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): **August 31, 2022**

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(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). x

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.

Avenue Therapeutics, Inc. (the "**Company**") previously disclosed that, on March 18, 2022, the Company received an Appeal Denied Letter (the "**Letter**") from the Office of New Drugs of the Food and Drug Administration (the "**FDA**") in response to a formal dispute resolution request submitted by the Company with the Office of Neuroscience of the FDA on July 27, 2021. The Letter recommended that as a path forward, the Company "request a meeting with the Division regarding additional studies that can better assess the appropriate clinical setting for the administration of tramadol IV and to evaluate the potential risk for opioid stacking".

On August 31, 2022, the Company disclosed that, on June 17, 2022, following the receipt of the Letter, the Company submitted a Type A Meeting Request and related briefing documents to the FDA. The meeting was granted by the Division of Anesthesia, Analgesia, and Addiction Products ("**DAAAP**") on June 27, 2022, and scheduled for August 9, 2022. The Company submitted a briefing document presenting a study design that the Company believed has the potential to address the comments and deficiencies noted in the Letter and sought the DAAAP's guidance to refine the study design that would support a resubmission of a New Drug Application for the Company's current lead product candidate, intravenous Tramadol. The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. The Company expects to receive official meeting minutes by mid-September and expects to evaluate further the potential to generate data supportive of an FDA approval.

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: August 31, 2022

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