
**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): **March 28, 2018**

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:

- ☐ 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 March 28, 2018, Avenue Therapeutics, Inc. (“Avenue”) issued a press release to announce receipt of Notices of Allowance from the U.S. Patent and Trademark Office for two patent applications covering methods of administration for Avenue’s lead product candidate IV tramadol. A copy of such press release is being furnished as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
<u>99.1</u>	<u>Press release issued by Avenue Therapeutics, Inc., dated March 28, 2018.</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: March 28, 2018

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



Avenue Therapeutics Receives Notices of Allowance for Patent Applications Covering Methods of Administration for Intravenous Tramadol

New York, NY – March 28, 2018 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) (“Avenue”), a company focused on the development and commercialization of intravenous (IV) tramadol, today announced receipt of Notices of Allowance from the U.S. Patent and Trademark Office (USPTO) for two patent applications covering methods of administration for its lead product candidate IV tramadol.

The first patent application is a continuation of issued U.S. patent 8,895,622, titled "Intravenous Administration of Tramadol." The patent to be issued from the allowed application (U.S. Application No. 15/407,133) carries a patent term to at least 2032. The second patent application is a continuation of issued U.S. patent 9,693,949, titled "Intravenous Administration of Tramadol." The patent to be issued from the allowed application (U.S. Application No. 15/612,665) carries a patent term to at least 2036.

Also, the USPTO has indicated that a Notice of Allowance is being issued for U.S. Application No. 15/622,910 (a continuation-in-part application of U.S. patent 9,693,949). All patents to be issued from these allowed applications contain claims directed to Avenue’s proposed administration of IV tramadol. Issuance of these patents is expected in the second quarter of 2018.

“The allowance of these patents further expands our patent portfolio and strengthens the protection of the methods of administration for IV tramadol in postoperative pain,” said Lucy Lu, M.D., Avenue’s President and Chief Executive Officer. “We are pleased that the USPTO has allowed these applications during this important stage in IV tramadol’s pivotal development program, as we look forward to reporting topline data from our Phase 3 trial in patients following bunionectomy surgery in the second quarter of 2018, and to initiating a Phase 3 trial in patients following abdominoplasty surgery in the third quarter.”

These patent applications fall under Avenue’s licensing agreement with Revogenex Ireland Ltd.

About Avenue Therapeutics

Avenue Therapeutics, Inc. (“Avenue”), a Fortress Biotech (NASDAQ: FBIO) Company, is a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) tramadol for the management of moderate to moderately severe postoperative pain. IV tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAIDs and IV conventional narcotics. Avenue is currently evaluating IV tramadol in a pivotal Phase 3 program for the management of postoperative pain. Avenue is headquartered in New York City. For more information, visit www.avenuetx.com.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensings, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. 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 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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