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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 5, 2022**

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**AVALO THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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Delaware

(State or other jurisdiction of incorporation)

**001-37590**  
(Commission File Number)

**45-0705648**  
(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**

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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.

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**Item 2.02 Results of Operations and Financial Condition**

On May 5, 2022, Avalo Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2022. 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:

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release, dated May 5, 2022.</a>
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 5, 2022

By: /s/ Christopher Sullivan

Christopher Sullivan  
Chief Financial Officer



## Avalo Therapeutics First Quarter 2022 Financial Results and Business Updates

- Reaffirms milestone timing for Phase 2 clinical trial of AVTX-002 in non-eosinophilic asthma (NEA) and pivotal trial of AVTX-803 in leukocyte adhesion deficiency type II (LAD II)
- Executed workforce reduction to align with previously announced pipeline prioritization
- Disclosed cash and cash equivalents of \$38 million as of March 31, 2022

WAYNE, PA AND ROCKVILLE, MD, May 5, 2022 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and first quarter 2022 financial results.

*“The first quarter has been highly productive for the Avalo Therapeutics team. We executed our pipeline prioritization plan and right-sized the organization needed to deliver what we think will provide the greatest value for our shareholders,”* said Dr. Garry Neil, Chief Executive Officer of Avalo Therapeutics. *“We remain focused on driving our highest value programs forward to meet our timelines. These include our Phase 2 clinical trial of AVTX-002 in NEA and our pivotal trial of ATX-803 in LAD II. We have now initiated both programs, and we expect to dose our first patients in both studies in the second quarter, keeping the programs on track to meet our year-end data release milestones.”*

### Business Updates:

- The Company executed a reduction in workforce in March to align with its previously announced, focused pipeline. With these changes, the Company believes it will achieve substantial cost savings over time while creating a more appropriately sized workforce needed to successfully achieve the Company’s 2022 objectives, most notably obtaining and releasing data for its Phase 2 clinical trial of AVTX-002 in NEA and pivotal trial of AVTX-803 in LAD II. Headcount was reduced by approximately one third from December 31, 2021.

### Program Updates and Milestones:

- **AVTX-002:** Anti-LIGHT monoclonal antibody (mAb) targeting immune-inflammatory diseases.
  - **NEA:** The Company has initiated its Phase 2 randomized, double-blind, placebo-controlled clinical trial evaluating AVTX-002 in 80 patients with poorly controlled NEA. Top-line data from the trial are expected in the fourth quarter of 2022.
  - **IBD:** The Company continues to consider initiating a randomized, double-blind, placebo-controlled clinical study in moderate-to-severe refractory patients in inflammatory bowel disease (IBD).
- **AVTX-007:** Anti-IL-18 mAb targeting adult-onset Still’s disease (AOSD).
  - **AOSD:** The Company is evaluating AVTX-007 in a multicenter, Phase 1b study in 12 refractory or steroid-dependent patients with AOSD in two cohorts. Management is currently reviewing preliminary data and the path forward related to this indication. Top-line data are currently expected in 2023, which is subject to change and refinement pending finalization of the review.

- **AVTX-800 programs (AVTX-801 and AVTX-803):** Monosaccharide therapies for two congenital disorders of glycosylation (CDGs): leukocyte adhesion deficiency type II (LAD II, also known as SLC35C1-CDG) and PGM1-CDG.
  - **LAD II:** The Company has initiated a single-center (U.S.), double-blind (followed by an open-label extension) pivotal study of AVTX-803 in patients with LAD II. Data from this pivotal trial are expected in the fourth quarter of 2022.
  - **PGM1-CDG:** Avalo and the study sponsor remain in dialogue with the U.S. Food and Drug Administration (FDA) to align on a suitable clinical study design for AVTX-801 (PGM1-CDG). Pivotal trial data are expected in 2023. Avalo is currently working with the study sponsor to refine milestone timing.

#### **First Quarter 2022 Financial Update:**

As of March 31, 2022, Avalo had \$38.5 million in cash and cash equivalents, representing a \$16.1 million decrease as compared to December 31, 2021. The decrease was primarily driven by operating expenditures to fund and support pipeline development.

