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 13, 2026

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 2.02 Results of Operations and Financial Condition.

On May 13, 2026, Avalo Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2026. A copy of the press release is furnished hereto as Exhibit 99.1.

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, as amended (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, as amended, 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 13, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 13, 2026

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

Avalo Therapeutics Reports First Quarter 2026 Financial Results and Recent Business Updates

- *Achieved positive topline results in Phase 2 LOTUS trial of abdakibart in moderate to severe hidradenitis suppurativa (HS) and plan to advance into a registrational phase 3 program*
- *Completed public offering of equity securities for gross proceeds of $431.3 million*
- *Cash, cash equivalents, and short-term investments of $82 million as of March 31, 2026, not including the subsequent financing*

WAYNE, PA, May 13, 2026 — Avalo Therapeutics, Inc. (Nasdaq: AVTX) ("Avalo"), a clinical stage biotechnology company fully dedicated to developing IL-1β-based treatments for immune-mediated inflammatory diseases, today announced business updates and first quarter 2026 financial results.

"The positive Phase 2 LOTUS trial results of abdakibart in HS, which demonstrated a deep and consistent clinical response across both HiSCR75 and HiSCR50 endpoints, mark the beginning of a transformative period for Avalo," said Garry Neil, MD, Chief Executive Officer of Avalo. "With our recently secured financing, Avalo is well-positioned to advance abdakibart into a registrational phase 3 program. Our focus remains on delivering this innovative mechanism of action via a patient-friendly potential monthly dosing regimen to provide a much-needed new treatment option for those living with HS."

Recent Corporate Highlights:

- On May 5, 2026, Avalo reported positive topline Phase 2 LOTUS results for abdakibart in adults with moderate to severe HS. The trial successfully met its primary endpoint at both doses studied (p=0.018 150mg, p=0.015 300mg and p=0.004, combined), demonstrating a 42.2% and 42.9% absolute improvement in HiSCR75 response rates at Week 16, respectively (42.5% combined; placebo rate 25.6%). These results represented the highest absolute improvement in HiSCR75 and HiSCR50 reported in similarly sized (or larger) HS trials at each individual dose and on a combined dose basis. Abdakibart also demonstrated statistically significant benefit across the key secondary endpoints, including HiSCR50, change in IHS4, and change in draining tunnel count.

- On May 7, 2026, Avalo completed an underwritten public offering of its common stock and pre-funded warrants to purchase shares of common stock for gross proceeds of $431.3 million.

- On April 26, 2026, Avalo entered into a Milestone Buyout Option and Amendment Agreement related to its March 2024 acquisition of AlmataBio, Inc. Under the agreement, Avalo paid the former AlmataBio securityholders $2.25 million for an option, exercisable within 90 days of the effective date, to pay $5.125 million in cash or shares of Avalo common stock (or a combination) in lieu of the previously disclosed $15 million contingent milestone payment due upon dosing the first patient in a Phase 3 trial of abdakibart.

First Quarter 2026 Financial Update:

- **Cash, cash equivalents and short-term investments** were $82.0 million as of March 31, 2026. Net cash used in operating activities was $17.7 million for the three months ended March 31, 2026. Subsequent to March 31, 2026, the Company completed an underwritten public offering of its common

stock and pre-funded warrants for net proceeds of approximately $405.0 million. Our current cash, cash equivalents, and short-term investments are expected to fund operations into 2029.

- **Research and development expenses** were $14.0 million for the three months ended March 31, 2026, an increase of $4.9 million from the prior year, driven by costs related to and supporting the Phase 2 LOTUS trial.

- **General and administrative expenses** were $6.9 million for the three months ended March 31, 2026, an increase of $1.3 million from the prior year, primarily driven by headcount additions and stock-based compensation expense.

