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): March 20, 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.)**

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 2.02 Results of Operations and Financial Condition.

On March 20, 2025, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2024. 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 March 20, 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: March 20, 2025

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

Avalo Reports 2024 Financial Results and Recent Business Updates

- *Topline data from Phase 2 LOTUS Trial of AVTX-009 for the treatment of hidradenitis suppurativa expected in 2026*
- *Appointed Jennifer Riley as Chief Strategy Officer*
- *Cash on hand of approximately $135 million as of December 31, 2024 expected to provide runway into at least 2027*

WAYNE, PA AND ROCKVILLE, MD, March 20, 2025 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), a clinical stage biotechnology company focused on the treatment of immune dysregulation, today announced business updates and year-end financial results for 2024.

“2024 was a transformational year for Avalo, and I am proud of the accomplishments the team has made in a short amount of time,” said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. “In March 2024, we acquired AVTX-009, a promising monoclonal antibody targeting interleukin-1β. We filed our IND application with the FDA, designed and launched the Phase 2 LOTUS trial in hidradenitis suppurativa (“HS”) and rapidly progressed its initiation, including IND activation in July and enrollment of the first patient in October. Our primary focus in 2025 is executing the LOTUS trial to release data in 2026, while exploring broader applications for AVTX-009 and announcing a second indication.”

Recent Corporate Highlights and Upcoming Anticipated Milestones:

- Initiation of 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.
- Appointment of Jennifer Riley as Chief Strategy Officer: Effective January 1, 2025, Ms. Riley is guiding strategy and pipeline planning for HS and other inflammatory market opportunities.

2024 Financial Update:

- **Cash and cash equivalents** were $134.5 million as of December 31, 2024, supported by $185 million in gross proceeds received from a private placement in 2024. Net cash used in operating activities was $49.1 million for the year ended December 31, 2024, which includes $12.5 million of milestone payments to former shareholders of AlmataBio, Inc. pursuant to the terms of the acquisition. The Company's current cash on hand is expected to fund operations into at least 2027.

- **Research and development expenses** were $24.4 million in 2024, an increase of $10.7 million from 2023, driven by costs of the Phase 2 LOTUS trial, which were partially offset by discontinued legacy program expenses from the prior year.

- **General and administrative expenses** were $17.2 million in 2024, an increase of $6.9 million from 2023, primarily driven by employee compensation costs, including stock-based compensation expense, as well as increased consulting, legal and other professional expenses following and largely related to the acquisition and financing in the first quarter of 2024.

- **Net loss** was $35.1 million for 2024, an increase of $3.6 million from the net loss of $31.5 million in 2023, mainly driven by a $39.7 million increase in operating expenses; this was partially offset by a $37.7 million increase in other income primarily related to the warrants issued as part of the private placement in 2024. The increase in operating expenses was attributable to a $27.6 million acquired in-process research and development charge for the acquisition of AlmataBio, Inc, as well as increases to research and development expenses and the general and administrative expenses as discussed above. Basic net loss per share, based on 4,426,149 weighted average common shares, was $7.94 for 2024 compared to a basic net loss per share of $113.58, based on 227,727 weighted average common shares outstanding, for 2023. Diluted net loss per share, based on 7,496,389 weighted average diluted common shares and which excludes the change in fair value of the warrant liability from diluted net loss, was $20.91 for 2024 compared to $113.58, based on 227,727 weighted average diluted common shares outstanding, for 2023.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 134,546	$ 7,415
Other receivables	611	136
Prepaid expenses and other current assets	3,714	843
Restricted cash, current portion	19	1
Total current assets	138,890	8,395
Property and equipment, net	1,209	1,965
Goodwill	10,502	10,502
Restricted cash, net of current portion	131	131
Total assets	$ 150,732	$ 20,993
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 283	$ 446
Accrued expenses and other current liabilities	6,317	4,172
Derivative liability, current	360	—
Total current liabilities	6,960	4,618
Royalty obligation	2,000	2,000
Deferred tax liability, net	270	155
Derivative liability, non-current	8,120	5,550
Other long-term liabilities	350	1,366
Total liabilities	17,700	13,689
Mezzanine equity:		
Series D Preferred Stock—$0.001 par value; 1 and 0 shares of Series D Preferred Stock authorized at December 31, 2024 and 2023, respectively; 1 and 0 shares of Series D Preferred Stock issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Series E Preferred Stock—$0.001 par value; 1 and 0 shares of Series E Preferred Stock authorized at December 31, 2024 and 2023, respectively; 1 and 0 shares of Series E Preferred Stock issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2024 and 2023; 10,471,934 and 801,746 shares issued and outstanding at December 31, 2024 and 2023, respectively	10	1
Series C Preferred Stock—$0.001 par value; 34,326 and 0 shares of Series C Preferred Stock authorized at December 31, 2024 and 2023, respectively, 24,896 and 0 shares of Series C Preferred Stock issued and outstanding at December 31, 2024 and 2023, respectively	—	—
Additional paid-in capital	503,285	342,437
Accumulated deficit	(370,263)	(335,134)
Total stockholders' equity	133,032	7,304
Total liabilities, mezzanine equity and stockholders' equity	$ 150,732	$ 20,993

The consolidated balance sheets as of December 31, 2024 and 2023 have been derived from the audited financial statements, 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)

	Year Ended December 31,	
	2024	2023
Revenues:		
Product revenue, net	$ 441	$
License and other revenue	—	
Total revenues, net	441	
Operating expenses:		
Cost of product sales	(366)	
Research and development	24,437	1
Acquired in-process research and development	27,641	
General and administrative	17,241	1
Goodwill impairment	—	
Total operating expenses	68,953	2
Loss from operations	(68,512)	(2
Other income (expense):		
Excess of initial warrant fair value over private placement proceeds	(79,276)	
Change in fair value of warrant liability	121,611	
Private placement transaction costs	(9,220)	
Change in fair value of derivative liability	(2,930)	
Interest income (expense), net	3,317	(
Other expense, net	(5)	
Total other income (expense), net	33,497	(
Loss before income taxes	(35,015)	(3
Income tax expense	114	
Net loss	$ (35,129)	$ (3
Net loss per share of common stock:		
Basic	$ (7.94)	$ (1
Diluted	$ (20.91)	$ (1

The consolidated statements of operations for the year ended December 31, 2024 and 2023 have been derived from the audited 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 and safety 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). The number of patients with anti-drug antibodies, safety, and tolerability will be assessed. 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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