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): October 29, 2025

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.)**

1500 Liberty Ridge Drive, Suite 321, Wayne, Pennsylvania 19087

(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 October 29, 2025, Avalo Therapeutics, Inc. issued a press release announcing the completion of enrollment of its Phase 2 LOTUS Trial of AVTX-009 for the treatment of hidradenitis suppurativa. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release, dated October 29, 2025.
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: October 29, 2025

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

Avalo Therapeutics Announces Completion of Enrollment in Phase 2 LOTUS Trial of AVTX-009 for the Treatment of Hidradenitis Suppurativa

WAYNE, PA., October 29, 2025 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), a clinical stage biotechnology company fully dedicated to developing IL-1β-based treatments for immune-mediated inflammatory diseases, today announced that the Company has completed enrollment in its Phase 2 LOTUS trial of AVTX-009 in adults with hidradenitis suppurativa (HS). The LOTUS trial exceeded target enrollment of 222 patients with approximately 250 patients enrolled. Topline data from the trial is expected in mid-2026.

“The completion of enrollment in the LOTUS trial marks another important milestone in our AVTX-009 program,” said Dr. Garry Neil, Chief Executive Officer. “We are encouraged by the strong investigator and patient engagement in this trial, which reflects the high unmet need that exists for people living with HS. With AVTX-009’s high-affinity inhibition of IL-1β, we believe we are one step closer to offering a differentiated, potentially best-in-disease, treatment option for patients suffering from this chronic and painful condition.”

The LOTUS trial is a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial with two AVTX-009 dose regimens to evaluate the efficacy, safety and tolerability of AVTX-009 in approximately 250 adults with moderate to severe HS. Subjects were randomized (1:1:1) to receive either one of two dosing regimens of AVTX-009 or placebo during a 16-week treatment phase. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16. Secondary objectives include but are not limited to: the proportion of patients achieving HiSCR50 and HiSCR90 as well as change from baseline in: International HS Severity Score System (IHS4), draining fistula count, abscess and inflammatory nodule (AN) count, and patients achieving at least a 30% reduction on a numerical rating scale in Patient's Global Assessment of Skin Pain (PGA Skin Pain). For additional information on this trial (NCT06603077), please visit www.clinicaltrials.gov or www.lotustrial.com.

About Avalo Therapeutics

Avalo Therapeutics is a clinical stage biotechnology company fully dedicated to developing IL-1β-based treatments for immune-mediated inflammatory diseases. Our lead asset, AVTX-009, is in a Phase 2 clinical trial for hidradenitis suppurativa (HS). We’re also exploring additional opportunities to make an impact in prevalent indications that have significant remaining unmet needs. For more information about Avalo, please visit www.avalotx.com.

About AVTX-009

AVTX-009 is a humanized monoclonal antibody (IgG4) that binds to interleukin-1β (IL-1β) with high affinity and neutralizes its activity. IL-1β is a pro-inflammatory cytokine that plays a central role in the pathogenesis of a wide range of human diseases.[1] It activates immune cells that generate proinflammatory cytokines, including IL-6, TNF-α, and IL-17. Dysregulated IL-1β signaling is a major driver of inflammation, contributing to the progression of autoimmune disorders. IL-1β inhibition has proven effective in multiple immune-mediated inflammatory diseases.[1-3]

References:[1]Dinarello CA. Immunol Rev. 2018;281(1):8-27. [2]Kany S et al. Int J Mol Sci. 2019;20(23):6008. [3]Kimball AB et al. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA.

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: drug development costs, timing of trials and trial results and other risks, including reliance on investigators and enrollment of patients in clinical trials; reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the war in Ukraine and the Middle East; and those other risks detailed in Avalo's filings with the Securities and Exchange Commission, available at www.sec.gov. 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
Christopher Sullivan, CFO
Avalo Therapeutics, Inc.
ir@avalotx.com
410-803-6793

or

Meru Advisors
Lauren Glaser
lglaser@meruadvisors.com