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

DIVISION OF
CORPORATION FINANCE

April 1, 2024

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

Re: Actuate Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted March 4, 2024
CIK No. 0001652935

Dear Daniel Schmitt:

We have reviewed your 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.

Draft Registration Statement on Form S-1 Submitted March 4, 2024

Prospectus Summary
Our Lead Product Candidate, page 1

1. We note your disclosure in the last paragraph on page 1 that "[o]bjective responses and durable disease control were observed in both the single agent and combination treatment arms of the study" and that you observed a "median overall survival (mOS) of 15.3 months in the efficacy evaluable (n=29) patient population." Please clarify if these results were based on studies powered for statistical significance.

Pipeline and Development Timeline, page 2

2. We note that your pipeline table includes the investigator-initiated studies with elraglusib. We further note your disclosure on page 90 that “[t]hese studies are exploratory and not considered critical path for [you] at this stage and will not be discussed further beyond the

summary in Figure 14." Please provide us with your analysis as to whether these investigator-initiated studies are material and should be included in your pipeline table.

3. For clarity, please revise your pipeline table to identify the study names (e.g., Actuate-1801) covered by each row. Please also shorten the length of the arrow in the first row of the pipeline table, or tell us why you do not believe the revision is appropriate. In this regard, the arrow appears to indicate that you are further along in your phase 2 trials, nearing phase 3, than indicated in your disclosures throughout the registration statement. For example, we note your disclosure on page 90 that a randomized, controlled phase 2 trial has finished accrual.

4. We note your disclosure on page 2 that you are also evaluating the potential for additional exploratory development of Elraglusib Injection in other pediatric cancer indications, including neuroblastoma. Please tell us why your pipeline table shows you may be pursuing Elraglusib Oral Tablet for neuroblastoma or revise your disclosure as appropriate.

5. We note your disclosure on page 2 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 based on data from the Actuate-1801 study once the RP2D has been identified." If the RP2D for these indications has not been established, please tell us why your pipeline table shows Elraglusib Oral Tablet for melanoma and colorectal cancer as being part way through Phase 2 or revise your disclosure as appropriate.

Our Strategy, page 4

6. We note your disclosure in the third bullet point that "[o]ne of [y]our strategic objectives is to obtain development incentives in the United States and in other countries that could accelerate [y]our path to drug approval: Orphan Drug Designation, Fast-Track designation and Breakthrough Therapy Designation (BTD) in the United States; Orphan and priority medicines (PRIME) designations in the EU; and Orphan designations in Japan and Australia." Please balance this disclosure with a statement similar to the one on page 22 that such designations may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that a product candidate will receive FDA approval.

The Offering

Assumed offering price, page 8

7. We note that the assumed offering price is based on the purchase of "one-half of a share" of your common stock. Please revise this disclosure to reconcile to the remainder of your disclosure or advise.

Risks Related to Clinical Development and Regulatory Approval
We rely on third parties for the manufacture and shipping of elraglusib . . . , page 26

8. We note your disclosure in this risk factor regarding the risk of your suppliers' inability to manufacture your products in sufficient quantities or at defined quality specifications. Please also address the risk, to the extent applicable, that your suppliers are under no obligation to supply products to you. In this regard, we note your disclosure on page 110 that you currently obtain your supplies on a purchase order basis and do not have any long-term supply agreements in place.

Use of Proceeds, page 67

9. We note your disclosure in the third paragraph that you currently intend to use proceeds from this offering, together with your existing cash and cash equivalents, to fund clinical trials and product development, research and development, clinical manufacturing, as well as for working capital and other general corporate purposes, including pre-commercial activity. We further note your disclosure in the penultimate paragraph that these funds will not be sufficient to complete development in all potential indications of elraglusib. Please revise your disclosure to identify how you intend to allocate the proceeds among these different purposes. Please also clarify which elraglusib trials you currently intend to fund with the proceeds from this offering, how the proceeds will be allocated among these trials and indications, and how far into the development process you anticipate such proceeds to enable you to reach.

10. We note your disclosure on page 8 that some shares of your common stock are subject to a right of repurchase by you. If a portion of the proceeds from this offering will be used to repurchase shares, please make that clear or otherwise disclose how the repurchase rights will be impacted by your offering.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation, page 83

11. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. Please discuss with the staff how to submit your response.

Business
Our Pipeline and Development Timeline, page 89

12. When discussing your clinical studies, we note several references to your pursuit of certain studies if "adequate funding" or "requisite funding" is secured. Please clarify

whether the proceeds from this offering will provide “adequate funding” or the “requisite funding” for these studies or parts thereof.

Elraglusib Clinical Development, page 94

13. We note your disclosure that a "safe" dose was identified. Please revise to remove any statements regarding safety or efficacy determinations as such determinations are solely within the authority of the FDA.

Northwestern University License Agreement, page 108

14. Please revise your disclosure to specify when the last to expire of the patent rights licensed under the NU License Agreement is scheduled to expire.

University of Illinois-Chicago Exclusive License Agreement with Equity, page 108

15. Please revise your disclosure to briefly describe the "Patent Rights" licensed to you under the UIC License Agreement and specify when the last of those patent rights is scheduled to expire.

Intellectual Property, page 109

16. We note your disclosure that you “own or have licensed 76 issued patents and pending patent applications worldwide.” Please disclose the specific product candidates or product candidate groups to which these patents and patent applications relate. Please also disclose the expected expiration of any issued patents that are material to your business, including the original composition of matter patents covering elraglusib in-licensed from The University of Illinois-Chicago and the new composition of matter patent applications that cover elraglusib polymorphs.

