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 4, 2022

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 4, 2022, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 4, 2022.
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 4, 2022

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

Avalo Reports Second Quarter 2022 Financial Results and Provides Business Updates

- Transferred anti-IL 18 monoclonal antibody product (AVTX-007) to Apollo Therapeutics in July with the approximate $15 million of upfront payment received in August
- Dosed first patient in the Phase 2 PEAK Trial of its anti-LIGHT monoclonal antibody (AVTX-002) for the treatment of non-eosinophilic asthma (NEA)
- Dosed first patient in the Pivotal LADDER Trial of AVTX-803 for the treatment of Leukocyte Adhesion Deficiency Type II (LAD II)
- Disclosed cash and cash equivalents of $11 million as of June 30, 2022, which does not include the approximate $15 million received in August

WAYNE, PA AND ROCKVILLE, MD, August 4, 2022 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and financial results for the second quarter of 2022.

"We have made significant progress advancing our clinical trials while also securing critical nondilutive capital since our first quarter business update," said Dr. Garry Neil, President and Chief Executive Officer of Avalo Therapeutics. *"We are pleased to have enrolled the first patient in both our Phase 2 PEAK trial of AVTX-002 in NEA as well as our pivotal LADDER trial of ATX-803 in LAD II. Additionally, it's critically important that we secured approximately $15 million of initial consideration from our license and transfer of our AVTX-007 program. The transaction allows us to operationally and financially focus on our most promising programs, most notably AVTX-002."*

Business Updates:

- In July 2022, Avalo granted an exclusive license to Apollo Therapeutics Group Limited (Apollo) granting rights to Apollo to research, develop, manufacture and commercialize AVTX-007. The AVTX-007 program was originally licensed to Avalo by MedImmune Limited, a subsidiary of AstraZeneca plc, and such license was transferred to Apollo as part of the transaction.
  - Avalo received approximately $15 million of upfront consideration.
  - Avalo is also entitled to up to $74 million of milestone payments, as well as a royalty payment of a low single digit percentage of annual net sales.
- On July 7, 2022, Avalo effected a 1-for-12 reverse stock split to increase the per share price of its common stock to regain compliance with the listing requirements of the Nasdaq Capital Market. On July 22, 2022, the Company received written notification from Nasdaq that Avalo had regained compliance and that the matter is now closed.
- In June 2022, Avalo, prepaid $15 million under its loan venture loan and security agreement (the Loan Agreement), of which $14.8 million was applied to principal and the remainder applied to accrued interest. As of June 30, 2022, the remaining principal payments were $21.2 million.

Program Updates and Milestones:

- **AVTX-002:** Anti-LIGHT monoclonal antibody (mAb) targeting immune-inflammatory diseases.
  - NEA: Avalo has initiated its Phase 2 PEAK trial (A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of AVTX-002 for

the Treatment of **P**oorly Controlled Non-**E**osinophilic **A**sthma **K**) evaluating the safety and efficacy of AVTX-002 in 80 patients with poorly controlled NEA. The first patient was dosed in May 2022. Top-line data from the trial are expected in the first half of 2023.

- **AVTX-800 programs (AVTX-803 and AVTX-801):** 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: Avalo has initiated its pivotal LADDER trial (A Phase 3, Randomized, Double-blind, Two-period, Crossover, Withdrawal Study to Assess the Efficacy and Safety of AVTX-803 in Subjects with **L**eukocyte **A**dhesion **D**eficiency Type II (LA**D** II) **ER**) evaluating the safety and efficacy of AVTX-803 in patients with LAD II (n=2). The first patient was dosed in July 2022. Data from this pivotal trial are expected in the first half of 2023.
  - PGM1-CDG: Milestone timing and the development plan is under review as a result of recent feedback from the U.S. Food and Drug Administration (FDA).

Second Quarter 2022 Financial Update:

Avalo had $11.2 million in cash and cash equivalents as of June 30, 2022, representing a $43.4 million decrease as compared to December 31, 2021. The decrease was primarily driven by operating expenditures to fund and support pipeline development and a $15.0 million partial prepayment under the Loan Agreement. Subsequent to June 30, 2022, Avalo received the approximate $15 million of upfront payment from its transfer of AVTX-007.

