
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): **October 21, 2021**

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:

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

- 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.

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 October 25, 2021, Avenue Therapeutics, Inc. ("Avenue"), announced that it has received a written interim response from the Office of New Drugs ("OND") of the U.S. Food and Drug Administration ("FDA") with regard to the Formal Dispute Resolution Request ("FDRR") addressing intravenous ("IV") tramadol. The letter indicated that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR.

Accordingly, the FDA will convene an Advisory Committee meeting and seek advice from the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The letter stated that the OND will respond to the FDRR within 30 calendar days after the Advisory Committee meeting.

The regulatory history of the NDA for IV tramadol, the anticipated FDRR process and other pertinent information regarding these topics were previously disclosed.

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: October 25, 2021

By: /s/ Lucy Lu, M.D.
Lucy Lu, M.D.
President and Chief Executive Officer
