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): May 12, 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)

540 Gaither Road, Suite 400, Rockville, Maryland 20850
(Former name or former address, if changed since last report)

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 2.02 Results of Operations and Financial Condition.

On May 12, 2025, Avalo Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2025. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

Information in this Item 2.02 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press release, dated May 12, 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: May 12, 2025

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

Avalo Reports First Quarter 2025 Financial Results and Recent Business Updates

- *Mike Heffernan appointed as Chairman of the Board*
- *Topline data from Phase 2 LOTUS trial of AVTX-009 for the treatment of hidradenitis suppurativa expected in 2026*
- *Cash on hand of approximately $125 million as of March 31, 2025 expected to provide runway into 2027, with optionality to extend into 2028*

WAYNE, PA, May 12, 2025 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), a clinical stage biotechnology company focused on the treatment of immune dysregulation, today announced business updates and financial results for the first quarter of 2025.

“We have made considerable progress in our Phase 2 LOTUS trial in hidradenitis suppurativa (HS) with site activations, screenings and enrollment progress all in line with our original projections as we have begun to meaningfully climb the enrollment curve. As such, we believe we are on track to deliver topline data in 2026 and look forward to demonstrating AVTX-009’s potential as a leading treatment in HS” said Dr. Garry Neil, Chief Executive Officer. “We are cognizant of current market conditions and are fortunate to have more than sufficient capital to reach our LOTUS trial data readout. Given the current environment, the Company is carefully evaluating the optimal timing for pursuing additional development activities beyond the LOTUS trial, such as the initiation of a second indication, to preserve capital until markets stabilize. Changes to the timing of implementing these secondary development activities could extend cash runway into 2028.”

Recent Corporate Highlights and Upcoming Anticipated Milestones:

- Phase 2 LOTUS trial: The global study design includes approximately 180 adults with HS to evaluate the efficacy and safety of subcutaneous bi-weekly and monthly dosing regimens compared to placebo.
  - Topline data is expected in 2026.
- Second Indication Exploration: Avalo continues to evaluate AVTX-009 for additional immune-mediated diseases with plans to announce a second indication.

First Quarter 2025 Financial Update:

- **Cash and cash equivalents** were $125.0 million as of March 31, 2025. Net cash used in operating activities was $9.5 million for the first quarter of 2025. The Company’s current cash on hand is expected to fund operations into at least 2027.

- **Research and development expenses** were $9.1 million for the first quarter of 2025, an increase of $7.0 million from the first quarter of 2024, driven by direct costs and indirect supporting costs of the Phase 2 LOTUS trial.

- **General and administrative expenses** were $5.5 million for the first quarter of 2025, an increase of $2.4 million from the first quarter of 2024, primarily driven by stock-based compensation expense during the period related to increased equity grants and headcount additions.

- **Net loss** was $13.1 million for the first quarter of 2025, a decrease of $108.2 million from $121.3 million in the first quarter of 2024. The difference was driven primarily by a $90.0 million decrease in other expenses from the prior period primarily related to the warrants issued as part of the private placement in 2024. Additionally, operating expenses decreased by $18.1 million, which was attributable to a $27.5 million acquired in-process research and development charge for the acquisition of AlmataBio, Inc. in the prior period, partially offset by increased research and development and general and administrative expenses in the first quarter of 2025. Basic and diluted net loss per share, based on 10,514,901 weighted average common shares outstanding, was $1.25 for the first quarter of 2025 compared to $141.14, based on 859,381 weighted average common shares outstanding for the first quarter of 2024.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 125,046	$ 134,546
Prepaid expenses and other current assets	1,833	4,325
Restricted cash, current portion	62	19
Total current assets	126,941	138,890
Property and equipment, net	949	1,209
Goodwill	10,502	10,502
Restricted cash, net of current portion	131	131
Total assets	$ 138,523	$ 150,732
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 681	$ 283
Accrued expenses and other current liabilities	4,574	6,317
Derivative liability, current	360	360
Total current liabilities	5,615	6,960
Royalty obligation	2,000	2,000
Deferred tax liability, net	278	270
Derivative liability, non-current	7,740	8,120
Other long-term liabilities	275	350
Total liabilities	15,908	17,700
Mezzanine equity:		
Series D Preferred Stock—$0.001 par value; 1 share of Series D Preferred Stock authorized at March 31, 2025 and December 31, 2024; 1 share of Series D Preferred Stock issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Series E Preferred Stock—$0.001 par value; 1 share of Series E Preferred Stock authorized at March 31, 2025 and December 31, 2024; 1 share of Series E Preferred Stock issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at March 31, 2025 and December 31, 2024; 10,827,620 and 10,471,934 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	11	10
Series C Preferred Stock—$0.001 par value; 34,326 shares of Series C Preferred Stock authorized at March 31, 2025 and December 31, 2024; 24,696 and 24,896 shares of Series C Preferred Stock issued and outstanding at March 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	506,016	503,285
Accumulated deficit	(383,412)	(370,263)
Total stockholders' equity	122,615	133,032
Total liabilities, mezzanine equity and stockholders' equity	$ 138,523	$ 150,732

