

**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 15, 2022**

**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:

- 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 Exchange Act:

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

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 15, 2022, Avenue Therapeutics, Inc., announced the outcome of the U.S. Food and Drug Administration joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee on the Company's New Drug Application for IV Tramadol. A copy of such press release is being furnished as Exhibit 99.1 to this report.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

<u>Exhibit Number</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press release issued by Avenue Therapeutics, Inc., dated February 15, 2022.</a>
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL)

**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.

Date: February 16, 2022

**AVENUE THERAPEUTICS, INC.**  
(Registrant)

By: /s/ Lucy Lu, M.D.

Name: Lucy Lu, M.D.

Title: President and Chief Executive Officer

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### **Avenue Therapeutics Announces Outcome of FDA Advisory Committee Meeting on IV Tramadol**

**New York, NY – Feb. 15, 2022** – Avenue Therapeutics, Inc. (NASDAQ: ATXI) (“Avenue”), a company focused on the development of intravenous (“IV”) tramadol for the U.S. market, today announced the outcome of the U.S. Food and Drug Administration (“FDA”) joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee on IV tramadol.

In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: “Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?” The results are 8 yes votes and 14 no votes.

FDA Advisory Committees provide the FDA with independent advice and non-binding recommendations. The FDA has previously stated that input from an Advisory Committee is needed for the Office of New Drugs (“OND”) to reach a decision on Avenue’s formal dispute resolution request (“FDRR”) and that the OND will respond to Avenue’s FDRR within 30 calendar days after the Advisory Committee meeting.

#### **About Avenue Therapeutics**

Avenue Therapeutics is a specialty pharmaceutical company whose mission is to develop IV tramadol, a potential alternative that could reduce the use of conventional opioids, for patients suffering from acute pain in the U.S. Avenue is headquartered in New York City. For more information, visit [www.avenuetx.com](http://www.avenuetx.com).

#### **Forward-Looking Statements**

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks related to us obtaining regulatory approval from the FDA for our product candidate, risks relating to the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner, risks relating to our growth strategy; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

#### **Contacts:**

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