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): November 7, 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 November 7, 2024, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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 November 7, 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: November 7, 2024

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

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Avalo Reports Third Quarter 2024 Financial Results and Recent Business Updates

- *Dosed first patient in Phase 2 LOTUS Trial of AVTX-009 for the treatment of hidradenitis suppurativa (HS), with topline data expected in 2026*
- *Cash position of approximately $82 million as of September 30, 2024 with subsequent receipt of approximately $58 million of warrant exercise proceeds in 4Q 2024, provides expected runway into at least 2027*

WAYNE, PA AND ROCKVILLE, MD, November 7, 2024 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), a clinical stage biotechnology company focused on the treatment of immune dysregulation, today announced business updates and financial results for the third quarter of 2024.

"We made significant progress in the third quarter and have dosed the first HS patient in our Phase 2 LOTUS trial of AVTX-009, a promising monoclonal antibody targeting interleukin-1β, a key player in inflammation. This achievement moves us closer to offering a vital new treatment for HS patients, with topline data anticipated in 2026. Our goal with the LOTUS trial is to showcase AVTX-009's potential as a leading treatment for HS due to its potency, specificity, and convenient dosing. We're committed to executing the trial effectively and exploring AVTX-009's broader applications for other immune-mediated diseases as we work toward the selection of our second indication," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board of Avalo Therapeutics.

Recent Corporate Highlights and Upcoming Anticipated Milestones:

- In October 2024, the first patient was dosed in the Phase 2 LOTUS trial for the treatment of HS.
  - The Phase 2 LOTUS trial is a global study in approximately 180 adults with HS to assess the efficacy and safety of convenient subcutaneous bi-weekly and monthly dosing regimens of AVTX-009, compared to placebo.
  - Topline data is expected in 2026.
- Avalo continues to evaluate AVTX-009 in additional immune-mediated diseases as it works toward the selection of a second indication.
- Subsequent to September 30, 2024 and through November 6, 2024, Avalo received $58.1 million from the exercise of warrants issued in the first quarter of 2024 private placement.

Third Quarter 2024 Financial Update:

- **Cash and cash equivalents** were $81.9 million as of September 30, 2024. Net cash used in operating activities was $34.0 million for the nine months ended September 30, 2024, which includes a $7.5 million milestone payment to AlmataBio, Inc. pursuant to the terms of the acquisition in the first quarter. Subsequent to September 30, 2024 and through November 6, 2024, Avalo received gross proceeds of $58.1 million pursuant to the exercise of 10,026,847 warrants which resulted in the issuance of 711,580 shares of common stock and 9,315.267 shares of preferred stock. Each share of preferred stock is convertible into 1,000 shares of common stock, subject to certain beneficial ownership limitations. The Company's current cash on hand is expected to fund operations into at least 2027.

- **Research and development expenses** were $9.5 million for the third quarter of 2024, an increase of $8.3 million compared to $1.2 million for the same period in 2023. This increase was primarily due to AVTX-009 LOTUS trial initiation and development costs.

- **General and administrative expenses** were $4.3 million for the third quarter of 2024, an increase of $1.8 million compared to $2.5 million for the same period in 2023. This increase was primarily driven by employee compensation costs, including stock-based compensation expense, as well as increased consulting, legal and other professional expenses following the acquisition and financing that took place in the first quarter of 2024.

- **Net income** was $23.0 million for the three months ended September 30, 2024 as compared to net loss of $5.2 million for the same period in 2023. The increase to net income was driven by a $37.4 million increase to other income, net which largely related to the change in the fair value of the warrant liability for the period, partially offset by increased operating expenses discussed above. Basic net income per share, based on 5,546,257 weighted average common shares, was $0.98 for the three months ended September 30, 2024 compared to a basic net loss per share of $26.83, based on 194,851 weighted average common shares outstanding, for the same period in 2023. Diluted net loss per share, based on 10,784,037 weighted average diluted common shares and which excludes the change in fair value of the warrant liability from diluted net loss, was $2.83 for the three months ended September 30, 2024 compared to $26.83, based on 194,851 weighted average diluted common shares outstanding, for the same period in 2023.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 81,858	$ 7,415
Other receivables	998	136
Prepaid expenses and other current assets	3,251	843
Restricted cash, current portion	41	1
Total current assets	86,148	8,395
Property and equipment, net	1,674	1,965
Goodwill	10,502	10,502
Restricted cash, net of current portion	131	131
Total assets	$ 98,455	$ 20,993
Liabilities, mezzanine equity and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,811	$ 446
Accrued expenses and other current liabilities	7,033	4,172
Warrant liability	46,830	—
Contingent consideration	5,000	—
Total current liabilities	60,674	4,618
Royalty obligation	2,000	2,000
Deferred tax liability, net	154	155
Derivative liability	11,810	5,550
Other long-term liabilities	1,083	1,366
Total liabilities	75,721	13,689
Mezzanine equity:		
Series C Preferred Stock—$0.001 par value; 34,326 and 0 shares of Series C Preferred Stock authorized at September 30, 2024 and December 31, 2023, respectively; 13,710 and 0 shares of Series C Preferred Stock issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1,658	—
Series D Preferred Stock—$0.001 par value; 1 and 0 shares of Series D Preferred Stock authorized at September 30, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series D Preferred Stock issued and outstanding at September 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 September 30, 2024 and December 31, 2023, respectively; 1 and 0 shares of Series E Preferred Stock issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 9,682,374 and 801,746 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	10	1
Additional paid-in capital	355,990	342,437
Accumulated deficit	(334,924)	(335,134)
Total stockholders' equity	21,076	7,304
Total liabilities, mezzanine equity and stockholders' equity	$ 98,455	$ 20,993

The consolidated balance sheets as of September 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 249	$ 236	$ 249	$
Total revenues, net	249	236	249	
Operating expenses:				
Cost of product sales	(714)	247	(453)	
Research and development	9,538	1,249	16,254	
Acquired in-process research and development	—	—	27,641	
General and administrative	4,286	2,490	12,008	
Total operating expenses	13,110	3,986	55,450	
Loss from operations	(12,861)	(3,750)	(55,201)	
Other income (expense):				
Excess of initial warrant fair value over private placement proceeds	—	—	(79,276)	
Change in fair value of warrant liability	36,025	—	148,071	
Private placement transaction costs	—	—	(9,220)	
Change in fair value of derivative liability	(1,100)	100	(6,260)	
Interest income (expense), net	964	(1,553)	2,101	
Other expense, net	(5)	(17)	(5)	
Total other income (expense), net	35,884	(1,470)	55,411	
Income (loss) before taxes	23,023	(5,220)	210	
Income tax (benefit) expense	(14)	8	—	
Net income (loss)	$ 23,037	$ (5,228)	$ 210	$
Net income (loss) per share of common stock[1]:				
Basic	$ 0.98	$ (26.83)	$ 0.01	$
Diluted	$ (2.83)	$ (26.83)	$ (22.63)	$

[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 nine months ended September 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. 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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