



DIVISION OF
CORPORATION FINANCE

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

July 2, 2024

Christopher Sullivan
Chief Financial Officer
Avalo Therapeutics, Inc.
540 Gaither Road, Suite 400
Rockville, MD 20850

Re: Avalo Therapeutics, Inc.
Form 10-K for Fiscal Year Ended December 31, 2023
Form 10-Q for Fiscal Quarter Ended March 31, 2024
File No. 001-37590

Dear Christopher Sullivan:

We have reviewed your filings and have the following comments.

Please respond to this letter within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe a comment applies to your facts and circumstances, please tell us why in your response.

After reviewing your response to this letter, we may have additional comments.

Form 10-K for Fiscal Year Ended December 31, 2023

Item 1. Business.

Our Strategy, page 1

1. Please confirm that you will revise this disclosure in future filings to clarify that there is no guarantee that your products will receive regulatory approval and to describe the additional steps and clinical trials that you must complete before you can submit applications for regulatory approval.

Pipeline - Overview, Competition, and Intellectual Property, page 2

2. We note that the Next Generation IL-1B (extended half-life), AVTX-002 (anti-LIGHT mAb) and AVTX-008 (BTLA agonist fusion protein) product candidates appear in your pipeline table with undisclosed target indications, and that there is either minimal or no discussion of the status of these programs in your disclosure. Please confirm that you will address the following in future filings, as appropriate:
 - To the extent these are currently material programs, disclose the targets and provide more fulsome descriptions of these programs. If you have not yet identified target

indications that you are currently pursuing, please remove them from the table or explain the basis for your belief that they are material and should be included in your pipeline table.

- In an appropriate place in the Business section, revise to explain what you mean when you say that AVTX-002 and AVTX-008 are "under strategic review," and disclose the current status of such reviews. To the extent you are not currently developing and/or do not plan to further develop these product candidates, please remove them from your pipeline table in future filings.

Please note that we will not object to a narrative discussion of your aspirational plans for such product candidates or next steps with respect to these programs in your Summary and Business sections.

3. Please revise your pipeline table in future filings as follows:
 - Revise the "Anticipated Milestones" column so that it only includes the next step in the regulatory process. To the extent your Phase 2 trial of AVTX-009 has not commenced, please remove references here and elsewhere to when Phase 2 data is expected.
 - To the extent you have not identified a specific autoimmune indication for AVTX-009, please remove this row from your pipeline table in future filings.
4. Please confirm that in future filings you will revise your disclosure regarding each of your license agreements to include a discussion of all material terms, including quantifying the following as appropriate:
 - amounts paid to date, such as upfront fees and any installments thereof;
 - annual or maintenance fees payable;
 - the applicable royalty rates to be paid by each party. In the event a range is provided in place of the actual royalty rate, each such range should be within ten percentage points. By way of example only and not limitation, you should revise your disclosure that under the terms of the Lilly License Agreement, the Company will be responsible for paying royalties equal to a "mid-single digit-to-low double digit" percentage of Avalo or its sublicensees' annual net sales;
 - the duration of the agreement and royalty term; and
 - termination provisions.
5. Please confirm that with respect to all completed clinical trials of AVTX-009 and AVTX-002 referenced in this section, you will revise future filings to provide results within proper context. In this regard:
 - Please disclose the sponsor, the date(s) of the trials and the location(s), indication(s) studied, the trial phase, the primary and any secondary endpoints, the number of trial participants, the results observed relative to the endpoints, any serious adverse events, and whether statistical significance was demonstrated, including supporting p-values as appropriate.
 - Disclose the prior names used for AVTX-009, if any.
 - With respect to AVTX-002, please explain what you mean when you state you observed "positive trends" in an open-label study of Chron's Disease, and a reduction

in "asthma-related events" in a Phase 2 trial in patients with poorly controlled NEA.

Quisovalimab (AVTX-002): Anti-LIGHT mAb targeting immune-inflammatory diseases. Overview, page 2

6. We note your disclosure that Quisovalimab (AVTX-002) has shown "a favorable safety and tolerability profile, in all indications studied..." As safety and efficacy determinations are solely within the authority of the FDA and comparable regulatory bodies, please confirm that you will remove any statements that state or imply that your product candidates are safe or effective from future filings. We will not object to statements that your drug candidates were well-tolerated or that no serious adverse events deemed to be study related were reported, if true.

Intellectual Property Overview, page 3

7. Please confirm that in future filings you will revise your disclosure with respect to the Company's material patents to clearly describe on an individual or patent family basis the type of patent protection granted for each product candidate or technology (composition of matter, use, or process), whether such patent is owned or licensed, the expiration year of each patent, and the jurisdiction, including any foreign jurisdiction, of each material pending or issued patent.

Item 1A. Risk Factors, page 12

8. We note your disclosure on page 3 that certain patents related to quisovalimab (AVTX-002) that are exclusively licensed from KKC may provide exclusivity in the United States through 2028 absent any extension. Please confirm that you will revise future filings as appropriate to explain the material impact, if any, of the patent expiration on your business. In this regard, we note your disclosure on page 3 that your success depends in part on your ability to obtain and maintain proprietary protection for the technology and know-how upon which your product candidates are based.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited., page 13

9. Please confirm that you will revise future filings to revise this risk factor to quantify the NOLs accumulated through the end of 2017 and any other tax attributes that are or may become subject to limitation.

We intend to conduct clinical trials for certain of our product candidates at sites outside the United States..., page 23

10. Please confirm that in future filings you will revise this risk factor, the Business section, and elsewhere throughout as appropriate to disclose, to extent known, any jurisdiction(s) outside the United States where you intend to conduct or are conducting clinical trials for any candidate, including the indication.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. Overview, page 49

11. Please confirm that you will revise future filings, as appropriate, to support your statement here and elsewhere throughout that recently acquired product candidate AVTX-009 is

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“Phase 2-ready.” In this regard, we note that it is unclear from your disclosure whether you have an active IND for this product candidate in the indications you state you are currently pursuing.

Form 10-Q for Fiscal Quarter Ended March 31, 2024

Exhibit 32.1, page 40

12. We note that the 906 Certification in Exhibit 32.1 is incorrectly dated March 13, 2024. In a full amended filing, please provide a correctly dated Section 906 certification along with currently dated Section 302 certifications.

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.

Please contact Gary Newberry at 202-551-3761 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Hamill at 303-844-1008 or Alan Campbell at 202-551-4224 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Andrew Gibbons