- **Net loss** was $19.6 million for the three months ended March 31, 2026, as compared to net loss of $13.1 million for the three months ended March 31, 2025. The difference was driven by a $6.2 million increase in operating expenses due to the $4.9 million increase in research and development expenses, as discussed above, and $1.3 million increase in general and administrative expenses, as discussed above. Basic and diluted net loss per share was $0.98 and $1.25 for the three months ended March 31, 2026 and 2025, based on 20,106,925 and 10,514,901 weighted average common shares outstanding, respectively.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 24,988	$ 15,858
Short-term investments	57,005	82,478
Prepaid expenses and other current assets	6,685	6,913
Restricted cash, current portion	147	37
Total current assets	88,825	105,286
Property and equipment, net	375	460
Goodwill	10,502	10,502
Restricted cash, net of current portion	183	210
Total assets	$ 99,885	$ 116,458
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 356	$ 137
Accrued expenses and other current liabilities	11,243	12,803
Total current liabilities	11,599	12,940
Royalty obligation	2,000	2,000
Deferred tax liability, net	446	434
Derivative liability, non-current	17,520	18,000
Other long-term liabilities	—	35
Total liabilities	31,565	33,409
Mezzanine equity:		
Series D Preferred Stock—$0.001 par value; 1 share of Series D Preferred Stock authorized at March 31, 2026 and December 31, 2025; 1 share of Series D Preferred Stock issued and outstanding at March 31, 2026 and December 31, 2025	—	—
Series E Preferred Stock—$0.001 par value; 1 share of Series E Preferred Stock authorized at March 31, 2026 and December 31, 2025; 1 share of Series E Preferred Stock issued and outstanding at March 31, 2026 and December 31, 2025	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at March 31, 2026 and December 31, 2025; 24,637,807 and 18,512,757 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	25	18
Series C Preferred Stock—$0.001 par value; 34,326 shares of Series C Preferred Stock authorized at March 31, 2026 and December 31, 2025; 13,036 and 18,792 shares of Series C Preferred Stock issued and outstanding at March 31, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	536,453	531,485
Accumulated other comprehensive (loss) income	(6)	68
Accumulated deficit	(468,152)	(448,522)
Total stockholders' equity	68,320	83,049
Total liabilities, mezzanine equity and stockholders' equity	$ 99,885	$ 116,458

The consolidated balance sheets as of March 31, 2026 and December 31, 2025 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,	
	2026	**2025**
Operating expenses:		
Research and development	14,047	9,123
General and administrative	6,854	5,546
Total operating expenses	20,901	14,669
Loss from operations	(20,901)	(14,669)
Other income:		
Change in fair value of derivative liability	480	380
Interest income, net	803	1,148
Total other income, net	1,283	1,528
Loss before taxes	(19,618)	(13,141)
Income tax expense	12	8
Net loss	$ (19,630)	$ (13,149)
Net loss per share of common stock, basic and diluted	$ (0.98)	$ (1.25)
Weighted average common shares outstanding	20,106,925	10,514,901

The consolidated statements of operations for the three months ended March 31, 2026 and 2025 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, abdakibart, is an anti-IL-1β monoclonal antibody (mAb). Positive topline data was recently reported for abdakibart in a Phase 2 clinical trial in 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 Abdakibart

Abdakibart 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 was a randomized, double-blind, placebo-controlled, parallel-group Phase 2 trial with two dose regimens to evaluate the efficacy, safety and tolerability of abdakibart in approximately 250 adults with moderate to severe hidradenitis suppurativa. Subjects were randomized (1:1:1) to receive either one of two dosing regimens of abdakibart 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 tunnel 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 includes forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995 and other federal securities laws. 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 our control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to our 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: therapeutic

potential, clinical benefits and safety profiles of abdakibart (AVTX-009); plans to advance abdakibart into a registrational phase 3 program; expectations regarding timing, success and data announcements of ongoing preclinical studies and clinical trials; drug development costs, reliance on investigators and enrollment of patients in clinical trials; and our plans to develop and commercialize our current and any future product candidates and the implementation of our business model and strategic plans for our business.

Any forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements including, without limitation, risks associated with: the timing and anticipated results of our current and future preclinical studies and clinical trials, supply chain, strategy and future operations; the delay of any current and future preclinical studies or clinical trials or the development of our product candidates; the risk that the results of prior preclinical studies and clinical trials may not be predictive of future results in connection with current or future preclinical studies and clinical trials, including those for abdakibart; the risk that cross-trial comparisons may not be reliable as no head-to-head trials of abdakibart have been conducted; the timing and outcome of any interactions with regulatory authorities; obtaining, maintaining and protecting our intellectual property; the availability of funding sufficient for our operating expenses and capital expenditure requirements, 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 our filings with the Securities and Exchange Commission, available at www.sec.gov. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. In addition, any forward-looking statements represent our view only as of today and should not be relied upon as representing its views as of any subsequent date. You should not rely upon forward-looking statements as predictions of future events and actual results or events could differ materially from the plans, intentions and expectations disclosed herein. Except as required by applicable law, we expressly disclaim any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our 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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