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 9, 2024**

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 9, 2024, Avenue Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 30, 2024. A copy of such press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information, including Exhibit 99.1, in this Current Report on 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 Current Report on 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 9, 2024
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 9, 2024

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

Avenue Therapeutics Reports Second Quarter 2024 Financial Results and Recent Corporate Highlights

- Last patient visit complete in Phase 1b/2a clinical trial of AJ201 for spinal and bulbar muscular atrophy; topline data anticipated in second half of 2024

- Raised $4.4 million in gross proceeds from a May 2024 warrant exercise transaction -

Miami, FL – August 9, 2024 – 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, 2024.

"We continue to make meaningful progress advancing our pipeline of innovative treatments for neurologic diseases," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue. "In the second quarter, we completed the last patient visit in our Phase 1b/2a trial of AJ201 for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease. AJ201 is the most advanced investigational treatment in development for SBMA in the U.S., and we are pleased to reach this important milestone as we work to bring this novel asset to patients suffering from this rare neurodegenerative disease. We anticipate reading out topline data from our Phase 1b/2a trial of AJ201 in the second half of this year, and we remain focused on our goal of delivering this breakthrough treatment to SBMA patients who currently have no effective, approved therapeutic options."

Recent Corporate Highlights:

AJ201 *(Nrf1 and Nrf2 activator, androgen receptor degradation enhancer for SBMA)*

- In May 2024, Avenue announced the last patient visit was complete in the Phase 1b/2a clinical trial of AJ201 for the treatment of SBMA, marking the final clinical milestone ahead of the anticipated topline data announcement in the second half of 2024. The 12-week, multicenter, randomized, double-blind Phase 1b/2a clinical trial of AJ201 enrolled 25 patients randomly assigned to AJ201 (600 mg/day) or placebo. The primary endpoint of the study is to assess safety and tolerability of AJ201 in subjects with clinically and genetically defined SBMA. Secondary endpoints include pharmacokinetic and pharmacodynamic data measuring change from baseline in mutant AR protein levels in skeletal muscle and changes from baseline in expression of Nrf2-activated genes in skeletal muscle. Exploratory objectives of the study include changes in the fat and muscle composition as seen on MRI scans. These endpoints are believed to be biomarkers indicating likelihood for longer term clinical improvement. Further details about this study can be found at ClinicalTrials.gov (Identifier: NCT05517603).

BAER-101 *($GABA_A$ α2/3 positive allosteric modulator)*

- Subject to the receipt of additional financing, Avenue continues plans to initiate a Phase 2a clinical trial of BAER-101 in patients with focal epilepsy and other seizure disorders. Preclinical mouse models have demonstrated BAER-101 as a therapeutic with the ability to fully suppress seizure activity, with the effect being fast in onset and stable throughout the duration of testing. Data from these models were presented earlier this year at the American Society for Experimental Neurotherapeutics ("ASENT") 2024 Annual Meeting in March and also published in *Drug Development Research* in February.

IV Tramadol

- Earlier in 2024, Avenue reached final agreement with the U.S. Food and Drug Administration ("FDA") on the safety study protocol and statistical analysis approach for the Phase 3 study of intravenous ("IV") tramadol, which is being developed for the treatment of acute post-operative pain in a medically supervised setting. The proposed study will randomize approximately 300 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 aims to initiate the Phase 3 safety study pending additional financing or a partnership.

General Corporate

- In April, the Company raised $4.4 million in gross proceeds from a warrant exercise transaction, before deducting placement agent fees and other expenses payable by Avenue in connection with the transaction. Additionally, the Company effected a 1-for-75 reverse stock split of its issued and outstanding common stock effective April 26, 2024.
- In May 2024, the Company received formal notice from the Nasdaq Stock Market LLC that it evidenced compliance with all applicable criteria for continued listing on the Nasdaq Capital Market, concluding the previously disclosed listing matter.

