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 2, 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 March 2, 2022, Avalo Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2021. 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 2, 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: March 2, 2022

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

Avalo Therapeutics Reports 2021 Financial Results and Provides Business Updates

- **Dr. Garry Neil and Chris Sullivan promoted to Chief Executive Officer and Chief Financial Officer, respectively**
- **Announced plans to initiate a Phase 2 randomized, double-blind, placebo-controlled trial in moderate to severe Non-eosinophilic Asthma (NEA) patients. Topline data anticipated in the fourth quarter of 2022**
- **Pipeline optimized to focus on most promising candidates and indications**
- **Cash and cash equivalents of $54.6 million as of December 31, 2021**

WAYNE, Pa. and ROCKVILLE, Md., March 02, 2022 — Avalo Therapeutics, Inc. (Nasdaq: AVTX), a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet need in immunology and rare genetic diseases, today announced business updates and year-end financial results for 2021.

"2021 was an important year for Avalo in that the Company produced compelling data for AVTX-002 in both acute and chronic inflammatory diseases. Furthermore, it positioned the Company to launch a placebo-controlled trial in NEA (AVTX-002), as well as two rare disease pivotal trials in 2022," said Dr. Garry Neil, Chief Executive Officer of Avalo Therapeutics. *"We are focused on the operational execution of these programs and their corresponding milestones, which have great potential to drive shareholder value in the coming year. We believe the recent pipeline prioritization will allow for greater focus on these most promising programs while also allowing for a reduction in cash burn."*

Business Updates:

- Promoted Dr. Garry Neil to Chief Executive Officer and Chris Sullivan to Chief Financial Officer. Dr. Neil brings to this position extensive clinical development and leadership experience in the biopharmaceutical industry including his current role as Chairman of the Board for Arena Pharmaceuticals and prior senior positions in leading pharmaceutical companies including Johnson & Johnson, Merck and AstraZeneca. Mr. Sullivan brings strong financial leadership to Avalo from his prior senior level finance/accounting positions for various Nasdaq-listed life science companies and Ernst & Young.
- Appointed June Almenoff M.D., Ph.D., and Mitchell Chan to the Board of Directors. Dr. Almenoff brings close to 25 years of leadership experience focused on research and development and commercialization including her time as the President and Chief Medical Officer of Furiex Pharmaceuticals. Mr. Chan has more than 15 years of finance experience in the life sciences industry including his time as Chief Financial Officer of Viela Bio and senior financial positions at AstraZeneca and Genentech-Roche.
- Announced plans to conduct a new Phase 2 randomized, double-blind, placebo-controlled trial of AVTX-002 for the treatment of moderate to severe NEA; top-line data anticipated in the fourth quarter of 2022. NEA is subtype of asthma with a poor prognosis that encompasses approximately half of asthma patients. Biomarker data suggests that LIGHT plays a strong role in inflammation and airway remodeling in NEA and support the development of AVTX-002 for poorly controlled NEA patients.
- Optimized the pipeline, with Avalo winding down internal development efforts of AVTX-006 in lymphatic malformations and AVTX-007 for the treatment of multiple myeloma (as previously announced) while pausing current development efforts for AVTX-802 (MPI-CDG). We plan to pursue strategic alternatives

for AVTX-006. Avalo also intends to focus on placebo-controlled trials for AVTX-002 going forward, starting with NEA. We will therefore not be moving forward with the uncontrolled cohort of AVTX-002 in ulcerative colitis (UC) patients. Avalo will consider planning for a possible randomized, double-blind, placebo-controlled clinical study in moderate to severe refractory patients with inflammatory bowel disease.

- Presented data from Phase 1b, open-label, dose-escalation, signal-finding, multi-center study evaluated the safety, tolerability, pharmacokinetics, and short-term efficacy of AVTX-002 in adults with moderate to severe, active Crohn's disease (CD) who have previously failed anti-tumor necrosis factor alpha (anti-TNFα) treatment. Fifty percent (4/8 patients) demonstrated evidence of mucosal healing as determined by colonoscopy and adjudicated by a central reader with one patient achieving remission (SES-CD=0).

Program Updates and Milestones:

- **AVTX-002:** Anti-LIGHT monoclonal antibody (mAb) targeting immune-inflammatory diseases including Non-eosinophilic Asthma and inflammatory bowel disease (Crohn's disease and Ulcerative Colitis).
  - Non-eosinophilic Asthma: An investigational new drug (IND) application is active for AVTX-002 for the treatment of NEA and Avalo expects to initiate a Phase 2 randomized, double-blind, placebo-controlled Phase 2 clinical trial in 80 patients with poorly controlled NEA. Top-line data from the trial are currently expected in the fourth quarter of 2022.
  - Inflammatory Bowel Disease: Presented positive Phase 1b data in CD with efficacy signal demonstrated in heavily pre-treated patients supports further evaluation in inflammatory bowel disease patients' refractory to three or more treatments, including anti-TNFα and other biologics. As Avalo intends to focus on placebo-controlled trials for AVTX-002 going forward, we will not be moving forward with the uncontrolled cohort of AVTX-002 in UC patients. Avalo will consider planning for a possible randomized, double-blind, placebo-controlled clinical study in moderate to severe refractory patients in inflammatory bowel disease.

