

**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 26, 2024**

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.)
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**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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On November 26, 2024, Avenue Therapeutics, Inc. (the "Company") received a delist letter (the "Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC notifying the Company that it was not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(1). Nasdaq Listing Rule 5550(b)(1) requires companies listed on The Nasdaq Capital Market to maintain stockholders' equity of at least \$2,500,000 (the "Stockholders' Equity Requirement"). The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024 reported stockholders' equity of \$1,652,000.

In a decision dated June 3, 2024, a Nasdaq Hearings Panel (the "Panel") previously had confirmed that the Company regained compliance with the Stockholders' Equity Requirement. In the decision, the Panel imposed a Mandatory Panel Monitor for a period of one year or until May 21, 2025, which would require Staff to issue a Delist Determination Letter in the event that the Company failed to maintain compliance with the Stockholders' Equity Requirement (the "Panel Monitor"). Due to the Panel Monitor, the Company is not eligible to submit a plan to the Staff to request an extension of up to 180 calendar days in which to regain compliance with the Stockholders' Equity Requirement and as a result, the Staff has determined to delist the Company's securities from The Nasdaq Capital Market.

Neither the Letter nor the Company's noncompliance have an immediate effect on the listing or trading of the Company's common stock, which will continue to trade on The Nasdaq Capital Market under the symbol "ATXI."

Pursuant to the Letter, under Nasdaq Listing Rules, the Company may request a hearing before an independent Hearings Panel (the "Panel") by December 3, 2024. Accordingly, the Company intends to timely request a hearing before the Panel. The hearing request will stay any suspension or delisting action pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. While the Company's Form 10-Q reported stockholders' equity of \$1,652,000 as of September 30, 2024, as noted in Note 9 of the Form 10-Q, the Company believes that as of the date of the filing of the Form 10-Q, the Company had regained compliance with the \$2,500,000 stockholders' equity requirement. At the hearing, the Company intends to demonstrate its current compliance with the stockholders' equity requirement and its ability to sustain long term equity compliance.

Forward-Looking Statements

This Current Report on Form 8-K 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 Current Report on Form 8-K, 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 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, 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; our failure to satisfy applicable listing standards of the Nasdaq Capital Market resulting in a potential delisting of our common stock; 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 Current Report on Form 8-K, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

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 29, 2024

By: /s/ David Jin

David Jin

Interim Chief Financial Officer and Chief Operating Officer
