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): August 7, 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 August 7, 2025, Avalo Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 August 7, 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: August 7, 2025

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

Avalo Reports Second Quarter 2025 Financial Results and Recent Business Updates

- *Topline data from Phase 2 LOTUS trial of AVTX-009 for the treatment of hidradenitis suppurativa expected mid-2026*
- *Rita Jain, M.D. appointed to Board of Directors*
- *Cash and short-term investments of approximately $113 million as of June 30, 2025 expected to provide runway into 2028*

WAYNE, PA, August 7, 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 business updates and financial results for the second quarter of 2025.

“The team has made tremendous progress on the execution of the Phase 2 LOTUS trial in hidradenitis suppurativa (HS). We have enrolled over three-quarters of the planned patients and are on track to complete enrollment by year end with top-line results expected mid-2026,” said Dr. Garry Neil, Chief Executive Officer. “We are focused on executing the LOTUS trial and advancing toward Phase 3 readiness.”

Recent Corporate Highlights and Upcoming Anticipated Milestones:

- Phase 2 LOTUS trial: The global study design includes approximately 222 adults with HS to evaluate the efficacy and safety of subcutaneous bi-weekly and monthly dosing regimens compared to placebo.
  - Topline data expected in mid-2026.
- Appointed Rita Jain, M.D. to the Board of Directors. Dr. Jain brings extensive experience spanning clinical development, regulatory strategy, and executive leadership at development-stage biopharma companies.

Second Quarter 2025 Financial Update:

- **Cash, cash equivalents and short-term investments** were $113.3 million as of June 30, 2025. Net cash used in operating activities was $20.8 million for the six months ended June 30, 2025. The Company’s current cash, cash equivalents and short-term investments are expected to fund operations into 2028.

- **Research and development expenses** were $14.1 million for the second quarter of 2025, an increase of $9.5 million from the second quarter of 2024, driven by costs related to and supporting the Phase 2 LOTUS trial.

- **General and administrative expenses** were $5.2 million for the second quarter of 2025, an increase of $0.7 million from the second quarter of 2024, primarily driven by stock-based compensation expense.

- **Net loss** was $20.8 million for the second quarter of 2025, as compared to net income of $98.5 million for the second quarter of 2024. The difference was driven by a $109.5 million change in other expenses in the prior period primarily related to the warrants issued in the March 2024 private placement, all of which were fully exercised in 2024. Additionally, research and development expenses increased $9.5 million, as discussed above. Basic and diluted net loss per share was $1.92 for the second quarter of 2025 compared to basic net income per share of $4.21, based on 10,829,760 weighted average

common shares outstanding and 1,034,130 weighted average basic common shares outstanding, respectively. Diluted net loss per share for the second quarter of 2024 was $14.07, based on 7,653,302 weighted average diluted common shares outstanding.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	June 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 42,290	$ 134,546
Short-term investments	70,972	—
Prepaid expenses and other current assets	1,903	4,325
Restricted cash, current portion	20	19
Total current assets	115,185	138,890
Property and equipment, net	686	1,209
Goodwill	10,502	10,502
Restricted cash, net of current portion	210	131
Total assets	$ 126,583	$ 150,732
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,366	$ 283
Accrued expenses and other current liabilities	6,523	6,317
Derivative liability, current	370	360
Total current liabilities	9,259	6,960
Royalty obligation	2,000	2,000
Deferred tax liability, net	293	270
Derivative liability, non-current	10,260	8,120
Other long-term liabilities	197	350
Total liabilities	22,009	17,700
Mezzanine equity:		
Series D Preferred Stock—$0.001 par value; 1 share of Series D Preferred Stock authorized at June 30, 2025 and December 31, 2024; 1 share of Series D Preferred Stock issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Series E Preferred Stock—$0.001 par value; 1 share of Series E Preferred Stock authorized at June 30, 2025 and December 31, 2024; 1 share of Series E Preferred Stock issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at June 30, 2025 and December 31, 2024; 10,837,356 and 10,471,934 shares issued and outstanding at June 30, 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 June 30, 2025 and December 31, 2024; 24,696 and 24,896 shares of Series C Preferred Stock issued and outstanding at June 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	508,774	503,285
Accumulated other comprehensive loss	(34)	—
Accumulated deficit	(404,177)	(370,263)
Total stockholders' equity	104,574	133,032
Total liabilities, mezzanine equity and stockholders' equity	$ 126,583	$ 150,732

