

**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): **November 10, 2022**

Avenue Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38114
(Commission File Number)

47-4113275
(IRS Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	ATXI	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).

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 November 10, 2022, Avenue Therapeutics, Inc. (the "Company" or "Avenue") issued a press release to provide a corporate update and to announce its financial results for the three months ended September 30, 2022. A copy of such press release is being furnished as Exhibit 99.1 to this report.

The information, including Exhibit 99.1, in this Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are furnished herewith:

Exhibit Number	Description
<u>99.1</u>	<u>Press release dated November 10, 2022</u>
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVENUE THERAPEUTICS, INC.

(Registrant)

Date: November 10, 2022

By: /s/ David Jin

David Jin

Interim Principal Financial Officer and Chief Operating Officer



Avenue Therapeutics Reports Third Quarter 2022 Financial Results and Recent Corporate Highlights

New York, NY – November 10, 2022 – Avenue Therapeutics, Inc. (Nasdaq: ATXI) (“Avenue” or the “Company”), a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of central nervous system diseases (“CNS”), today reported financial results and recent corporate highlights for the third quarter ended September 30, 2022.

“I am pleased that Avenue has achieved important financial milestones providing a path to continue developing drugs for central nervous system disorders. We recently had a collaborative meeting with the U.S. Food and Drug Administration (“FDA”) laying the foundation for conducting a study that could support NDA resubmission for IV Tramadol, and we also completed the acquisition of Baergic Bio, which added a novel clinical-stage anxiolytic and antiepileptic therapy to our portfolio,” said Alexandra MacLean, M.D., Avenue’s Chief Executive Officer.

Recent Corporate Highlights (for Third Quarter and Subsequent Events):

- In September 2022, Avenue received the official meeting minutes from the FDA regarding a meeting conducted on August 9, 2022, for IV Tramadol. At the meeting, Avenue presented a study design for a single safety clinical trial that Avenue believes could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to Avenue upon review of a more detailed study protocol. The Company intends to incorporate the FDA’s suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.
- Also in September 2022, Avenue effected a 1-for-15 reverse stock split and, in October 2022, closed a \$12 million underwritten public offering, to bring the Company in compliance with Nasdaq listing requirements. In October 2022, Avenue received correspondence from Nasdaq indicating that the Company had evidenced compliance with the Nasdaq Listing Rules and all other applicable criteria for continued listing on The Nasdaq Capital Market.
- Avenue received net proceeds from the offering of approximately \$10.4 million after deducting underwriting discounts and commissions and other expenses of the offering. In addition, concurrent with the closing of the offering, Avenue completed the buyout of a minority shareholder through the acquisition of their shares for \$3.0 million.
- In November 2022, Avenue completed the acquisition of Baergic Bio, Inc. (“Baergic”) through a Share Contribution Agreement with Fortress Biotech, Inc. (“Fortress”), an affiliate of Avenue. The acquisition provides Avenue with another clinical-stage CNS drug (“BAER-101”) that Avenue expects to develop for conditions with high unmet need, potentially including refractory epilepsies and panic disorders. BAER-101 is a novel oral small molecule selective GABA-A $\alpha 2/3$ receptor positive allosteric modulator originally developed at and licensed from AstraZeneca plc. BAER-101 has been shown to be safe with mild to moderate side effects in over 700 patients to-date.

Financial Results:

- **Cash Position:** As of September 30, 2022, Avenue’s cash and cash equivalents totaled \$0.2 million, compared to \$3.8 million at December 31, 2021, a decrease of \$3.6 million year-to-date. Subsequently, in October 2022, Avenue received net proceeds of approximately \$10.4 million upon the closing of its underwritten public offering.

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- **R&D Expenses:** Research and development expenses for the third quarter of 2022 were \$0.2 million, compared to \$0.3 million in the third quarter of 2021.
 - **G&A Expenses:** General and administrative expenses for the third quarter of 2022 were \$0.5 million, compared to \$0.6 million in the third quarter of 2021.
 - **Net Loss:** Net loss attributable to common stockholders for the third quarter of 2022 was \$0.7 million, or \$0.45 per share, compared to a net loss of \$0.9 million, or \$0.79 per share, in the third quarter of 2021.

About Avenue Therapeutics

Avenue Therapeutics, Inc. (Nasdaq: ATXI) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of central nervous system diseases. Avenue is headquartered in New York City and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.avenuetx.com.

Forward-Looking Statements

This press release contains predictive or “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of current or historical fact contained in this press release, including statements that express our intentions, plans, objectives, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “should,” “would” and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in, or implied by, the forward-looking statements due to numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from: expectations for increases or decreases in expenses; expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidate or any other products we may acquire or in-license; our use of clinical research centers and other contractors; expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities; expectations for generating revenue or becoming profitable on a sustained basis; expectations or ability to enter into marketing and other partnership agreements; expectations or ability to enter into product acquisition and in-licensing transactions; expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidate; acceptance of our products by doctors, patients or payors; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our products; estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments; the volatility of our stock price; expected losses expectations for future capital requirements; ability to successfully integrate Baergic Bio in the Company’s operations; and those risks discussed in our filings which we make with the SEC. Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this press release, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

Contact:
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AVENUE THERAPEUTICS, INC.
Condensed Balance Sheets
(\$ in thousands, except for share and per share amounts)

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 217	\$ 3,763
Other receivables - related party	–	90
Deferred financing costs	338	–
Prepaid expenses and other current assets	20	107
Total Assets	\$ 575	\$ 3,960
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 573	\$ 451
Accounts payable and accrued expenses – related party	41	58
Total current liabilities	614	509
Total Liabilities	\$ 614	\$ 509
Commitments and contingencies		
Stockholders' Equity (Deficit)		
Preferred Stock (\$0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 shares issued and outstanding as of September 30, 2022 and December 31, 2021	–	–
Common Stock (\$0.0001 par value), 20,000,000 shares authorized		
Common shares, 1,481,439 and 1,405,934 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	–	2
Additional paid-in-capital	81,087	80,448
Accumulated deficit	(81,126)	(76,999)
Total Stockholders' Equity (Deficit)	(39)	3,451
Total Liabilities and Stockholders' Equity (Deficit)	\$ 575	\$ 3,960

AVENUE THERAPEUTICS, INC.
Condensed Statements of Operations
(\$ in thousands, except for share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating Expenses				
Research and development	\$ 194	\$ 278	\$ 2,153	\$ 864
General and administrative	469	594	1,978	1,960
Loss from operations	(663)	(872)	(4,131)	(2,824)
Interest income	(1)	(1)	(4)	(6)
Net Loss	\$ (662)	\$ (871)	\$ (4,127)	\$ (2,818)
Net loss per common share outstanding, basic and diluted	\$ (0.45)	\$ (0.79)	\$ (2.86)	\$ (2.55)
Weighted average common shares outstanding, basic and diluted	1,465,691	1,108,495	1,441,542	1,105,352