

**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 2, 2022**

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.)

**1140 Avenue of the Americas, Floor 9
New York, New York 10036**
(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 Exchange 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).

Emerging growth company

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 8.01. Other Events

As previously disclosed, on February 15, 2022 the Company announced the outcome of the U.S. Food and Drug Administration joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee on the Company's New Drug Application for IV Tramadol. Avenue's management team, with the Avenue board of directors' approval, is currently exploring a range of strategic transaction options for the Company with the support of outside financial and legal advisors.

Importantly, any such transaction (if it includes an equity issuance, a "Strategic Transaction") would be subject to the prior written approval of InvaGen Pharmaceuticals Inc. ("InvaGen"), pursuant to one or more InvaGen consent rights under that certain Stockholders Agreement, dated as of November 12, 2018, by and among Avenue, InvaGen, and the other shareholders party thereto (the "Stockholders Agreement") and may in some cases be subject to InvaGen's agreement to terminate the Stockholders Agreement. If InvaGen withholds its consent with respect to all Strategic Transactions that the Company presents to InvaGen, the Company may not be able to consummate any such transaction, which would likely mean the Company would have to commence liquidation and wind-down of its operations in the very near future. Even if InvaGen does provide such consent with respect to a given Strategic Transaction, there can be no assurance that any such Strategic Transaction (or any other transaction involving Avenue) will ever be consummated, or that the terms upon which InvaGen may condition its approval would be acceptable to Avenue. Specifically, the completion of any such Strategic Transaction could be conditioned upon or adversely affected by numerous other factors, including without limitation: Avenue's cash on hand and the availability of other resources, the status of de-listing discussions with Nasdaq, the ability of Avenue and its potential counterparties to perform satisfactory due diligence in a timely manner, as well as possible Company-level and third-party approvals.

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

On March 2, 2022, Avenue Therapeutics, Inc. (the "Company" or "Avenue"), received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") which indicated that the Company's listed securities had not regained compliance with the minimum market value of listed securities of \$35,000,000 (the "MVLS Requirement") during the cure period afforded to it by Nasdaq. This deficiency was previously reported by the Company on a Current Report on Form 8-K on September 3,

2021.

Due to the deficiency, the Company's securities would be delisted from Nasdaq on March 11, 2022 unless the Company appeals Nasdaq's determination to a Hearings Panel (the "Panel"), which the Company intends to do on March 9, 2022. A hearing request will stay the suspension of the Company's securities pending the Panel's decision.

Additionally, as previously disclosed, the Company received a delinquency notification letter from Nasdaq which indicated that the Company was not in compliance with Nasdaq rules that require listed securities to maintain a closing bid price of at least \$1.00 per share. The Company was afforded a grace period of 180 calendar days to regain compliance. The grace period is set to expire on August 8, 2022. As of the date of this Current Report on Form 8-K, the Company has not been able to maintain a minimum closing bid price and as such is not in compliance with Nasdaq Listing Rule 5550(a)(2).

The Company intends to monitor its MVLS and the closing bid price of its common stock, and consider its available options to resolve the noncompliance with the MVLS Requirement and the noncompliance with the minimum bid price requirement.

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 8, 2022

AVENUE THERAPEUTICS, INC.
(Registrant)

By: /s/ Lucy Lu, M.D.
Name: Lucy Lu, M.D.
Title: President, Chief Executive Officer, and Interim Chief Financial Officer
