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

Exhibit No.	Description
99.1	Press Release, dated March 29, 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: March 29, 2023

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

Avalo Reports 2022 Financial Results and Provides Business Updates

- Completed enrollment of the Phase 2 PEAK Trial of AVTX-002 in non-eosinophilic asthma (NEA); topline data expected in the second quarter of 2023
- Disclosed cash of approximately $13 million as of December 31, 2022, non-inclusive of the February 2023 public offering
- Increased cash position with closing of public offering of common stock and warrants for gross proceeds of $15 million on February 7, 2023

WAYNE, PA AND ROCKVILLE, MD, March 29, 2023 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and year-end financial results for 2022.

"We made significant strategic and operational progress over the past year, by executing our goals of streamlining the pipeline to the most promising assets/trials, implementing corresponding infrastructure cost reductions, executing operationally and extending the cash runway through business development transactions," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. *"2023 will be a transformational year for Avalo as we look forward to our upcoming data readout of the Phase 2 PEAK trial of AVTX-002 in patients with NEA in the second quarter."*

Program Updates and Milestones:

- **AVTX-002:** Anti-LIGHT monoclonal antibody (mAb) targeting immune-inflammatory diseases.
  - NEA: Avalo 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.

2022 Financial Update:

Avalo had $13.2 million in cash and cash equivalents as of December 31, 2022, representing a $41.4 million decrease compared to December 31, 2021. The decrease was primarily driven by operating expenditures and a $15.0 million partial prepayment under its loan and security agreement, partially offset by $19.5 million of upfront payments received from out-license and business development activity. In February 2023, we closed an equity financing in which we raised approximately $13.7 million in net proceeds.

Total net revenues increased $12.7 million for the year ended December 31, 2022. The increase was driven by $14.5 million of upfront consideration received pursuant to the out-license of AVTX-007. Total operating expenses decreased $32.0 million for the year ended December 31, 2022, mainly driven by significantly reduced research and development expenses. Research and development expenses decreased $28.5 million as a result of our narrowed focus in 2022 on primarily progressing our lead development asset, AVTX-002, as opposed to the progression of multiple programs in 2021. We also recognized a $10.0 million upfront license

fee in 2021 for the AVTX-002 expanded indication license agreement that did not repeat in 2022. As a result of the focused pipeline, Avalo executed a cost reduction plan, including reducing its headcount and supporting infrastructure. Selling, general and administrative expenses decreased $3.9 million as a result, however, these decreases were partially offset by $6.7 million of severance and stock-based compensation expense from employee separations.

The net loss and net loss per share for the year ended December 31, 2022 was largely driven by operating expenses and partially offset by revenue from business development transactions.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 13,172	$ 54,585
Accounts receivable, net	—	1,060
Other receivables	1,919	3,739
Inventory, net	20	38
Prepaid expenses and other current assets	1,290	2,372
Restricted cash, current portion	15	51
Total current assets	16,416	61,845
Property and equipment, net	2,411	2,695
Other long-term asset	—	1,000
Intangible assets, net	—	38
Goodwill	14,409	14,409
Restricted cash, net of current portion	131	227
Total assets	$ 33,367	$ 80,214
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,882	$ 3,369
Deferred revenue	88	—
Accrued expenses and other current liabilities	13,214	16,519
Notes payable, current	5,930	—
Total current liabilities	22,114	19,888
Notes payable, non-current	13,486	32,833
Royalty obligation	2,000	2,000
Deferred tax liability, net	141	113
Derivative liability	4,830	—
Other long-term liabilities	1,711	2,298
Total liabilities	44,282	57,132
Stockholders' (deficit) equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 9,430,535 and 9,399,517 shares issued and outstanding at December 31, 2022 and 2021, respectively[1]	9	9
Additional paid-in capital[1]	292,900	285,239
Accumulated deficit	(303,824)	(262,166)
Total stockholders' (deficit) equity	(10,915)	23,082
Total liabilities and stockholders' (deficit) equity	$ 33,367	$ 80,214

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

The consolidated balance sheets as of December 31, 2022 and 2021 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,	
	2022	2021
Revenues:		
Product revenue, net	$ 3,364	$ 4,773
License and other revenue	14,687	625
Total revenues, net	18,051	5,398
Operating expenses:		
Cost of product sales	3,434	1,491
Research and development	31,308	59,835
Selling, general and administrative	20,711	24,658
Amortization expense	38	1,548
Total operating expenses	55,491	87,532
	(37,440)	(82,134)
Other expense:		
Interest expense, net	(4,170)	(2,391)
Other expense, net	(20)	(20)
Total other expense, net from continuing operations	(4,190)	(2,411)
Loss from continuing operations before income taxes	(41,630)	(84,545)
Income tax expense (benefit)	28	(196)
Loss from continuing operations	$ (41,658)	$ (84,349)
Loss from discontinued operations	—	(27)
Net loss	$ (41,658)	$ (84,376)
Net (loss) income per share of common stock, basic and diluted [1]:		
Continuing operations	$ (4.43)	$ (9.95)
Discontinued operations	—	0.00
Net loss per share of common stock, basic and diluted	$ (4.43)	$ (9.95)
Net (loss) income per share of preferred stock, basic and diluted [1]:		
Continuing operations		$ (4.15)
Discontinued operations		—
Net loss per share of preferred stock, basic and diluted		$ (4.15)

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

The consolidated statements of operations for the year ended December 31, 2022 and 2021 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-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: 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 debt and cash position and the need for it to raise additional capital in the near future; 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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