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 4, 2023

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 4, 2023, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 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 May 4, 2023.
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 4, 2023

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

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THERAPEUTICS

Avalo Reports First Quarter 2023 Financial Results and Provides Business Updates

- Topline data expected in the second quarter of 2023 from the Phase 2 PEAK Trial of AVTX-002 in non-eosinophilic asthma (NEA)
- Disclosed cash of approximately $16.7 million as of March 31, 2023

WAYNE, PA AND ROCKVILLE, MD, May 4, 2023 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and financial results for the first quarter of 2023.

"We made significant progress advancing our Phase 2 PEAK trial of AVTX-002 in patients with NEA and we are very excited to be on the cusp of the corresponding and potentially transformational topline data release," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"There is strong clinical evidence that cytokines regulated by decoy receptor 3 (DcR3): LIGHT (and its signaling network including BTLA), TL1A and FasL are key drivers of inflammatory diseases in the lung, gut and skin. We believe our upcoming data readout will validate the opportunity for AVTX-002 in NEA and support further development in eosinophilic asthma and COPD, as well as other chronic inflammatory diseases of the lung."*

Program Updates and Milestones:

- **AVTX-002:** Anti-LIGHT monoclonal antibody (mAb) targeting immune-inflammatory diseases.
  - NEA: Avalo has completed enrollment of the Phase 2 PEAK trial evaluating the safety and efficacy of AVTX-002 in 91 patients with NEA. Topline data expected in the second quarter of 2023.

- **AVTX-008:** B and T Lymphocyte Attenuator (BTLA) agonist fusion protein targeting immune dysregulation disorders.
  - Avalo identified a lead molecule and is currently evaluating several immune dysregulation disorders, with a target IND submission planned in 2024.

- **AVTX-803:** Fucose replacement for leukocyte adhesion deficiency type II (LAD II, also known as SLC35C1-CDG), a congenital disorder of glycosylation (CDG).
  - Timing of pivotal data from the pivotal LADDER trial evaluating the safety and efficacy of AVTX-803 in approximately 2 patients with LAD II is under evaluation.

First Quarter 2023 Financial Update:

Avalo had $16.7 million in cash and cash equivalents as of March 31, 2023, representing a $3.5 million increase compared to December 31, 2022. The increase was driven by $13.7 million of net proceeds from an equity financing offset by operating expenditures. Total operating expenses decreased $12.8 million for the three months ended March 31, 2023 as compared to the three months ended March 31, 2022. This decrease was primarily driven by decreases to both selling, general and administrative and research and development expenses as a result of cost savings initiatives implemented in the first quarter of 2022.

The net loss and net loss per share for the three months ended March 31, 2023 was largely driven by operating expenses.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 16,687	$ 13,172
Other receivables	857	1,919
Inventory, net	19	20
Prepaid expenses and other current assets	1,627	1,290
Restricted cash, current portion	63	15
Total current assets	19,253	16,416
Property and equipment, net	2,442	2,411
Goodwill	14,409	14,409
Restricted cash, net of current portion	131	131
Total assets	$ 36,235	$ 33,367
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,565	$ 2,882
Deferred revenue	111	88
Accrued expenses and other current liabilities	8,273	13,214
Notes payable, current	9,296	5,930
Total current liabilities	23,245	22,114
Notes payable, non-current	10,470	13,486
Royalty obligation	2,000	2,000
Deferred tax liability, net	148	141
Derivative liability	5,010	4,830
Other long-term liabilities	1,629	1,711
Total liabilities	42,502	44,282
Stockholders' deficit:		
Common stock—$0.001 par value; 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 13,200,535 and 9,430,535 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	13	9
Additional paid-in capital	307,499	292,900
Accumulated deficit	(313,779)	(303,824)
Total stockholders' deficit	(6,267)	(10,915)
Total liabilities and stockholders' deficit	$ 36,235	$ 33,367

The condensed consolidated balance sheets as of March 31, 2023 and December 31, 2022 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 (Unaudited)

(In thousands, except per share data)

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product revenue, net	$ 475	$ 1,173
Total revenues, net	475	1,173
Operating expenses:		
Cost of product sales	551	720
Research and development	6,008	9,584
Selling, general and administrative	2,708	11,684
Amortization expense	—	38
Total operating expenses	9,267	22,026
	(8,792)	(20,853)
Other expense:		
Interest expense, net	(949)	(1,169)
Change in fair value of derivative liability	(180)	—
Other expense, net	(26)	(20)
Total other expense, net	(1,155)	(1,189)
Loss before taxes	(9,947)	(22,042)
Income tax expense	8	9
Net loss and comprehensive loss	$ (9,955)	$ (22,051)
Net loss per share of common stock, basic and diluted [1]	$ (0.85)	$ (2.35)

[1] *Amounts for prior periods presented have been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022.*

The unaudited condensed consolidated statements of operations for the three months ended March 31, 2023 and 2022 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-002

AVTX-002, Avalo's lead development asset, 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, including NEA. AVTX-002 previously demonstrated proof of concept in COVID-19 induced acute respiratory distress syndrome including reduction in mortality and respiratory failure.

About AVTX-002 PEAK Trial

The Phase 2 PEAK Trial is a randomized, double-blind, placebo-controlled, parallel group trial designed to evaluate the safety and efficacy of AVTX-002 for the treatment of poorly controlled NEA (NCT05288504).

Following 12 weeks of treatment, the efficacy and safety of AVTX-002 will be evaluated compared with placebo. The primary endpoint is the proportion of patients who experience any of the following asthma-related events: (i) ≥6 additional reliever puffs of a short-acting beta-agonist (compared to baseline) in a 24-hour period on 2 consecutive days, or (ii) increase in inhaled corticosteroid dose ≥4 times than the dose at baseline, or (iii) a decrease in peak flow of 30% or more (compared to baseline) on 2 consecutive days of treatment, or (iv) an asthma exacerbation requiring the use of systemic corticosteroids (tablets, suspension, or injection) for at least 3 days, or (v) a hospitalization or emergency room visit because of an asthma exacerbation.

About Avalo Therapeutics

Avalo Therapeutics is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT network.

LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**erpesvirus Entry Mediator (HVEM), a receptor expressed by **T** lymphocytes; also referred to as TNFSF14) is an immunoregulatory cytokine. LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin β receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator (BTLA), and CD160 (the LIGHT-signaling network). Accumulating evidence points to the dysregulation of the LIGHT network as 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.

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: timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; the future financial and operational outlook; the development of product candidates or products; and other statements that are not historical. These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: Avalo's debt and cash position and the need for it to raise additional capital in the near future; the results of our clinical and pre-clinical studies; drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; reliance on key personnel; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and the war in Ukraine; and those other risks detailed in Avalo's filings with the SEC. 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.

For media and investor inquiries

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