

**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 18, 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.

On March 18, 2022, Avenue Therapeutics, Inc. (the "Company" or "Avenue"), received an Appeal Denied Letter from the Office of New Drugs of the Food and Drug Administration (the "FDA") in Response to its Formal Dispute Resolution Request submitted in August 2021 with respect to the Complete Response Letters previously issued by the FDA to Avenue related to its intravenous ("IV") tramadol New Drug Application. The Company is evaluating the next steps with regard to IV tramadol.

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: March 21, 2022

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