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 3, 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 August 3, 2023, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 3, 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: August 3, 2023

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

Avalo Reports Second Quarter 2023 Financial Results and Provides Business Updates

- Announced AVTX-002 (quisovalimab) did not meet its primary endpoint in its Phase 2 PEAK Trial in non-eosinophilic asthma, however AVTX-002 significantly reduced serum LIGHT levels for study duration indicating strong target engagement
- Disclosed cash of approximately $6.3 million as of June 30, 2023

WAYNE, PA AND ROCKVILLE, MD, August 3, 2023 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and financial results for the second quarter of 2023.

"Although the PEAK trial did not meet its primary endpoint, mechanistically I believe AVTX-002 has promise in other inflammatory driven diseases including IBD and other diseases of the lung, gut and skin. Additionally, we believe an opportunity remains in asthma, particularly in a subset of patients with higher baseline LIGHT levels. We also have high confidence in our preclinical stage fully human BTLA agonist fusion protein (AVTX-008) to potentially treat a wide range of autoimmune diseases and are excited by the drug's novel mechanism of action and potential usage in patients not responsive to anti-TNF therapy," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"The team is working tirelessly to determine the best path forward for these assets, including indication selection and funding to support development."*

Corporate Updates:

- In June of 2023, Avalo prepaid $6 million of principal under its loan and security agreement. As of June 30, 2023, the remaining principal payments were $15.2 million.
- On July 20, 2023, Avalo entered into a forbearance agreement with its debt lenders, pursuant to which the parties agreed that an event of default had occurred due to a material adverse change in the Company's business and the lenders agreed to forbear from enforcing its full remedies, including acceleration of the amounts due, until August 15, 2023 or earlier triggering event.
- Avalo is considering out-licensing or sale of its non-core and potentially its core assets to increase focus and reduce future expenses. In July of 2023, Avalo entered into a non-binding letter of intent for the potential sale of AVTX-801 (D-galactose), AVTX-802 (D-mannose) and AVTX-803 (L-fucose).

Program Updates:

- **AVTX-002: Anti-LIGHT monoclonal antibody (mAb) targeting immune-inflammatory diseases.**
  - Avalo announced that its Phase 2 PEAK trial in patients with NEA did not meet its primary endpoint, measured by the proportion of patients who experienced an asthma-related event (ARE), however AVTX-002 demonstrated a significant and sustained reduction in LIGHT levels and a favorable safety and tolerability profile. Further, a preliminary post-hoc analyses for a sub-population of patients with baseline LIGHT levels over 125 pg/mL, which represented over 50% of patients, showed an approximately 50% reduction in AREs for patients treated with AVTX-002 compared to placebo.
  - Previously demonstrated AVTX-002 was statistically significant in reducing respiratory failure and mortality in patients hospitalized with COVID-19 ARDS in a randomized placebo-controlled trial. AVTX-002 also demonstrated positive trends in an open-label study in Crohn's Disease.
  - AVTX-002 showed a rapid and sustained reduction of LIGHT levels in all indications studied including COVID-19 ARDS, Crohn's Disease and NEA.
  - Avalo will continue to evaluate the topline results of the Phase 2 PEAK trial, while also pursuing funding for the program, to inform future development plans.

- **AVTX-008: B and T Lymphocyte Attenuator (BTLA) agonist fusion protein targeting immune dysregulation disorders.**
  - Avalo previously identified a lead molecule, is evaluating several immune dysregulation disorders to pursue and plans to rapidly progress the asset to IND, subject to funding.
- **AVTX-803: Fucose replacement for leukocyte adhesion deficiency type II (LAD II, also known as SLC35C1-CDG), a congenital disorder of glycosylation (CDG).**
  - In July of 2023, Avalo entered into a non-binding letter of intent for the potential sale of AVTX-801 (D-galactose), AVTX-802 (D-mannose) and AVTX-803 (L-fucose).

Second Quarter 2023 Financial Update:

Avalo had $6.3 million in cash and cash equivalents as of June 30, 2023, representing a $6.9 million decrease compared to December 31, 2022. The decrease was driven by operating expenditures to fund pipeline development and a $6 million partial prepayment under the loan and security agreement and were partially offset by $20.3 million of net proceeds from equity financings.

Total operating expenses decreased $17.8 million for the six months ended June 30, 2023 as compared to the same period in 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 and fewer programs ongoing in the current year.

The net loss and net loss per share for the three months ended June 30, 2023 was largely driven by operating expenses.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 6,307	$ 13,172
Accounts receivable	38	—
Other receivables	6	1,919
Inventory, net	18	20
Prepaid expenses and other current assets	1,135	1,290
Restricted cash, current portion	15	15
Total current assets	7,519	16,416
Property and equipment, net	2,176	2,411
Goodwill	14,409	14,409
Restricted cash, net of current portion	131	131
Total assets	$ 24,235	$ 33,367
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 751	$ 2,882
Deferred revenue	—	88
Accrued expenses and other current liabilities	7,588	13,214
Notes payable, current	14,115	5,930
Total current liabilities	22,454	22,114
Notes payable, non-current	—	13,486
Royalty obligation	2,000	2,000
Deferred tax liability, net	156	141
Derivative liability	5,050	4,830
Other long-term liabilities	1,544	1,711
Total liabilities	31,204	44,282
Stockholders' deficit:		
Common stock—$0.001 par value; 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 14,036,940 and 9,430,535 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	14	9
Additional paid-in capital	314,755	292,900
Accumulated deficit	(321,738)	(303,824)
Total stockholders' deficit	(6,969)	(10,915)
Total liabilities and stockholders' deficit	$ 24,235	$ 33,367

The condensed consolidated balance sheets as of June 30, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	$ 643	$ 1,033	$ 1,117	$ 2,20
Total revenues, net	643	1,033	1,117	2,20
Operating expenses:				
Cost of product sales	708	1,567	1,259	2,28
Research and development	4,658	8,510	10,667	18,09
Selling, general and administrative	2,427	2,784	5,134	14,46
Amortization expense	—	—	—	3
Total operating expenses	7,793	12,861	17,060	34,88
	(7,150)	(11,828)	(15,943)	(32,68
Other expense:				
Interest expense, net	(996)	(1,154)	(1,945)	(2,32
Change in fair value of derivative liability	(40)	—	(220)	-
Other expense, net	—	—	(25)	(2
Total other expense, net	(1,036)	(1,154)	(2,190)	(2,34
Loss before taxes	(8,186)	(12,982)	(18,133)	(35,02
Income tax expense	7	5	15	1
Net loss and comprehensive loss	$ (8,193)	$ (12,987)	$ (18,148)	$ (35,03
Net loss per share of common stock, basic and diluted[1]	$ (0.59)	$ (1.38)	$ (1.41)	$ (3.7

[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 and six months ended June 30, 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 (quisovalimab)

AVTX-002 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. AVTX-002 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 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.

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-signaling network.

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: the future financial and operational outlook; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; 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, including the risk that its lender will call the debt on or before the August 15, 2023 end of the current forbearance agreement; 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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