

**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 30, 2023**

**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.)

**1111 Kane Concourse, Suite 301  
Bay Harbor Islands, Florida 33154**  
(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:

<u>Title of Class</u>	<u>Trading Symbol(s)</u>	<u>Exchange Name</u>
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 March 30, 2023, Avenue Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the three months and full year ended December 31, 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:

<u>Exhibit Number</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press release dated March 30, 2023</a>
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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**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.

Date: March 30, 2023

**AVENUE THERAPEUTICS, INC.**  
(Registrant)

By: /s/ David Jin  
David Jin  
Interim Principal Financial Officer and  
Chief Operating Officer

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### Avenue Therapeutics Reports Full Year 2022 Financial Results and Recent Corporate Highlights

**Miami, FL – March 30, 2023** – 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 rare and neurologic diseases, today reported financial results and recent corporate highlights for the year ended December 31, 2022.

“Avenue has transformed into a neuro-focused specialty pharmaceutical company with the in-licensing of AJ201, a first in class small molecule in an ongoing Phase 1b/2a clinical trial for the treatment of Spinal and Bulbar Muscular Atrophy (“SBMA”), also known as Kennedy’s Disease, a rare debilitating neurologic disease. This asset joins BAER-101, also acquired in 2022, and IV Tramadol in our clinical-stage pipeline,” said Alexandra MacLean, M.D., Avenue’s Chief Executive Officer. “In 2023, we look forward to providing updates on AJ201’s clinical progress in its SBMA trial, our collaborative discussions with the U.S. Food and Drug Administration (“FDA”) regarding IV Tramadol to treat post-operative pain, and the continued development of BAER-101 for epilepsy and acute anxiety. With this foundational portfolio, we believe Avenue will build value for our investors and has the potential to provide impactful therapies to treat patients with rare and neurologic diseases.”

#### Recent Corporate Highlights:

##### AJ201

- In March 2023, Avenue announced that it entered into an exclusive license agreement with AnnJi Pharmaceutical Co., Ltd., to acquire rights to AJ201, a first-in-class clinical asset in a Phase 1b/2a study in the U.S. for the treatment of SBMA, which currently has no FDA approved therapy. AJ201 completed a Phase 1 clinical trial in 2021, which demonstrated the safety of the molecule. The Phase 1b/2a multicenter, randomized, double-blind clinical trial is being conducted in six clinical sites across the U.S., and screening of patients with SBMA has begun. This study aims to evaluate the safety and clinical response of AJ201 in patients suffering from SBMA. AJ201 has been granted Orphan Drug Designation (“ODD”) by the FDA for the indications of SBMA, Huntington’s Disease and Spinocerebellar Ataxia.

##### IV Tramadol

- In September 2022, Avenue received the official meeting minutes from the FDA regarding a meeting conducted in August 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 appeared 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. Avenue incorporated the FDA’s suggestions from the meeting minutes and submitted 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. In March 2023, Avenue participated in a Type C meeting with the FDA to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV Tramadol relative to an approved opioid analgesic. The Company expects to provide an update on the outcome of the meeting in April 2023, after receipt of the meeting minutes from the FDA.

#### General Corporate

- In September 2022, Avenue effected a 1-for-15 reverse stock split to bring the company in compliance with the minimum bid price listing requirements of the Nasdaq Capital Market.
- In October 2022, Avenue closed a \$12 million underwritten public offering. Avenue received net proceeds of approximately \$10.4 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.
- In November 2022, Avenue announced the completion of the acquisition of Baergic Bio, Inc. from Fortress Biotech, Inc., pursuant to a Share Contribution Agreement.
- In January 2023, Avenue completed a registered direct offering and concurrent private placement to an institutional accredited investor priced at the market under Nasdaq rules for total gross proceeds of approximately \$3.25 million. Avenue received net proceeds of approximately \$2.8 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.
- In March 2023, Alexandra MacLean, M.D., Chief Executive Officer of Avenue, was appointed to Avenue’s Board of Directors. In addition, Jay Kranzler, M.D., Ph.D., a current Director of Avenue, was appointed as the Chairman of Avenue. Lindsay Rosenwald, M.D., will remain a Director of Avenue.

#### 2022 Financial Results:

- **Cash Position:** As of December 31, 2022, our cash and cash equivalents totaled \$6.7 million, compared to \$3.8 million at December 31, 2021, an increase of \$2.9 million.
- **R&D Expenses:** Research and development expenses for the full year 2022 were \$2.7 million, compared to \$1.3 million in 2021.
- **G&A Expenses:** General and administrative expenses for the full year 2022 were \$5.3 million, compared to \$2.5 million in 2021.
- **Net Loss:** Net loss attributable to common stockholders for the full year 2022 was \$3.6 million, or \$1.63 per share, compared to a net loss of \$3.7 million, or \$3.29 per share, in 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 neurologic and rare diseases. It is currently developing three assets including AJ201, a first-in-class asset for spinal and bulbar muscular atrophy, BAER-101, an oral small molecule selective GABA-A  $\alpha 2/3$  receptor positive allosteric modulator for CNS diseases, and IV Tramadol, which is in Phase 3 clinical development for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting. Avenue is headquartered in Miami, FL and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit [www.avenuetx.com](http://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 candidates; 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; 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.**  
**Consolidated Balance Sheets**  
(\$ in thousands, except for share and per share amounts)

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 6,708	\$ 3,763
Other receivables - related party	—	90
Prepaid expenses and other current assets	137	107
<b>Total Assets</b>	<b>\$ 6,845</b>	<b>\$ 3,960</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 949	\$ 451
Accounts payable and accrued expenses - related party	21	58
Warrant liability	2,609	—
Total current liabilities	3,579	509
<b>Total Liabilities</b>	<b>3,579</b>	<b>509</b>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
<b>Preferred Stock (\$0.0001 par value), 2,000,000 shares authorized</b>		
Class A Preferred Stock, 250,000 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
<b>Common Stock (\$0.0001 par value), 20,000,000 shares authorized</b>		
Common shares, 4,773,841 and 1,405,959 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	84,456	80,450
Accumulated deficit	(80,551)	(76,999)
Total Stockholders' Equity attributed to the Company	3,905	3,451
Non-controlling interests	(639)	—
Total Stockholder's Equity	3,266	3,451
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 6,845</b>	<b>\$ 3,960</b>

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

	<b>For the Years Ended</b>	
	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Operating expenses:		
Research and development	\$ 2,698	\$ 1,254
General and administrative	5,345	2,484

Loss from operations	<u>(8,043)</u>	<u>(3,738)</u>
Interest income	(20)	(7)
Financing costs – warrant liabilities	1,160	—
Change in fair value of warrant liabilities	(5,580)	—
<b>Net Loss</b>	<b><u>\$ (3,603)</u></b>	<b><u>\$ (3,731)</u></b>
Net loss attributable to non-controlling interests	51	—
<b>Net loss attributable to common stockholders</b>	<b><u>\$ (3,552)</u></b>	<b><u>\$ (3,731)</u></b>
Net loss per common share attributable to common stockholders, basic and diluted	\$ (1.63)	\$ (3.29)
Weighted average number of common shares outstanding, basic and diluted	2,185,159	1,133,170

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