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 10, 2023**

Avenue Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38114**	**47-4113275**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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:

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 August 10, 2023, 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 June 30, 2023. 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
99.1	Press release dated August 10, 2023
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: August 10, 2023

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

Exhibit 99.1

Avenue Therapeutics Reports Second Quarter 2023 Financial Results and Recent Corporate Highlights

- First patient dosed in Phase 1b/2a clinical trial of AJ201; topline data anticipated in first half of 2024 -

- Positive BAER-101 preclinical data demonstrate excellent anti-seizure activity in translational animal model; Phase 2a trial in epilepsy planned to initiate in 2024 -

- Agreement reached with U.S. FDA on study design and analysis approach for Phase 3 safety study of IV tramadol -

Miami, FL – August 10, 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 neurologic diseases, today reported financial results and recent corporate highlights for the second quarter ended June 30, 2023.

"Avenue continues to make significant progress across our compelling pipeline of first- and best-in-class neurologic therapies for patients facing great unmet need," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue. "Recently, we advanced our lead product candidate AJ201 into the clinic, dosing the first patient in the Phase 1b/2a clinical trial for spinal and bulbar muscular atrophy ("SBMA"), a rare and devastating disease with no effective approved therapies. Additionally, we reported promising preclinical results for BAER-101 that show robust anti-seizure activity in a translational animal model of absence epilepsy. These results, combined with BAER-101's safety and tolerability profile in multiple clinical trials, demonstrate its potential to overcome treatment limitations of both current standard-of-care as well as investigational therapies in development, and we look forward to initiating a Phase 2a trial in 2024. Importantly, we also reached alignment with the U.S. Food and Drug Administration ("FDA") on the final Phase 3 safety study design for IV tramadol, a crucial milestone for the program as positive results have the potential to support the submission of a complete response to the second Complete Response Letter from the FDA and a subsequent U.S. approval. Pending additional financing, we aim to initiate this Phase 3 safety study shortly. We look forward to providing updates as we continue to advance these much-needed drugs for patients in the coming months, and execute on our mission of providing impactful therapies to patients suffering from neurologic diseases."

Recent Corporate Highlights:

AJ201

- In July 2023, the first patient was dosed in the Phase 1b/2a clinical trial of AJ201 for the treatment of SBMA, also known as Kennedy's Disease. The 12-week, multicenter, randomized, double-blind Phase 1b/2a clinical trial of AJ201 is expected to enroll approximately 24 patients, randomly assigned to AJ201 (600 mg/day) or placebo. Topline data for the Phase 1b/2a clinical trial of AJ201 in SBMA are expected in the first half of 2024. More information about this study can be found at ClinicalTrials.gov (Identifier: NCT05517603). Information on clinicaltrials.gov does not constitute part of this release.

BAER-101

- In August 2023, Avenue reported preclinical results for BAER-101, a potentially best-in-class selective GABA-A α2,3 positive allosteric modulator, demonstrating that it significantly suppressed seizures in a translational animal model of absence epilepsy. In an *in vivo* evaluation using the SynapCell's Genetic Absence Epilepsy Rat from Strasbourg ("GAERS") model of absence epilepsy, BAER-101 fully suppressed seizure activity with a minimal effective dose of 0.3 mg/kg, PO. The effect was fast in onset and stable throughout the duration of testing. The detailed preclinical results will be presented at an upcoming scientific meeting. The combination of safety and tolerability in hundreds of patients and the preclinical efficacy data support BAER-101's continued development in a Phase 2a trial, which the Company plans to initiate in 2024.

IV Tramadol

- In July 2023, Avenue reached an agreement with the FDA on the trial design and analysis approach of the Phase 3 safety study for intravenous ("IV") tramadol, which is in development for the treatment of acute post-operative pain in a medically supervised setting. The non-inferiority study is designed to assess the theoretical risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine. The study will randomize post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. Patients will have access to IV hydromorphone, a Schedule II opioid, for rescue of breakthrough pain. Avenue is submitting the revised protocol to the FDA including the statistical plan, which reflects the now agreed upon study design, for final review. Pending additional financing, Avenue aims to initiate the Phase 3 safety study as soon as feasible.

Financial Results:

- **Cash Position:** As of June 30, 2023, our cash and cash equivalents totaled $1.6 million, compared to $6.7 million at December 31, 2022, a decrease of $5.1 million.
- **R&D Expenses:** Research and development expenses for the second quarter of 2023 were $3.0 million, compared to $0.2 million for the second quarter of 2022.
- **G&A Expenses:** General and administrative expenses for the second quarter of 2023 were $0.9 million, compared to $0.5 million for the second quarter of 2022.
- **Net Loss:** Net loss attributable to common stockholders for the second quarter of 2023 was $4.0 million, or $0.52 per share, compared to a net loss of $0.6 million, or $0.41 per share, for the second quarter of 2022.

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 diseases. The Company 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 α2/3 receptor positive allosteric modulator for CNS diseases, and IV tramadol, which is in Phase 3 clinical development for the management of acute postoperative 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.

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.

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,571	$ 6,708
Other receivables - related party	26	—
Prepaid expenses and other current assets	69	137
Total assets	**$ 1,666**	**$ 6,845**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 886	$ 949
Accounts payable and accrued expenses - related party	54	21
Accrued licenses acquired	1,000	—
Warrant liability	5,872	2,609
Total current liabilities	7,812	3,579
Total liabilities	7,812	3,579
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 June 30, 2023 and December 31, 2022	—	—
Common stock ($0.0001 par value), 75,000,000 shares authorized		
Common shares, 7,920,485 and 4,773,841 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1	—
Additional paid-in capital	86,757	84,456
Accumulated deficit	(92,094)	(80,551)
Total stockholders' equity attributed to the Company	(5,336)	3,905
Non-controlling interests	(810)	(639)
Total stockholders' equity (deficit)	(6,146)	3,266
Total liabilities and stockholders' equity	**$ 1,666**	**$ 6,845**

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 3,027	$ 151	$ 4,242	$ 1,959
Research and development - licenses acquired	—	—	4,230	—
General and administrative	896	454	1,880	1,509
Loss from operations	(3,923)	(605)	(10,352)	(3,468)
Other income (expense)				
Interest income	57	1	94	3
Financing costs – warrant liabilities	—	—	(332)	—
Change in fair value of warrant liabilities	(150)	—	(1,028)	—
Total other income (expense)	(93)	1	(1,266)	3
Net loss	**$ (4,016)**	**$ (604)**	**$ (11,618)**	**$ (3,465)**
Net loss attributable to non-controlling interests	9	—	75	—
Net loss attributable to common stockholders	**$ (4,007)**	**$ (604)**	**$ (11,543)**	**$ (3,465)**
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.52)	$ (0.41)	$ (1.73)	$ (2.42)
Weighted average number of common shares outstanding, basic and diluted	7,758,153	1,461,067	6,667,550	1,429,283