
**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): **December 11, 2019**

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.)

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:

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 December 11, 2019, Avenue Therapeutics, Inc. announced it submitted a New Drug Application to the U.S. Food and Drug Administration for IV tramadol for the management of moderate to moderately severe pain in adults in a medically supervised health care setting. 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:

Exhibit Number	Description
<u>99.1</u>	<u>Press release issued by Avenue Therapeutics, Inc., dated December 11, 2019.</u>

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: December 11, 2019

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



Avenue Therapeutics Announces Submission of New Drug Application for IV Tramadol

New York, NY – December 11, 2019 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) (“Avenue”), a company focused on the development of intravenous (“IV”) tramadol for the U.S. market, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for IV tramadol for the management of moderate to moderately severe pain in adults in a medically supervised health care setting.

The NDA for IV tramadol is based on positive results from two pivotal Phase 3 clinical efficacy and safety trials in patients following bunionectomy and abdominoplasty surgeries, as well as an open-label safety study with a total of more than 500 patients who received the IV tramadol 50 mg dosing regimen. In addition, the NDA includes an epidemiology study on abuse of tramadol in the U.S. and in certain European countries where IV tramadol is available. The study finds that reports of abuse with tramadol are infrequent, both in absolute number and relative to other prescription opioids, and that abuse of tramadol via injection is uncommon relative to oral tramadol in countries where it is available.

“As a potential alternative that could reduce the use of conventional opioids, IV tramadol may fill a gap between IV acetaminophen/NSAIDs and IV conventional narcotics in the acute pain space,” said Lucy Lu, M.D., Avenue’s President and Chief Executive Officer. “The submission of this NDA is an important milestone for our company, and we look forward to working closely with the FDA during the review process.”

About Avenue Therapeutics

Avenue Therapeutics is a specialty pharmaceutical company whose mission is to develop intravenous (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 and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit 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 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.

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