The consolidated balance sheets as of June 30, 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 June 30,		Six Months Ende June 30,	
	2025	2024	2025	
Operating expenses:				
Cost of product sales	$ —	$ 343	$ —	$
Research and development	14,074	4,601	23,195	
General and administrative	5,242	4,528	10,789	
Acquired in-process research and development	—	103	—	
Total operating expenses	19,316	9,575	33,984	
Loss from operations	(19,316)	(9,575)	(33,984)	
Other (expense) income:				
Change in fair value of derivative liability	(2,530)	(5,040)	(2,150)	
Interest income, net	1,102	1,039	2,249	
Excess of initial warrant fair value over private placement proceeds	—	—	—	
Change in fair value of warrant liability	—	112,046	—	
Private placement transaction costs	—	—	—	
Other expense, net	(5)	—	(5)	
Total other (expense) income, net	(1,433)	108,045	94	
(Loss) income before taxes	(20,749)	98,470	(33,890)	
Income tax expense	16	7	24	
Net (loss) income	$ (20,765)	$ 98,463	$ (33,914)	$
Net (loss) income per share of common stock - basic	$ (1.92)	$ 4.21	$ (3.18)	$
Net loss per share of common stock - diluted	$ (1.92)	$ (14.07)	$ (3.18)	$
Weighted average common shares outstanding - basic	10,829,760	1,034,130	10,673,200	
Weighted average common shares outstanding - diluted	10,829,760	7,653,302	10,673,200	

The unaudited consolidated statements of operations for the three and six months ended June 30, 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 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]

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 222 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: 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 this trial (NCT06603077), please visit www.clinicaltrials.gov or www.lotustrial.com.

About Hidradenitis Suppurativa

Hidradenitis suppurativa (HS) is a chronic, progressive, often debilitating inflammatory skin disease that causes painful nodules, abscesses, and tunnels to form under the skin.[4-6,8] Areas commonly affected by HS include the nape of the neck, breasts, chest, armpits, abdomen, buttocks and anus, groin and genitals, and inner thighs.[7] If not adequately and promptly treated, the chronic inflammation characteristic of HS may progress to tissue destruction and permanent scarring.[4-6,9] HS typically first presents in late adolescence or early adulthood and is estimated to affect 0.7–1.2% of the U.S. population, though some sources suggest the prevalence may be as high as 2–4%.[10,11,12]

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. [4]Diaz MJ, et al. Curr Iss Mol Bio. 2023;45:4400-4415. [5]Agnese ER, et al. Cureus. 2023;15(11):e49390. [6]de Oliveira ASLE, et al. Biomolecules. 2022;12(10):1371. [7]Ingram JR, et al. J Eur Acad Dermatol Venereol. 2022;36(9):1597-160. [8]Sabat R, et al. The Lancet. 2025;405(10476):P420-438. [9]Jemec GB. *Clinicalpractice. Hidradenitis suppurativa*. N Engl J Med. 2012;366(2):158–164. [10]Garg A, Kirby JS, Lavian J, Lin G, Strunk A. Sex- and Age-Adjusted Population Analysis of Prevalence Estimates for Hidradenitis Suppurativa in the United States. *JAMA Dermatol*. 2017;153(8):760–764. doi:10.1001/jamadermatol.2017.0201. [11]Ingram, John R.*British Journal of Dermatology*. doi:10.1111/bjd.19435. [12]Nguyen TV, et al. J Eur Acad Dermatol Venereol. 2021;35(1):50-61.

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.

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