- **AVTX-007:** Anti-IL-18 mAb targeting adult-onset Still's disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA).
  - AOSD: AVTX-007 is being evaluated 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 currently expected in 2023, though this is subject to change and refinement pending finalization of the review.
  - Multiple Myeloma: Data from a multicenter, Phase 1b study in relapsed and refractory multiple myeloma patients indicated AVTX-007 was generally safe and well tolerated at doses up to 14mg/kg. Additionally, pharmacodynamic data indicate deep reductions in IL-18 levels occur withing 24-hours after dosing. However, as previously announced, due to a lack of efficacy signal Avalo is winding down internal development efforts in this indication.

- **AVTX-006:** Dual mTORc1/c2 small molecule inhibitor for lymphatic malformations.
  - As a result of a portfolio prioritization review, Avalo is winding down internal development of AVTX-006 and has decided to pursue strategic alternatives for this program.

- **AVTX-800 programs (AVTX-801, AVTX-802, and AVTX-803):** Therapeutic doses of monosaccharide therapies for congenital disorders of glycosylation (CDGs).
  - Avalo is in the process of initiating a single-center (US), double-blind (followed by an open-label extension) pivotal study of AVTX-803 in patients with leukocyte adhesion deficiency type II (LAD II) caused by loss-of-function mutation in the SLC35C1 gene, with pivotal trial data expected in the fourth quarter of 2022.
  - Avalo and the study sponsor remain in dialogue with the 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.
  - The Company is pausing internal development of AVTX-802 (MPI-CDG) at this time due to challenges with study feasibility.

2021 Financial Update:

As of December 31, 2021, Avalo had $54.6 million in cash and cash equivalents, representing a $35.7 million increase as compared to December 31, 2020. The increase was primarily driven by gross proceeds of approximately $72.2 million from underwritten public offerings and $35.0 million from a debt facility. Such increases were partially offset by operating expenditures, the majority of which were related to pipeline development.

Total operating expenses increased $8.0 million for the year ended December 31, 2021 as compared to the year ended December 31, 2020. The increase in operating expenses was largely driven by a $27.6 million increase in research and development expenses to support our maturing pipeline and a $4.4 million increase in general and administrative expenses, partially offset by a $25.5 million reduction in acquired in-process research and development expense as this charge in 2020 did not repeat.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 54,585	$ 18,919
Accounts receivable, net	1,060	2,177
Other receivables	3,739	2,208
Inventory, net	38	3
Prepaid expenses and other current assets	2,372	2,660
Restricted cash, current portion	51	38
Total current assets	61,845	26,005
Property and equipment, net	2,695	1,607
Other long-term asset	1,000	—
Intangible assets, net	38	1,585
Goodwill	14,409	14,409
Restricted cash, net of current portion	227	149
Total assets	$ 80,214	$ 43,755
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,369	$ 2,574
Accrued expenses and other current liabilities	16,519	11,310
Income taxes payable	—	—
Current liabilities of discontinued operations	—	1,341
Total current liabilities	19,888	15,225
Notes payable, net	32,833	—
Royalty obligation	2,000	2,000
Deferred tax liability, net	113	90
Other long-term liabilities	2,298	1,878
Total liabilities	57,132	19,193
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at December 31, 2021 and 2020; 112,794,203 and 75,004,127 shares issued and outstanding at December 31, 2021 and 2020, respectively	113	75
Preferred stock—$0.001 par value; 5,000,000 shares authorized at December 31, 2021 and 2020; 0 and 1,257,143 shares issued and outstanding at December 31, 2021 and 2020, respectively	—	1
Additional paid-in capital	285,135	202,276
Accumulated deficit	(262,166)	(177,790)
Total stockholders' equity	23,082	24,562
Total liabilities and stockholders' equity	$ 80,214	$ 43,755

The consolidated balance sheets as of December 31, 2021 and 2020 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,	
	2021	2020
Revenues:		
Product revenue, net	$ 4,773	$ 6,699
License revenue	625	—
Total revenues, net	5,398	6,699
Operating expenses:		
Cost of product sales	1,491	300
Research and development	59,835	32,193
Acquired in-process research and development	—	25,549
General and administrative	21,832	17,418
Sales and marketing	2,826	2,341
Amortization expense	1,548	1,741
Total operating expenses	87,532	79,542
	(82,134)	(72,843)
Other (expense) income:		
Change in fair value of Investment in Aytu	—	5,208
Other (expense) income, net	(20)	409
Interest (expense) income, net	(2,391)	49
Total other (expense) income, net from continuing operations	(2,411)	5,666
Loss from continuing operations before income taxes	(84,545)	(67,177)
Income tax benefit	(196)	(2,793)
Loss from continuing operations	$ (84,349)	$ (64,384)
(Loss) income from discontinued operations	(27)	884
Net loss	$ (84,376)	$ (63,500)
Net (loss) income per share of common stock, basic and diluted:		
Continuing operations	$ (0.83)	$ (0.87)
Discontinued operations	0.00	0.01
Net loss per share of common stock, basic and diluted	$ (0.83)	$ (0.86)
Net (loss) income per share of preferred stock, basic and diluted:		
Continuing operations	$ (4.15)	$ (4.38)
Discontinued operations	0.00	0.06
Net loss per share of preferred stock, basic and diluted	$ (4.15)	$ (4.32)

The consolidated statements of operations for the years ended December 31, 2021 and 2020 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 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: 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; Avalo's cash position and the potential need for it to raise additional capital; 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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