Total operating expenses decreased $16.7 million for the six months ended June 30, 2022 as compared to the same period in 2021. Research and development expenses decreased $19.7 million due to a $10.0 million upfront license fee incurred in the first quarter of 2021, which did not repeat, and a $9.2 million reduction due to specific timing of manufacturing, non-clinical activities and clinical trial activities. Selling, general and administrative expenses increased $1.7 million mainly due to severance and stock-based compensation expense driven by headcount reductions from the pipeline prioritization plan announced in the first quarter of 2022 and other separations, partially offset by decreases to legal, consulting and marketing expenses from cost savings initiatives. Cost of product sales increased $2.1 million due to the net profit share of our non-core commercialized product, Millipred®, that began in the third quarter of 2021. Additionally, in the second quarter of 2022, we fully reserved the $1.0 million receivable due in December 2024 pursuant to the transition service agreement with the third party that previously managed Millipred®'s commercial operations. The net loss and change in net loss was largely driven by operating expenses.

Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share and per share data)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 11,249	$ 54,585
Accounts receivable, net	544	1,060
Other receivables	1,306	3,739
Inventory, net	23	38
Prepaid expenses and other current assets	1,885	2,372
Restricted cash, current portion	14	51
Total current assets	15,021	61,845
Property and equipment, net	2,567	2,695
Other long-term asset	—	1,000
Intangible assets, net	—	38
Goodwill	14,409	14,409
Restricted cash, net of current portion	227	227
Total assets	$ 32,224	$ 80,214
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 2,164	$ 3,369
Accrued expenses and other current liabilities	13,231	16,519
Total current liabilities	15,395	19,888
Notes payable, non-current	18,713	32,833
Royalty obligation	2,000	2,000
Deferred tax liability, net	128	113
Other long-term liabilities	1,939	2,298
Total liabilities	38,175	57,132
Stockholders' (deficit) equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 9,405,724 and 9,399,517 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively[1]	9	9
Additional paid-in capital[1]	291,244	285,239
Accumulated deficit	(297,204)	(262,166)
Total stockholders' (deficit) equity	(5,951)	23,082
Total liabilities and stockholders' (deficit) equity	$ 32,224	$ 80,214

[1] Results have been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022.

The unaudited condensed consolidated balance sheets as of June 30, 2022 and December 31, 2021 have been derived from the reviewed 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.

Condensed Consolidated Statements of Operations (Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 1,033	$ 2,730	$ 2,206	$ 3,204
License revenue	—	625	—	625
Total revenues, net	1,033	3,355	2,206	3,829
Operating expenses:				
Cost of product sales	1,567	83	2,286	159
Research and development	8,510	12,569	18,094	37,774
Selling, general and administrative	2,784	7,404	14,468	12,751
Amortization expense	—	428	38	853
Total operating expenses	12,861	20,484	34,886	51,537
	(11,828)	(17,129)	(32,680)	(47,708)
Other expense:				
Other expense, net	—	(5)	(20)	(5)
Interest expense, net	(1,154)	(239)	(2,323)	(222)
Total other expense, net from continuing operations	(1,154)	(244)	(2,343)	(227)
Loss from continuing operations before taxes	(12,982)	(17,373)	(35,023)	(47,935)
Income tax expense (benefit)	5	(199)	15	(188)
Loss from continuing operations	$ (12,987)	$ (17,174)	$ (35,038)	$ (47,747)
Income (loss) from discontinued operations	—	69	—	(38)
Net loss	$ (12,987)	$ (17,105)	$ (35,038)	$ (47,785)
Net loss per share of common stock, basic and diluted [1]:				
Continuing operations	$ (1.38)	$ (2.12)	$ (3.73)	$ (5.97)
Discontinued operations	0.00	0.01	0.00	0.00
Net loss per share of common stock, basic and diluted	$ (1.38)	$ (2.11)	$ (3.73)	$ (5.97)
Net loss per share of preferred stock, basic and diluted [1]:				
Continuing operations		$ (0.88)		$ (2.49)
Discontinued operations		0.00		0.00
Net loss per share of preferred stock, basic and diluted		$ (0.88)		$ (2.49)

[1] Results 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, 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.

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 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, 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

Christopher Sullivan, CFO
Avalo Therapeutics, Inc.
ir@avalotx.com
410-803-6793

or

Chris Brinzey
ICR Westwicke
Chris.brinzey@westwicke.com
339-970-2843