



DIVISION OF
CORPORATION FINANCE

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

June 13, 2025

Michael J. Roberts
President and Chief Executive Officer
Adaptin Bio, Inc.
3540 Toringdon Way, Suite 200, #250
Charlotte, NC 28277

Re: Adaptin Bio, Inc.
Registration Statement on Form S-1
Filed May 16, 2025
File No. 333-287338

Dear Michael J. Roberts:

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

Please respond to this letter by amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to this letter, we may have additional comments.

Registration Statement on Form S-1

Cautionary Note..., page iii

1. Please revise to remove the reference to Section 27A and Section 21E. We note that these safe harbor provisions do not apply to initial public offerings.

Prospectus Summary, page 1

2. We note that disclosures here, and elsewhere in the prospectus, contain performance claims as well as statements indicating or suggesting that your product candidate is safe and/or effective. Because your product candidate is pre-clinical and because safety and efficacy determinations are in the exclusive purview of FDA and other similar foreign regulators, please revise or remove these statements. For example only, we note the following statements:

- On page 1, BRiTE "redirects patients' own T cells to recognize and destroy tumor

cells."

- On page 2, your technology "enable drugs to cross barriers and target tissues, including the brain[.]"
- On page 39, your product candidate "successfully activates human T cells against EGFRvIII expressing target cells . . . resulting in the secretion of Th-1-associated cytokines and tumor-killing."
- On page 39, your product candidate is "similarly effective[.]"
- On page 39, your product candidate "represents a critical conceptual advance in safety[.]"
- On page 42, you have "demonstrated an effective 'antidote[.]'"
- On page 42 your technology has an "acceptable safety profile."
- On page 42, your preclinical studies demonstrate a "safe, highly effective therapeutic option[.]"
- On page 49, your product candidate "is able to eliminate malignant glioma tumors[.]"

Strategy, page 2

3. We note your disclosure that "[d]rawing upon [y]our experience in commercializing specialty pharmaceutical products, [you] aim to build a specialized yet efficient infrastructure that will support the entire commercialization continuum[.]" Please provide the basis for your claim that you have experience "commercializing specialty pharmaceutical products." In this regard, we note your disclosure on page 8 that you have generated no revenue from commercial sales and your disclosure on page 18 that you "do not have experience in selling or marketing[.]"

Summary Risk Factors, page 3

4. Please include in your summary risk factors that you identified material weaknesses in your internal control over financial reporting that were present as of December 31, 2024 and continued to exist as of March 31, 2025.

Anti-takeover provisions in our charter documents and under Delaware law could make....
page 30

5. We note your disclosure that your Federal Forum Provision and your "exclusive forum provision" may "limit a stockholder's ability to bring a claim in a judicial forum of their choosing[.]" Please revise your disclosure to state that such provisions may also make it more costly for stockholders to bring a claim against you.

Business of the Company

Our Product Pipeline, page 39

6. We note your inclusion of Figures 1-4 in the registration statement. Please revise each of these graphics to ensure that all text is legible.
7. Please revise your disclosure to provide further details about the preclinical studies described in this section, including the structure of the studies, who conducted them and when they did so.

APTN-101 Clinical Studies, page 42

8. Please revise your disclosure here to clarify the clinical endpoints of the proposed Phase 1 study and whether it will be powered for statistical significance.
9. Please revise your disclosure to clarify if the Phase 1 clinical trial has begun. If the clinical trial has not yet begun, please explain why. In this regard, we note your reference on page 36, and elsewhere in the prospectus, to the "FDA's acceptance in May 2023 of the IND for APTN-101 for the treatment of glioblastoma[.]"
10. Please define the term "PK" in the first instance.

License Agreement

Patent License Agreement with Duke University, page 43

11. We note your disclosure that, pursuant to the SRA, Duke University agreed to perform research exploring the administration methods of your BRiRE Platform for a fixed fee. Please disclose the fixed fee referenced here.
12. We note your disclosure that you must pay Duke University "low to mid-double-digit percentages of any sublicensing fees as set forth in the Duke License." Please revise to specify the range of percentages of sublicensing fees to be within ten percentage points (i.e., a double-digit percentage in the teens).
13. Please revise your disclosure to state the amount that has been paid under the Duke License to date.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 51

14. Revise your discussions of research and development expenses to provide a breakdown by nature or type of costs for each period presented. As part of your breakdown, separately quantify your external clinical trial costs as well as in-process research and development charges.

Committee of the Board of Directors, page 62

15. We note your reference to a Compensation Committee on page 64. Accordingly, please disclose the composition of the Compensation Committee here.

Compensation of Directors and Executive Officers, page 63

16. We note your disclosure that your board of directors intends to grant each Independent Director equity awards equal to 0.20% of the Company's fully diluted shares outstanding at the time of grant. Please provide further details about these equity awards, including, but not limited to, when these equity awards are scheduled to be granted and whether they are tied to specific milestones or achievements.

Equity Compensation Plan Information, page 70

17. We note your reference to the "2025 Equity Incentive Plan" on page 70. Where appropriate, please provide a description of the 2025 Equity Incentive Plan within the prospectus.

Description of Capital Stock

Warrants and Placement Agent Warrants, page 77

18. Please explain here, and elsewhere as appropriate, how the Pre-Merger Warrants have an exercise price of "either \$3.30 per share or \$4.40 per share." Further, please revise your disclosure in this section to state when each of the outstanding warrants will expire.

Exhibits

19. Please remove all references to "information incorporated by reference" and attach all of your relevant exhibits to this registration statement or provide us with your analysis regarding your eligibility to incorporate by reference on Form S-1. In this regard, we note that companies that were either shell companies or blank check companies during the past three years are ineligible to incorporate by reference on Form S-1. Please refer to General Instruction VII.D of Form S-1 for guidance.

General

20. Please provide us with a detailed analysis regarding your basis for determining that this transaction is appropriately characterized as a secondary offering that is eligible to be made under Rule 415(a)(1)(i) rather than a primary offering. Please refer to Securities Act Rules Compliance & Disclosure Interpretations Question 612.09.
21. Notwithstanding comment 20 above, we note your disclosure that your common stock is "presently not traded on any market or securities exchange." Because there is no existing trading market for these securities for purposes of satisfying Item 503(b)(3) of Regulation S-K, please revise to disclose a fixed price at which the selling shareholders will offer and sell their shares.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Please contact Gary Newberry at 202-551-3761 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Joshua Gorsky at 202-551-7836 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences