

**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): **May 19, 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:

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 May 19, 2023, Avenue Therapeutics, Inc. (the "Company") received a deficiency 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 March 31, 2023, reported stockholders' equity of negative \$2,157,000. The Letter further noted that as of the letter date, the Company did not have a market value of listed securities of \$35 million, or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, the alternative quantitative standards for continued listing on The Nasdaq Capital Market.

The Letter has no immediate effect on the Company's continued listing on the Nasdaq Capital Market, subject to the Company's compliance with the other continued listing requirements. In accordance with Nasdaq rules, the Company has been provided 45 calendar days, or until July 3, 2023, to submit a plan to regain compliance (the "Compliance Plan"). If the Compliance Plan is acceptable to the Staff, it may grant an extension of 180 calendar days from the date of the Letter. If the Staff does not accept the Compliance Plan, the Staff will provide written notification to the Company that the Compliance Plan has been rejected. At that time, the Company may appeal the Staff's determination to a Nasdaq Hearings Panel.

The Company intends to submit a Compliance Plan on or before July 3, 2023. Further, the Company intends to take all reasonable measures available to regain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq. However, there can be no assurance that Nasdaq will approve the Compliance Plan or that the Company will ultimately regain compliance with all applicable requirements for continued listing.

Neither the Nasdaq 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."

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: 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 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: May 22, 2023

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