 2, and 3 of clinical trials. Alternatively, please tell us why you do not believe such disclosure would be appropriate.

3. We note your response to prior comment 3. Specifically, we note that the revised pipeline table now separately depicts Part 1 and 2, Part 3A, and Part 3B of the Actuate-1801 study, with the arrow for the Part 3A study indicating that the Part 3A study has completed phase 2. However, although we note a discussion of results of this study on page 110 of the prospectus, certain other disclosures in the prospectus suggest that the study is not yet complete. For example, on pages 4 and 109, you state that you "have initiated a Phase 2 trial testing Elraglusib Injection in combination with chemotherapy in pancreatic cancer under this Master protocol (Actuate-1801 Part 3A)." In addition, on page 91, you state that you have "amended and expanded the Stage 2 of the study to a randomized, controlled trial now powered for statistical significance (Actuate-1801 Part 3A)." Please revise your disclosures and, if applicable, your pipeline table as appropriate to clarify whether the Actuate-1801 Part 3A study has completed, or is ongoing in, phase 2.

4. We note that the revised pipeline table now indicates that the Actuate-1902 study for Ewing Sarcoma has commenced, or is initiating, phase 2, rather than being "in planning," as originally indicated. However, we note your disclosures on pages 2, 4, 92, 94, and 116 that you plan to amend the phase 2 protocol and reopen the phase 2 portion of the study to focus on Ewing Sarcoma. We further note your disclosure on page 116 that your plan to amend this protocol is subject to you having sufficient funding from the proceeds of this offering. Please revise the pipeline table to indicate, if true, that you have not yet commenced the Actuate-1902 phase 2 study for the given indication, or tell us why you do not believe such revision is appropriate.

Our Strategy, page 4

5. We note your response to prior comment 6, and we reissue the comment in part. Please further balance your disclosure in the third bullet point with a statement that the designations described in the bullet point do not increase the likelihood that a product candidate will receive FDA approval. This comment also applies to the disclosure in the third bullet point on page 109.

Risk Factors
We may also rely on certain third party vendors located in China...., page 31

6. We note your disclosure regarding the adverse impact on your current clinical development programs if your third-party vendors who are located in China, or who are owned by or associated with certain Chinese companies, were no longer permitted to provide services or products due to geopolitical pressures. Specifically, we note your disclosure that you could experience delays in finding suitable replacement service providers located outside China or not otherwise associated with Chinese companies. If known, please disclose whether you believe suitable alternative vendors are, or would be, available, particularly for your sole source manufacturer for elraglusib, as disclosed on page 29.

Use of Proceeds, page 71

7. We note your response to prior comment 9, and we reissue the comment in part. Please disclose the approximate amount of offering proceeds you intend to use for each identified purpose. In this regard, although we note a placeholder for the approximate amount of proceeds you intend to use to fund the research and development of elraglusib, including certain manufacturing activities, it is unclear how much of these proceeds you intend to use for each of the elraglusib trials and studies discussed in this section.

Business
Our Pipeline and Development Timeline, page 93

8. We note your response to prior comment 12. Specifically, we note your disclosure on page 79, and similar disclosures on pages 2, 92, 94, 95, and 116, that, subject to your receipt of the proceeds of this offering, you are "planning a Phase 1 study (Actuate-2401) to identify the RP2D for Elraglusib Oral Tablet in patients with advanced, refractory adult cancers" and that "[s]everal Phase 2 indications, including refractory, metastatic melanoma and refractory, metastatic colorectal cancer have been identified for further clinical development of Elraglusib Oral Tablet...." Please revise your disclosure to clarify, if true, that, although you intend to use a portion of the proceeds of this offering to finalize development plans for the Actuate-2401 phase 1 and phase 2 studies, you may require additional funds to initiate and complete the studies. In this regard, we note your disclosure on page 71 that you expect the net proceeds from this offering, together with your existing cash and cash equivalents, will allow you "to finalize development plans and to potentially initiate and complete a Phase 1 dose escalation study in patients with advanced, refractory solid cancer; and to finalize development plans for and potentially initiate a Phase 2 study in refractory metastatic melanoma."

