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): **February 26, 2021**

Avenue Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38114**	**47-4113275**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1140 Avenue of the Americas, Floor 9
New York, NY 10036
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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

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.

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 February 26, 2021, Avenue Therapeutics, Inc. (the "Company") received an acknowledgement letter from the U.S. Food and Drug Administration ("FDA") that the Company's resubmission of its New Drug Application ("NDA") for IV Tramadol, dated February 12, 2021, is a complete, class 1 response to the Complete Response Letter ("CRL") dated October 9, 2020. A Prescription Drug User Fee Act goal date has been set for April 12, 2021.

The NDA for IV Tramadol was resubmitted following the receipt of official minutes of a Type A meeting with the FDA, which was conducted following a CRL issued by the FDA in October 2020. The resubmission package included revised language relating to the proposed product label and a report relating to terminal sterilization validation.

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 1, 2021

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