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, 2024

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 May 13, 2024, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 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 May 13, 2024.
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 13, 2024

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

Avalo Reports First Quarter 2024 Financial Results and Provides Business Updates

- *Topline results from planned Phase 2 trial of AVTX-009 in hidradenitis suppurativa expected in 2026*
- *Cash on hand of approximately $110 million as of March 31, 2024 with expected cash runway into 2027*

WAYNE, PA AND ROCKVILLE, MD, May 13, 2024 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and financial results for the first quarter of 2024.

"Over the past month we have made considerable progress toward initiating our planned Phase 2 trial of AVTX-009 in hidradenitis suppurativa. Our experienced team has been working closely with subject matter experts on trial enabling activities, and we plan to have the trial underway this year," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"Our main focus remains on the initiation of the Phase 2 trial in hidradenitis suppurativa. Upon trial initiation, we plan to expand our focus to include the evaluation and announcement of a second indication, as well as pursuing the development of a next generation anti-IL-1β mAb."*

Program Updates and Milestones:

- **AVTX-009: Anti-IL-1β monoclonal antibody (mAb) targeting inflammatory diseases.**
  - Avalo is pursuing the development of AVTX-009 in hidradenitis suppurativa and expects topline data from its planned Phase 2 trial in hidradenitis suppurativa in 2026.
  - In addition to hidradenitis suppurativa, Avalo plans to develop AVTX-009 in at least one other chronic inflammatory indication.

- **Next Generation anti-IL-1β mAb.**
  - Avalo is pursuing a next generation anti-IL-1β with an extended half-life.

- **Quisovalimab (AVTX-002): Anti-LIGHT mAb targeting immune-inflammatory diseases.**
  - Avalo is conducting a strategic review of the quisovalimab program.

- **AVTX-008: B and T Lymphocyte Attenuator (BTLA) agonist fusion protein targeting immune dysregulation disorders.**
  - Avalo is conducting a strategic review of the AVTX-008 program.

First Quarter 2024 Financial Update:

As of March 31, 2024, Avalo had $110.2 million in cash and cash equivalents. In March 2024, the Company closed a private placement investment for up to $185.0 million in gross proceeds, including an initial upfront gross investment of $115.6 million. The Company could receive up to an additional $69.4 million of gross proceeds upon the exercise of the warrants issued in the financing. The Company's current cash on hand is expected to fund operations through the data readout of our planned Phase 2 trial in hidradenitis suppurativa and into 2027.