Management
Background of Directors and Executive Officers, page 128

17. Please revise your disclosure regarding Andrew P. Mazar, Ph.D., to identify his business experience between April 2019 through June 2022. Refer to Item 401(e)(1) of Regulation S-K.

Executive Compensation, page 136

18. We note that you have identified Daniel M. Schmitt, your President and Chief Executive Officer, and Andrew P. Mazar, Ph.D., your Chief Operating Officer, as your named executive officers for the year ended December 31, 2023. We further note that you have excluded Paul Lytle, your Interim Chief Financial Officer, from your list of named executive officers given that he was not appointed to his position until February 2024. Please confirm to us that no other person served as an executive officer (e.g., a predecessor Chief Financial Officer) for the Company in 2023. Alternatively, please

revise your disclosure to include such other executive officer(s) in your list of named executive officers. Refer to Item 402(m)(2)(ii) and (iii) of Regulation S-K.

Summary Compensation Table, page 136

19. We note from footnote 3 to your Summary Compensation Table that Andrew P. Mazar, Ph.D., assumed the role of Chief Operating Officer on April 1, 2022 as a consultant and that he became your employee on June 1, 2022. However, it does not appear that Dr. Mazar's consulting fees are included in the table. Please revise the table to include all compensation awarded to, earned by, or paid to Dr. Mazar for all services rendered to the Company in all capacities, including as a consultant, during the periods presented in the table. Refer to Item 402(m)(1) of Regulation S-K. Please also revise footnote 3 to provide context for the option awards granted to Dr. Mazar in 2023 and to include the information required by Instruction 1 to Item 402(n)(2)(vi) of Regulation S-K.

Employment Agreements
Interim Chief Financial Officer, page 138

20. Please disclose the material terms upon which the consulting agreement with Paul Lytle, your Interim Chief Financial Officer, may be terminated.

Outstanding Equity Awards at Year End, page 138

21. Please revise footnote 3 to the table to clarify which, if any, of the vesting conditions described in the footnote have been satisfied, and clarify how you arrived at the corresponding number of remaining unearned shares presented in the table.

Director Compensation, page 139

22. For each director, please disclose by footnote to the appropriate column of the Director Compensation Table the aggregate number of stock awards, if any, and the aggregate number of option awards outstanding at December 31, 2023. Refer to Instruction to Item 402(r)(2)(iii) and (iv) of Regulation S-K.

Certain Relationships and Related Party Transactions, page 146

23. If appropriate, in accordance with Item 404 of Regulation S-K, please disclose in this section the transactions described in Note 12 (Related Party) to the financial statements on page F-21, or tell us why such disclosure would not be appropriate. Please also provide us with your analysis as to whether Richard Kenley, your Vice President of Manufacturing, should be disclosed in the "Management" section pursuant to Item 401(b) of Regulation S-K.

Principal Securityholders, page 150

24. We note your disclosure on page 150 that the applicable percentage ownership presented in the beneficial ownership table gives effect to a number of actions, including the

conversion of all outstanding shares of your redeemable convertible preferred stock into shares of your common stock immediately prior to the closing of this offering. Accordingly, the beneficial ownership table appears to present the percentage ownership of your common stock only. However, your disclosures in footnotes 4 and 5 to the table indicate that the corresponding rows in the table include shares of preferred stock. Please revise the table and/or these footnotes as appropriate, including, if applicable, to clarify whether the numbers presented in the footnotes actually reflect the shares of common stock underlying the outstanding shares of preferred stock and, if so, how such numbers were calculated. Alternatively, please tell us why you do not believe such presentation is appropriate.

25. In footnote 5, we note your disclosure that Mr. Thomson shares voting and investment control with respect to shares held by the Kairos Venture Affiliated Funds. Please revise your disclosure to identify any other natural persons with whom Mr. Thomson shares voting and investment control of such shares.

26. In footnote 7, we note your disclosure that certain shares of common stock are held by the Catharine A. Zabrowski Irrevocable Trust, of which Catherine A. Zabrowski is the trustee. Although we also note your disclosure on page 150 that, unless otherwise indicated, you believe that all persons named in the table have sole voting and investment power with respect to all the common stock beneficially owned by them, please revise footnote 7 to clarify whether Daniel Zabrowski, as listed in the table, has sole voting and investment power over the shares held in the Catherine A. Zabrowski Irrevocable Trust or whether Catherine A. Zabrowski, in her capacity as trustee of such trust or otherwise, shares or has sole voting and investment power of such shares.

Description of Capital Stock
Choice of Forum, page 158

27. We note your disclosure that your amended and restated certificate of incorporation will provide that the federal district courts of the United States shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Please include a risk factor regarding the potential risks to investors from this forum provision, including, as examples only, increased costs to bring a claim and the possibility that such provision may discourage the filing of claims or limit investors' ability to bring a claim in a judicial forum that they find favorable.

Note 8 - Warrants, page F-17

28. Please revise to disclose the exercise price of all the warrants to purchase shares of your Series B-1 redeemable convertible preferred stock.

Item 16. Exhibits, page II-3

29. Please include the form of representative's warrants, as discussed on page 168, as an exhibit to the registration statement.

General

30. We note that many of the charts used in the registration statement, particularly in the business section, appear small and difficult to read. For example, we refer you to the figures on pages 95, 98, 99, 104, and 105. Please revise your registration statement to replace these figures with larger, more legible images.

31. 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.

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.