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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **May 1, 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, NY 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:

<b>Title of Class</b>	<b>Trading Symbol(s)</b>	<b>Exchange Name</b>
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.

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**Item 8.01. Other Events.**

On November 12, 2018, Avenue Therapeutics, Inc. (the “Company”) entered into a Stock Purchase and Merger Agreement (the “SPMA”) with InvaGen Pharmaceuticals, Inc. (“InvaGen”) and Madison Pharmaceuticals Inc., pursuant to which InvaGen agreed to purchase, for \$35 million, common shares representing 33.3% of the fully diluted capitalization of the Company, and subsequently acquire the remaining issued and outstanding capital stock of the Company for approximately \$180 million in a reverse subsidiary merger transaction (the “Merger Transaction”). Consummation of the Merger Transaction is conditioned upon, among other things, U.S. Federal Drug Administration (“FDA”) approval of IV Tramadol, its labeling and scheduling, and the absence of certain other restrictions in effect with respect to IV Tramadol. Pursuant to the SPMA, if FDA approval of IV Tramadol was not obtained on or before April 30, 2021, InvaGen would not be subject to the mandatory closing obligations set forth in the SPMA with respect to the Merger Transaction. As of May 1, 2021, the Company has not received approval from the FDA for IV Tramadol. InvaGen retains an option to complete the Merger Transaction until October 31, 2021, and also retains the option to terminate the SPMA.

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**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: May 3, 2021

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

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