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): **July 27, 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, 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 July 27, 2021, Avenue Therapeutics, Inc. ("Avenue"), submitted a Formal Dispute Resolution Request ("FDRR") to the Food and Drug Administration ("FDA") with respect to the Complete Response Letters (together, the "CRLs") previously issued by the FDA to Avenue related to its intravenous ("IV") tramadol New Drug Application ("NDA"). The submission of the FDRR follows a Post-Action Type A meeting with the FDA that did not resolve the issues identified in the CRLs. 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: July 29, 2021

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