For the three months ended March 31, 2024, Avalo generated a net loss of $121.3 million. The increase in net loss as compared to the prior period was primarily driven by the excess of warrant fair value over private placement proceeds. The warrants did not satisfy the conditions to be accounted for as an equity instrument and therefore were classified as a liability upon issuance. The initial fair value of the warrants at issuance was $194.9 million, which exceeded the upfront gross proceeds of $115.6 million, resulting in a $79.3 million loss recognized for the three months ended March 31, 2024. The fair value of the warrant liability was estimated using a Black-Scholes option-pricing model and the key variable input driving the fair value was the closing stock price of $21.75 on March 28, 2024, which was the initial valuation date, as well as the last trading day of the first quarter of 2024. Because the warrants are carried at fair value, future changes in fair value will be recognized in other (expense) income, net at each reporting period until the warrants are either exercised or expired. In addition, Avalo's acquisition of AlmataBio, Inc. was accounted for as an asset acquisition resulting in the recognition of $27.5 million of acquired in-process research and development ("IPR&D") expense. Finally, we recognized $9.2 million of private placement transaction expenses within other expense. Net loss per share of common stock decreased as a result of the increase in the shares outstanding from the first quarter of 2023, partially offset by the increase in net loss.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 110,177	$ 7,415
Other receivables	35	136
Prepaid expenses and other current assets	997	843
Restricted cash, current portion	4	1
Total current assets	111,213	8,395
Property and equipment, net	1,882	1,965
Goodwill	10,502	10,502
Restricted cash, net of current portion	131	131
Total assets	$ 123,728	$ 20,993
Liabilities, mezzanine equity and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 916	$ 446
Accrued expenses and other current liabilities	7,383	4,172
Warrant liability	194,901	—
Contingent consideration	12,500	—
Total current liabilities	215,700	4,618
Royalty obligation	2,000	2,000
Deferred tax liability, net	162	155
Derivative liability	5,670	5,550
Other long-term liabilities	1,281	1,366
Total liabilities	224,813	13,689
Mezzanine equity:		
Series C Preferred Stock—$0.001 par value; 34,326 and 0 shares of Series C Preferred Stock authorized at March 31, 2024 and December 31, 2023, respectively; 22,358 and 0 shares of Series C Preferred Stock issued and outstanding at March 31, 2024 and December 31, 2023, respectively	11,457	—
Series D Preferred Stock—$0.001 par value; 1 and 0 shares of Series D Preferred Stock authorized at March 31, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series D Preferred Stock issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Series E Preferred Stock—$0.001 par value; 1 and 0 shares of Series E Preferred Stock authorized at March 31, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series E Preferred Stock issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Stockholders' (deficit) equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 1,034,130 and 801,746 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	343,881	342,437
Accumulated deficit	(456,424)	(335,134)
Total stockholders' (deficit) equity	(112,542)	7,304
Total liabilities, mezzanine equity and stockholders' (deficit) equity	$ 123,728	$ 20,993

The consolidated balance sheets as of March 31, 2024 and December 31, 2023 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,	
	2024	2023
Revenues:		
Product revenue, net	$ —	$ 475
Total revenues, net	—	475
Operating expenses:		
Cost of product sales	(80)	551
Research and development	2,116	6,008
Acquired in-process research and development	27,538	—
General and administrative	3,193	2,708
Total operating expenses	32,767	9,267
	(32,767)	(8,792)
Other expense:		
Excess of warrant fair value over private placement proceeds	(79,276)	—
Private placement transaction costs	(9,220)	—
Change in fair value of derivative liability	(120)	(180)
Interest income, net	100	(949)
Other expense, net	—	(26)
Total other expense, net	(88,516)	(1,155)
Loss before taxes	(121,283)	(9,947)
Income tax expense	7	8
Net loss and comprehensive loss	$ (121,290)	$ (9,955)
Net loss per share of common stock, basic and diluted[1]	$ (141)	$ (204)

[1] Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-240 reverse stock split effected on December 28, 2023.

The unaudited consolidated statements of operations for the three months ended March 31, 2024 and 2023 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 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 quisovalimab (AVTX-002)

Quisovalimab is a fully human monoclonal antibody (mAb), directed against human LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with Herpes Virus **G**lycoprotein D for **H**erpesvirus Entry Mediator (HVEM), a receptor expressed by **T** lymphocytes). There is increasing evidence that the dysregulation of the LIGHT-signaling network which includes LIGHT, its receptors HVEM and LTβR and the downstream checkpoint BTLA, is a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders. Quisovalimab previously demonstrated proof of concept in COVID-19 induced acute

respiratory distress syndrome including reduction in mortality and respiratory failure, as well as a positive signal in patients with Crohn's Disease.

About AVTX-008

AVTX-008 is a fully human B and T Lymphocyte Attenuator (BTLA) agonist fusion protein in the IND-enabling stage. AVTX-008 is differentiated by having specific binding to BTLA, with no binding to LIGHT or CD160. AVTX-008 also has high-serum stability and solubility.

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. Avalo's pipeline also includes quisovalimab (anti-LIGHT mAb) and AVTX-008 (BTLA agonist fusion protein).

For more information about Avalo, please visit www.avalotx.com.

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: the intended use of the proceeds from the private placement; integration of AVTX-009 into our operations; drug development costs, timing of 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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