

**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 15, 2020**

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:

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 17, 2020, Avenue Therapeutics, Inc. provided a regulatory update following receipt of minutes from a meeting held with the U.S. Food and Drug Administration relating to 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:

Exhibit Number	Description
99.1	Press release issued by Avenue Therapeutics, Inc., dated December 17, 2020.

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 17, 2020

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



Avenue Therapeutics Provides Regulatory Update for IV Tramadol

Company Anticipates NDA Resubmission in February 2021

New York, NY – December 17, 2020 –Avenue Therapeutics, Inc. (NASDAQ: ATXI) (Avenue), a company focused on the development of intravenous (IV) tramadol for the U.S. market, today provided a regulatory update following receipt of the official meeting minutes from a November 2020 Type A meeting with the U.S. Food and Drug Administration (FDA) relating to a path forward for IV tramadol.

Avenue had requested this Type A meeting to address a Complete Response Letter (CRL) it received from the FDA regarding the New Drug Application (NDA) for IV tramadol. Avenue intends to resubmit the NDA in February 2021, barring any Covid-19 related or other setbacks. The NDA resubmission will incorporate revised language relating to the proposed product label and a report relating to terminal sterilization validation.

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 and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.avenuetx.com.

About Fortress Biotech

Fortress Biotech, Inc. (Fortress) is an innovative biopharmaceutical company that was ranked in Deloitte's 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage pharmaceutical products and product candidates. The company has five marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company's portfolio of product opportunities. Fortress has established partnerships with some of the world's leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion Pharmaceuticals, Inc., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, InvaGen Pharmaceuticals Inc. (a subsidiary of Cipla Limited), St. Jude Children's Research Hospital and Nationwide Children's Hospital. For more information, visit www.fortressbiotech.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:

Jaclyn Jaffe and William Begien
Avenue Therapeutics, Inc.
(781) 652-4500
ir@avenuetx.com
