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 12, 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 August 12, 2024, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 12, 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: August 12, 2024

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

Avalo Reports Second Quarter 2024 Financial Results and Provides Business Updates

- *Expects to enroll first patient in Phase 2 LOTUS Trial of AVTX-009 in hidradenitis suppurativa in the second half of 2024*
- *Appointed Dr. Mittie Doyle as Chief Medical Officer and Paul Varki as Chief Legal Officer*
- *Cash on hand of approximately $93.4 million as of June 30, 2024 with expected cash runway into 2027*

WAYNE, PA AND ROCKVILLE, MD, August 12, 2024 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and financial results for the second quarter of 2024.

"The team has made outstanding progress in a short amount of time toward initiating the Phase 2 LOTUS Trial, as highlighted by the activation of the IND in July," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"Furthermore, the Company is immediately benefiting from the addition of Mittie and Paul to the leadership team as CMO and CLO, respectively. Their deep expertise and leadership experience will guide us as we focus on initiating the LOTUS Trial, as well as the evaluation and announcement of a second indication, both of which we believe are on track for the second half of the year."*

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 (HS).
  - In July 2024, Avalo announced that the Investigational New Drug Application (IND) for the treatment of HS is active, permitting Avalo to commence its Phase 2 LOTUS Trial in patients with HS.
  - Avalo expects to enroll the first patient in its global Phase 2 LOTUS Trial in the second half of 2024.
  - In addition to hidradenitis suppurativa, Avalo plans to develop AVTX-009 in at least one other chronic inflammatory indication.

Second Quarter 2024 Financial Update:

As of June 30, 2024, Avalo had $93.4 million in cash and cash equivalents. Net cash used in operating activities was $22.5 million for the six months ended June 30, 2024, which includes a $7.5 million milestone payment to AlmataBio, Inc. pursuant to the acquisition in the first quarter. The Company's current cash on hand is expected to fund operations into 2027.

For the six months ended June 30, 2024, Avalo generated a net loss of $22.8 million, representing a $4.7 million increase in net loss as compared to the same period in 2023. Total operating expenses increased by $25.3 million and was primarily driven by the recognition of $27.6 million of acquired in-process research and development ("IPR&D") expense from the acquisition of AlmataBio, Inc. in the first quarter of 2024. The increase in operating expenses was partially offset by a $21.7 million increase in other income, net which largely related to the loss associated with warrant liability from the private placement in the first quarter being more than offset by the warrant liability change in fair value in the second quarter. Net loss per share of common stock decreased as a result of the increase in the shares outstanding from the second quarter of 2023, partially offset by the increase in net loss.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 93,426	$ 7,415
Other receivables	33	136
Prepaid expenses and other current assets	2,435	843
Restricted cash, current portion	—	1
Total current assets	95,894	8,395
Property and equipment, net	1,780	1,965
Goodwill	10,502	10,502
Restricted cash, net of current portion	131	131
Total assets	$ 108,307	$ 20,993
Liabilities, mezzanine equity and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 654	$ 446
Accrued expenses and other current liabilities	7,888	4,172
Warrant liability	82,855	—
Contingent consideration	5,000	—
Total current liabilities	96,397	4,618
Royalty obligation	2,000	2,000
Deferred tax liability, net	168	155
Derivative liability	10,710	5,550
Other long-term liabilities	1,183	1,366
Total liabilities	110,458	13,689
Mezzanine equity:		
Series C Preferred Stock—$0.001 par value; 34,326 and 0 shares of Series C Preferred Stock authorized at June 30, 2024 and December 31, 2023, respectively; 22,358 and 0 shares of Series C Preferred Stock issued and outstanding at June 30, 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 June 30, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series D Preferred Stock issued and outstanding at June 30, 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 June 30, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series E Preferred Stock issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Stockholders' (deficit) equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at June 30, 2024 and December 31, 2023; 1,034,130 and 801,746 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	344,352	342,437
Accumulated deficit	(357,961)	(335,134)
Total stockholders' (deficit) equity	(13,608)	7,304
Total liabilities, mezzanine equity and stockholders' (deficit) equity	$ 108,307	$ 20,993

The consolidated balance sheets as of June 30, 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ —	$ 643	$ —	$
Total revenues, net	—	643	—	
Operating expenses:				
Cost of product sales	343	708	263	
Research and development	4,601	4,658	6,716	
Acquired in-process research and development	103	—	27,641	
General and administrative	4,528	2,427	7,721	
Total operating expenses	9,575	7,793	42,341	
	(9,575)	(7,150)	(42,341)	
Other income (expense):				
Excess of initial warrant fair value over private placement proceeds	—	—	(79,276)	
Change in fair value of warrant liability	112,046	—	112,046	
Private placement transaction costs	—	—	(9,220)	
Change in fair value of derivative liability	(5,040)	(40)	(5,160)	
Interest income (expense), net	1,039	(996)	1,138	
Other expense, net	—	—	—	
Total other income (expense), net	108,045	(1,036)	19,528	
Income (loss) before taxes	98,470	(8,186)	(22,813)	
Income tax expense	7	7	14	
Net income (loss)	$ 98,463	$ (8,193)	$ (22,827)	$
Net income (loss) per share of common stock[1]:				
Basic	$ 4.21	$ (140.73)	$ (24.11)	$
Diluted	$ (14.07)	$ (140.73)	$ (30.63)	$

[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 and six months ended June 30, 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 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 also has two additional drug candidates, which include quisovalimab (anti-LIGHT mAb) and AVTX-008 (BTLA agonist fusion protein). 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. The primary efficacy endpoint is the proportion of subjects achieving Hidradenitis Suppurativa Clinical Response (HiSCR75) at Week 16. Subjects will be randomized (1:1:1) to receive either one of two doses of AVTX-009 or placebo.

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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