Total operating expenses decreased \$9.0 million for the three months ended March 31, 2022 as compared to the three months ended March 31, 2021. The decrease was mainly driven by a \$15.6 million decrease in research and development expenses. The decrease in research and development expenses was due to: 1) a \$10.0 million upfront license fee incurred in the first quarter of 2021, which did not repeat; and 2) a \$5.6 million reduction due to specific timing of manufacturing and clinical trial activities.

The decrease in operating expenses was partially offset by \$3.1 million of severance expense and \$4.3 million of non-cash stock-based compensation expense recognized in the first quarter of 2022 due to headcount reductions from the pipeline prioritization plan and the termination of employees prior to such plan. Most of these expenses were general and administrative, and they were the primary driver of the increase in general and administrative expenses period over period. The Company expects salary related expenses to decrease beginning in the second quarter as a result of the headcount reductions. The net loss and change in net loss was largely driven by operating expenses.

## Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	March 31, 2022 (unaudited) (a)	December 31, 2021 (a)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 38,469	\$ 54,585
Accounts receivable, net	938	1,060
Other receivables	1,445	3,739
Inventory, net	25	38
Prepaid expenses and other current assets	2,682	2,372
Restricted cash, current portion	100	51
Total current assets	43,659	61,845
Property and equipment, net	2,604	2,695
Other long-term asset	1,000	1,000
Intangible assets, net	—	38
Goodwill	14,409	14,409
Restricted cash, net of current portion	227	227
Total assets	\$ 61,899	\$ 80,214
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 3,757	\$ 3,369
Accrued expenses and other current liabilities	14,136	16,519
Total current liabilities	17,893	19,888
Notes payable	33,183	32,833
Royalty obligation	2,000	2,000
Deferred tax liability, net	122	113
Other long-term liabilities	2,358	2,298
Total liabilities	55,556	57,132
Stockholders' equity:		
Common stock—\$0.001 par value; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 112,794,203 shares issued and outstanding at March 31, 2022 and December 31, 2021	113	113
Additional paid-in capital	290,447	285,135
Accumulated deficit	(284,217)	(262,166)
Total stockholders' equity	6,343	23,082
Total liabilities and stockholders' equity	\$ 61,899	\$ 80,214

(a) The condensed consolidated balance sheets as of March 31, 2022 and December 31, 2021 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.

## Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended March 31,	
	2022 (a)	2021 (a)
Revenues:		
Product revenue, net	\$ 1,173	\$ 473
Total revenues, net	<u>1,173</u>	<u>473</u>
Operating expenses:		
Cost of product sales	720	77
Research and development	9,584	25,206
General and administrative	9,756	4,911
Sales and marketing	1,928	435
Amortization expense	38	424
Total operating expenses	<u>22,026</u>	<u>31,053</u>
	(20,853)	(30,580)
Other (expense) income:		
Other expense, net	(20)	—
Interest (expense) income, net	(1,169)	17
Total other (expense) income, net from continuing operations	<u>(1,189)</u>	<u>17</u>
Loss from continuing operations before taxes	(22,042)	(30,563)
Income tax expense	9	11
Loss from continuing operations	\$ (22,051)	\$ (30,574)
Loss from discontinued operations	—	(106)
Net loss	<u>\$ (22,051)</u>	<u>\$ (30,680)</u>
Net loss per share of common stock, basic and diluted:		
Continuing operations	\$ (0.20)	\$ (0.32)
Discontinued operations	0.00	0.00
Net loss per share of common stock, basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.32)</u>
Net loss per share of preferred stock, basic and diluted:		
Continuing operations		\$ (1.61)
Discontinued operations		(0.01)
Net loss per share of preferred stock, basic and diluted		<u>\$ (1.62)</u>

(a) The unaudited condensed consolidated statements of operations for the three months ended March 31, 2022 and 2021 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 leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology and rare genetic diseases. The Company has built a diverse portfolio of innovative therapies to deliver meaningful medical impact for patients in urgent need. The Company's clinical candidates commonly have a proven mechanistic rationale, biomarkers and/or an established proof-of-concept to expedite and increase the probability of success.

For more information about Avalo, please visit [www.avalotx.com](http://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 future financial and operational outlook; the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; 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 cash position and the potential need for it to raise additional capital; 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, including as a result of recent management changes; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and tensions 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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