Financial Results:

- **Cash Position:** As of June 30, 2024, cash and cash equivalents totaled $4.9 million, compared to $3.2 million at March 31, 2024 and $1.8 million at December 31, 2023, an increase of $1.7 million compared to the prior quarter and an increase of $3.1 million year-to-date.
- **R&D Expenses:** Research and development expenses for the second quarter of 2024 were $1.4 million, compared to $3.0 million for the second quarter of 2023.
- **G&A Expenses:** General and administrative expenses for the second quarter of 2024 were $1.5 million, compared to $0.9 million for the second quarter of 2023.
- **Net Loss:** Net loss attributable to common stockholders for the second quarter of 2024 was $2.7 million, or $6.43 per share, compared to a net loss of $4.0 million, or $38.74 per share, for the second quarter of 2023.

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. 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 $GABA_A$ α2, α3 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: the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized; the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates; our ability to successfully develop, partner, or commercialize any of our current or future product candidates including AJ201, IV tramadol, and BAER-101; the substantial doubt raised about our ability to continue as a going concern, which may hinder our ability to obtain future financing; the significant losses we have incurred since inception and our expectation that we will continue to incur losses for the foreseeable future; our need for substantial additional funding, which may not be available to us on acceptable terms, or at all, which unavailability of could force us to delay, reduce or eliminate our product development programs or commercialization efforts; our reliance on third parties for several aspects of our operations; our reliance on clinical data and results obtained by third parties that could ultimately prove to be inaccurate, or unreliable, or unacceptable to regulatory authorities; the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons; the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny; the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations; the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications; the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products; our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates; our exposure to potential product liability claims; related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products; our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business; the fact that Fortress Biotech, Inc. controls a majority of the voting power of our outstanding capital stock and has rights to receive significant share grants annually; 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.
Unaudited Condensed Consolidated Balance Sheets
($ in thousands, except for share and per share amounts)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,919	$ 1,783
Prepaid expenses and other current assets	69	67
Total assets	**$ 4,988**	**$ 1,850**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 714	$ 287
Accounts payable and accrued expenses - related party	400	323
Warrant liability	47	586
Total current liabilities	1,161	1,196
Total liabilities	**1,161**	**1,196**
Commitments and Contingencies		
Stockholders' equity		
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, 2024 and December 31, 2023	—	—
Common stock ($0.0001 par value) 200,000,000 and 75,000,000 shares authorized as of June 30, 2024 and December 31, 2023, respectively		
Common shares, 1,189,724 and 341,324 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	3
Additional paid-in capital	102,724	92,507
Accumulated deficit	(97,960)	(90,928)
Total stockholders' equity attributed to the Company	4,764	1,582
Non-controlling interests	(937)	(928)
Total stockholders' equity	3,827	654
Total liabilities and stockholders' equity	**$ 4,988**	**$ 1,850**

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 1,361	$ 3,027	$ 3,752	$ 4,242
Research and development - licenses acquired	—	—	—	4,230
General and administrative	1,462	896	2,778	1,880
Loss from operations	(2,823)	(3,923)	(6,530)	(10,352)
Other income (expense)				
Interest income	52	57	100	94
Financing costs – warrant liabilities	—	—	—	(332)
Loss on settlement of common stock warrant liabilities	(185)	—	(759)	—
Change in fair value of warrant liabilities	255	(150)	139	(1,028)
Total other income (expense)	122	(93)	(520)	(1,266)
Net loss	(2,701)	(4,016)	(7,050)	(11,618)
Net loss attributable to non-controlling interests	(9)	(9)	(18)	(75)
Net loss attributable to Avenue	$ (2,692)	$ (4,007)	$ (7,032)	$ (11,543)
Net loss attributable to common stockholders	$ (7,186)	$ (4,007)	$ (15,842)	$ (11,543)
Net loss per common share attributable to common stockholders, basic and diluted	$ (6.43)	$ (38.74)	$ (18.86)	$ (129.84)
Weighted average number of common shares outstanding, basic and diluted	1,117,769	103,442	839,900	88,901