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): **October 12, 2020**

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, 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 October 12, 2020, Avenue Therapeutics, Inc. announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration regarding its New Drug Application 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
99.1	Press release issued by Avenue Therapeutics, Inc., dated October 12, 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: October 12, 2020

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

Exhibit 99.1

Avenue Therapeutics Receives Complete Response Letter from the FDA for IV Tramadol

Management to Host Conference Call at 8:30 a.m. ET

New York, NY – October 12, 2020 –Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, today announced it has received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding the Company's New Drug Application ("NDA") for IV tramadol.

The CRL stated that although the pivotal Phase 3 clinical trials demonstrated statistically significant outcomes for all of the primary and many secondary endpoints, the FDA has determined that it cannot approve the application in its present form. The CRL stated that IV tramadol, intended to treat patients in acute pain who require an opioid, is not safe for the intended patient population. Specifically, if a patient requires an analgesic between the first dose of IV tramadol and the onset of analgesia, a rescue analgesic would be needed. The likely choice would be another opioid, which would result in opioid "stacking" and increase the likelihood of opioid-related adverse effects. Other than this potential safety concern, the FDA did not identify a safety signal in Avenue's clinical development program. In addition, the CRL stated that the FDA requires an adequate terminal sterilization validation prior to NDA approval, which is planned for later this quarter.

"We believe that our extensive clinical database strongly supports the value of treatment with IV tramadol as an effective alternative to intravenous Schedule II conventional opioids. We firmly stand behind the safety data in our NDA and the ultimate approvability of IV tramadol," said Lucy Lu, MD, President and Chief Executive Officer of Avenue Therapeutics. "We will request a meeting with the FDA as soon as possible and are committed to working closely with the agency to resolve these issues in order to bring this important medicine to patients and clinicians in the U.S."

Conference Call
Avenue management will be hosting a conference call today beginning at 8:30 a.m. ET. To access the conference call, please dial (833) 900-1539 (local) or (236) 712-2279 (international) a few minutes prior to the start time and refer to conference ID 9467696. An archived audio will be available in the Investors section under Events on the Company's website a few hours after the event and will be available for 30 days.

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 recently ranked number 10 in Deloitte's 2019 Technology Fast 500™, an annual ranking of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentage of fiscal year revenue growth over a three-year period. Fortress is focused on acquiring, developing and commercializing high-potential marketed pharmaceutical products and development-stage pharmaceutical 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.

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