The consolidated balance sheets as of March 31, 2025 and December 31, 2024 have been derived from the reviewed and audited financial statements, respectively, but do not include all of the information and footnotes required by accounting principles accepted in the United States for complete financial statements.

Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Cost of product sales	—	(80)
Research and development	9,123	2,116
General and administrative	5,546	3,193
Acquired in-process research and development	—	27,538
Total operating expenses	14,669	32,767
Loss from operations	(14,669)	(32,767)
Other income (expense):		
Change in fair value of derivative liability	380	(120)
Interest income, net	1,148	100
Excess of initial warrant fair value over private placement proceeds	—	(79,276)
Private placement transaction costs	—	(9,220)
Total other income (expense), net	1,528	(88,516)
Loss before taxes	(13,141)	(121,283)
Income tax expense	8	7
Net loss and comprehensive loss	$ (13,149)	$ (121,290)
Weighted average common shares outstanding	10,514,901	859,381
Net loss per share of common stock, basic and diluted	$ (1.25)	$ (141.14)

The unaudited consolidated statements of operations for the three months ended March 31, 2025 and 2024 have been derived from the reviewed financial statements, but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

About Avalo Therapeutics

Avalo Therapeutics is a clinical stage biotechnology company focused on the treatment of immune dysregulation. Avalo's lead asset is AVTX-009, an anti-IL-1β mAb, targeting inflammatory diseases. 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 central driver in the inflammatory process. Overproduction or dysregulation of IL-1β is implicated in many autoimmune and inflammatory diseases. IL-1β is a major, validated target for therapeutic intervention. There is evidence that inhibition of IL-1β could be effective in hidradenitis suppurativa and a variety of inflammatory diseases in dermatology, gastroenterology, and rheumatology.

About the LOTUS Trial

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 180 adults with moderate to severe hidradenitis suppurativa. Subjects will be 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: 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 this trial (NCT06603077), please visit www.clinicaltrials.gov.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic inflammatory skin condition characterized by painful nodules, abscesses, and tunnels that form in areas of the body such as the armpits, groin, and buttocks, severely impacting the quality of life of affected individuals.[1] HS is often underdiagnosed or misdiagnosed and therefore estimates of HS vary between 0.2-1.7% of the population worldwide.[2-5] The exact cause of HS is not fully understood but is believed to involve a combination of genetic, hormonal, and environmental factors. While advances in treatment have been made, limited treatment options are available. IL-1β plays a crucial role in the inflammatory cascade underlying HS, contributing to tissue damage, inflammation, and disease progression. Given the involvement of IL-1β in the inflammatory process of HS, we believe therapies that target IL-1β offer a potential treatment option for HS.

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; integration of AVTX-009 into our operations; 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.

References

[1]Patel ZS et al. Curr Pain Headache Rep. 2017;21(12):49.
[2]Egeberg A, et al. JAMA Dermatol 2016;152:429–34
[3]Phan K, et al Biomed Dermatol 2020; 4: 2-6
[4]Jfri, A, et al. JAMA Dermatol. 2021;157(8):924-31
[5]Nguyen TV, et al. J Eur Acad Dermatol Venereol. 2021;35(1):50-61

For media and investor inquiries

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