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): March 29, 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 March 29, 2024, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2023. 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 March 29, 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: March 29, 2024

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

Avalo Reports 2023 Financial Results and Provides Business Updates

- *Acquired AVTX-009, Phase-2 ready anti-IL-1β mAb, in March 2024*
- *Increased cash position with private placement financing in March 2024 providing up to $185 million, including initial upfront investment of $115.6 million*
- *Topline results from planned Phase 2 trial of AVTX-009 in hidradenitis suppurativa expected in 2026*
- *Expected cash runway into 2027*

WAYNE, PA AND ROCKVILLE, MD, March 29, 2024 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and year-end financial results 2023.

"We are very excited about the acquisition of AVTX-009 and concurrent financing of up to $185 million, $115.6 million of which we received upfront. The progress we made in 2023 to strengthen our balance sheet helped enable these transactions. I am proud of the team's efforts and continued dedication in executing our strategy focused on the treatment of inflammatory conditions," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"Our focus in 2024 is executing operationally on the development of AVTX-009 for the treatment of hidradenitis suppurativa. Our experienced team is ready to hit the ground running on progressing the drug candidate and is motivated by the potential of developing a meaningful treatment for patients suffering from hidradenitis suppurativa, many of whom are searching for improved treatment options."*

Corporate Updates

- On March 27, 2024, Avalo acquired AVTX-009, a Phase 2 ready anti-IL-1β mAb, through an acquisition of AlmataBio, Inc. The consideration included stock valued at $15 million, as well as a $7.5 million payment due upon closing of the private placement investment. Avalo is also required to pay development milestones to the former AlmataBio stockholders including $5 million due upon the first patient dosed in a Phase 2 trial in patients with hidradenitis suppurativa (HS) and $15 million due upon the first patient dosed in a Phase 3 trial, both of which are payable in cash, Avalo stock, or a combination thereof at the election of the former AlmataBio stockholders.

- On March 28, 2024, Avalo closed a private placement led by Commodore Capital and TCGX, with participation from BVF Partners, Deep Track Capital, OrbiMed, Petrichor, and RA Capital Management for gross proceeds of up to $185 million, including $115.6 million of initial upfront funding received at close. The upfront investment is expected to fund operations through Avalo's planned Phase 2 data readout in hidradenitis suppurativa and into 2027.

- As part of the private placement, the Company issued (i) an aggregate of $115.6 million of non-voting convertible preferred stock and (ii) warrants to purchase Avalo's common stock or an equivalent amount (as converted to common stock) of non-voting convertible preferred stock for an aggregate exercise price of $69.4 million. The warrants are exercisable for approximately $5.80 per underlying share of common stock until the earlier of five years from the date of issuance or 30 days after the public announcement of the first patient dosed in a Phase 2 trial of AVTX-009 in HS. On an as-converted basis and after accounting for the financing and acquisition (excluding the exercise of the warrants), the total number of shares of Avalo common stock outstanding would be approximately 23.4 million immediately after the closing of the transactions.

Program Updates and Milestones:

- **AVTX-009: Anti-IL-1β monoclonal antibody (mAb) targeting inflammatory diseases.**
  - Avalo intends to pursue 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 intends to develop AVTX-009 in at least one other chronic inflammatory indication.

- **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.

2023 Financial Update:

As of December 31, 2023, Avalo had $7.4 million in cash and cash equivalents. We raised approximately $46.2 million of net proceeds from equity financings in 2023 and fully retired our original $35 million of debt with principal payments of $21.2 million, inclusive of the full payoff of the loan in September 2023.

The decrease in net loss was primarily attributable to a $26.2 million decrease in operating expenses driven by significantly reduced research and development expenses and selling, general and administrative expenses partially offset by a decrease of $14.2 million in license and other revenue. The significant reduction of research and development expenses was driven by fewer development programs ongoing during 2023 (due to divestitures in both 2022 and 2023), the AVTX-002 trial reading out in June of 2023 with no new trials initiated in the second half of the year, and a reduction of manufacturing costs due to the timing of manufacturing runs. Selling, general and administrative expenses decreased due to a smaller infrastructure to support the focused pipeline, severance in 2022 that did not repeat, as well as cost savings initiatives. Net loss per share decreased as a result of the decrease in net loss and due to an increase in the shares outstanding.

In March 2024, we closed a private placement financing for gross upfront proceeds of $115.6 million. Avalo estimates upfront net proceeds of approximately $105 million after deducting estimated transaction fees and expenses from both the private placement financing and the acquisition of AlmataBio. We expect future research and development expenses and cash used in operating activities to increase in 2024 as a result of our development plans to initiate and progress a Phase 2 trial in hidradenitis suppurativa. Topline results from this planned Phase 2 trial are expected in 2026 and the upfront funding is expected to fund operations through this data readout and into 2027.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,415	$ 13,172
Other receivables	136	1,919
Inventory, net	—	20
Prepaid expenses and other current assets	843	1,290
Restricted cash, current portion	1	15
Total current assets	8,395	16,416
Property and equipment, net	1,965	2,411
Goodwill	10,502	14,409
Restricted cash, net of current portion	131	131
Total assets	$ 20,993	$ 33,367
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 446	$ 2,882
Deferred revenue	—	88
Accrued expenses and other current liabilities	4,172	13,214
Notes payable, current	—	5,930
Total current liabilities	4,618	22,114
Notes payable, non-current	—	13,486
Royalty obligation	2,000	2,000
Deferred tax liability, net	155	141
Derivative liability	5,550	4,830
Other long-term liabilities	1,366	1,711
Total liabilities	13,689	44,282
Stockholders' equity (deficit) :		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022; 801,746[1] and 39,294[1] shares issued and outstanding at December 31, 2023 and 2022, respectively	1	—
Additional paid-in capital[1]	342,437	292,909
Accumulated deficit	(335,134)	(303,824)
Total stockholders' equity (deficit)	7,304	(10,915)
Total liabilities and stockholders' equity (deficit)	$ 20,993	$ 33,367

[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 consolidated balance sheets as of December 31, 2023 and 2022 have been derived from the audited financial statements, 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)

	Year Ended December 31,	
	2023	2022
Revenues:		
Product revenue, net	$ 1,408	$ 3,364
License and other revenue	516	14,687
Total revenues, net	1,924	18,051
Operating expenses:		
Cost of product sales	1,284	3,434
Research and development	13,784	31,308
Selling, general and administrative	10,300	20,711
Goodwill impairment	3,907	—
Amortization expense	—	38
Total operating expenses	29,275	55,491
	(27,351)	(37,440)
Other expense:		
Interest expense, net	(3,417)	(4,170)
Change in fair value of derivative liability	(720)	—
Other expense, net	(42)	(20)
Total other expense, net	(4,179)	(4,190)
Loss before income taxes	(31,530)	(41,630)
Income tax expense	14	28
Net loss	$ (31,544)	$ (41,658)
Net loss per share of common stock, basic and diluted[1]	$ (114)	$ (1,063)

[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 consolidated statements of operations for the year ended December 31, 2023 and 2022 have been derived from the audited 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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