# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of**
**the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 26, 2023**

# AVALO THERAPEUTICS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | | |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | | |
| **001-37590** | | **45-0705648** |
| **(Commission File Number)** | | **(IRS Employer Identification No.)** |

**540 Gaither Road, Suite 400, Rockville, Maryland 20850**
**(Address of principal executive offices) (Zip Code)**

**Registrant's Telephone Number, Including Area Code: (410) 522-8707**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.001 Par Value | AVTX | Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01. Other Events.**

On June 26, 2023, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing the topline data results from its Phase 2 randomized, double-blind, placebo-controlled parallel group trial (the "PEAK Trial") evaluating AVTX-002 (anti-LIGHT mAb) in poorly controlled non-eosinophilic asthma ("NEA"). A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated June 26, 2023. |
| 104 | The cover pages of this Current Report on Form 8-K, formatted in Inline XBRL. |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**AVALO THERAPEUTICS, INC.**

Date: June 26, 2023

By: /s/ Christopher Sullivan
Christopher Sullivan
Chief Financial Officer

# Avalo Announces Topline Data from Phase 2 PEAK Trial for AVTX-002 (quisovalimab) in Patients with Non-Eosinophilic Asthma

- **AVTX-002 did not meet the primary endpoint measured by reduction in asthma related events compared to placebo, although positive trends were observed among a sub-population of patients with elevated baseline serum LIGHT levels**
- **AVTX-002 significantly reduced serum LIGHT levels for study duration indicating target engagement**
- **AVTX-002 demonstrated a favorable safety and tolerability profile**
- **Additional analyses are ongoing to inform path forward in asthma and potentially other inflammatory conditions**

WAYNE, PA AND ROCKVILLE, MD, June 26, 2023 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced topline results from the Phase 2 randomized, double-blind, placebo-controlled trial (PEAK trial) evaluating AVTX-002 (anti-LIGHT mAb) in patients with poorly controlled non-eosinophilic asthma (NEA). The trial did not meet its primary endpoint, measured by the reduction in asthma-related events. AVTX-002 demonstrated a favorable safety and tolerability profile. AVTX-002 significantly reduced LIGHT levels for the study duration indicating target engagement. Additionally, an exploratory analysis revealed a positive trend in reduction of asthma related events in patients treated with AVTX-002 as compared to placebo within a substantial sub-population of patients with elevated baseline LIGHT levels.

Dr. Michael Wechsler, Professor of Medicine, Director of Asthma Program at National Jewish Health and the PEAK Trial's Principal Investigator, said: *"Although this study did not reach its primary endpoint in this patient population, we have identified a positive trend in a sub-population of patients with high baseline LIGHT levels. This is exciting because it gives us a potential novel biomarker for treatment in patients with severe non-eosinophilic asthma, for whom new therapies are urgently needed. Further analyses to better characterize the patients that responded to this novel treatment are ongoing and should inform future studies in asthma where regulation of LIGHT could be beneficial for these patients."*

*"While the trial did not meet its primary endpoint, we are intrigued and encouraged by the finding that there was a trend toward fewer asthma related events in patients treated with AVTX-002 that had high serum baseline LIGHT levels,"* said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"Because LIGHT is the target of AVTX-002, this is consistent with the mechanism of action of the drug and our hypothesis going into the trial. We continue to analyze these data with our scientific advisors to inform our next steps in asthma and potentially other indications. I'd like to thank the Avalo team, as well as the patients and clinical investigators for participating in this trial."*

**About AVTX-002 PEAK Trial**
The Phase 2 PEAK trial was a randomized, double-blind, placebo-controlled, parallel group trial that enrolled a total of 91 patients and was designed to evaluate the safety and efficacy of AVTX-002 for the treatment of poorly controlled NEA (NCT05288504). Subjects were administered 600 mg of AVTX-002 or placebo subcutaneously at day 0, 28 and 56. Following 12 weeks of treatment, the efficacy and safety of AVTX-002 was evaluated compared with placebo through week 14. The primary endpoint was the proportion of patients who experience any of the following asthma-related events: (i) ≥6 additional reliever puffs of a short-acting beta-agonist (compared to baseline) in a 24-hour period on 2 consecutive days, or (ii) increase in inhaled corticosteroid dose ≥4 times than the dose at baseline, or (iii) a decrease in peak flow of 30% or more (compared to baseline) on 2 consecutive days of treatment, or (iv) an asthma exacerbation requiring the use of systemic corticosteroids (tablets, suspension, or injection) for at least 3 days, or (v) a hospitalization or emergency room visit because of an asthma exacerbation.

**About AVTX-002 (quisovalimab)**
AVTX-002 is a fully human monoclonal antibody (mAb), directed against human LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with Herpes Virus **G**lycoprotein D for **H**erpesvirus Entry Mediator (HVEM), a receptor expressed by **T** lymphocytes). There is increasing evidence that the dysregulation of the LIGHT-signaling network which includes LIGHT, its receptors HVEM and LTβR and the downstream checkpoint BTLA, is a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders. AVTX-002 previously demonstrated proof of concept in COVID-19 induced acute respiratory distress syndrome including reduction in mortality and respiratory failure, as well as a positive signal in Crohn's Disease.

**About Avalo Therapeutics**
Avalo Therapeutics is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT-signaling network.

LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin β receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator (BTLA), and CD160 (the LIGHT-signaling network). Accumulating evidence points to the dysregulation of the LIGHT network as a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders.

For more information about Avalo, please visit www.avalotx.com.

**Forward-Looking Statements**
This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Avalo's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Avalo's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: initiation, timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; the development of product candidates or products; Avalo's future financial and operational outlook; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; Avalo's debt and cash position and the need for it to raise additional capital in the near future; reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and the war in Ukraine; and those other risks detailed in Avalo's filings with the SEC. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Avalo expressly disclaims any obligations or undertaking to release

publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Avalo's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

**For media and investor inquiries**
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