Developing Elraglusib for the Treatment of mPDAC
Summary of Investigator-Initiated Trials, page 113

9. Here, or in another appropriate section of the registration statement, please describe the material terms of your arrangements with the IIT investigators or other sponsors of the investigator-initiated trials. In this regard, we note your added disclosure in the second bullet point on page 4 that you provide financial and resource support for IITs in exchange for rights to the trial data. We further note similar disclosure on pages 13, 71, and 109 regarding your "funding commitments for ongoing IIT studies for the use of Elraglusib Injection with other chemotherapy agents to treat mPDAC and a separate trial to treat recurrent salivary gland cancer." Your description should include the nature and extent of your obligations to fund the ongoing IIT studies, any material rights you have pursuant to these arrangements, and the termination provisions for such arrangements.

License Agreements, page 116

10. We note from Section 2.4 of the UIC License Agreement and Section 2.2 of the NU License Agreement that you agreed to manufacture products related to these license agreements in the United States, unless waived. Describe these provisions and indicate how you are currently in compliance with these provisions given your disclosure on page 29 that your current manufacturer is in China. Include risk factor disclosure if appropriate.

11. We note your response to prior comment 14. We also note that, consistent with your prior disclosure, Section 8.1 of the NU License Agreement provides that the "Agreement shall continue in effect, on a country-by-country basis, until the expiration of the last to expire patent rights covering 9-ING-41 and related GSK-3 inhibitors." Please tell us how to reconcile your current disclosure, that no patent rights are licensed by you under the NU License Agreement, with Section 8.1 of the NU License Agreement, and revise your disclosure, if appropriate, for clarification.

Intellectual Property, page 117

12. We note the added disclosure in the penultimate paragraph that you "may apply for PTE under Title II of Hatch-Waxman." Please clarify whether this statement applies generally to the U.S. patents described in this section or to specific patents. Please also disclose, if true, that there is no guarantee that PTE would be granted for any patent.

Manufacturing, page 118

13. We note your disclosure on page 29 that you rely upon a single company to manufacture the drug substance for your sole product candidate, elraglusib. Please expand your disclosure to include the name of your principal supplier. Refer to Item 101(h)(4)(v) of Regulation S-K.

Principal Securityholders, page 158

14. We note your response to prior comment 26. Please tell us how you determined that Daniel Zabrowski does not have voting and/or investment power with respect to the shares held in the Catherine A. Zabrowski Irrevocable Trust, for which Daniel Zabrowski's wife, Catherine A. Zabrowski, serves as trustee. Refer to Exchange Act Rule 13d-3 and Question 105.05 of the "Exchange Act Sections 13(d) and 13(g) and Regulation 13D-G Beneficial Ownership Reporting" Compliance and Disclosure Interpretations, available on our website. In your response, please explain to us, to the extent applicable:
    - the arrangement pursuant to which Daniel Zabrowski's equity compensation received for his services as a director is deposited into the trust, as disclosed in footnote 4 to the director compensation table on page 147;
    - whether Daniel Zabrowski has direct or indirect control or influence over the exercise of any voting and/or dispositive power over Company shares held in the trust; and
    - whether the trust agreement includes a mechanism to return voting and/or dispositive power over the shares to Daniel Zabrowski.

General

15. We note your response to prior comment 30. However, the left column of the charts in Figure 10 on page 103 and in Figure 16 on page 108 still appears to be illegible. In addition, it is difficult to read the axes and legends in Figure 15 on page 108. Please revise these figures to make them more legible.

Please contact Eric Atallah at 202-551-3663 or Kevin Kuhar at 202-551-3662 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Dickerson at 202-551-8013 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Janet Spreen, Esq.