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): **April 23, 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, 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:

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 April 23, 2020, Avenue Therapeutics, Inc. issued a press release to announce that two e-posters highlighting efficacy and safety results from its Phase 3 program are available for online viewing from the cancelled Annual Regional Anesthesiology and Acute Pain Medicine Meeting hosted by the American Society of Regional Anesthesia and Pain Medicine ("ASRA"). The meeting was originally scheduled to take place April 23-25, 2020 in San Francisco, CA and was cancelled due to COVID-19 concerns. 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 herewith:

Exhibit Number	Description
99.1	Press release issued by Avenue Therapeutics, Inc., dated April 23, 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: April 23, 2020

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

Exhibit 99.1

Avenue Therapeutics Announces Presentation of IV Tramadol E-Posters

New York, NY – April 23, 2020 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, today announced that two e-posters highlighting efficacy and safety results from its Phase 3 program are available for online viewing from the cancelled Annual Regional Anesthesiology and Acute Pain Medicine Meeting hosted by the American Society of Regional Anesthesia and Pain Medicine ("ASRA"). The meeting was originally scheduled to take place April 23-25, 2020 in San Francisco, CA and was cancelled due to COVID-19 concerns.

The e-poster (816) titled "Intravenous Tramadol is Effective in Management of Postoperative Pain Following Abdominoplasty: A 3-arm Randomized Controlled Trial" presents data from the Phase 3 abdominoplasty study and can be found here.

This Phase 3, multicenter, double-blind, placebo and active controlled trial evaluated the efficacy and safety of IV tramadol in 370 patients following abdominoplasty surgery. Patients were randomized to a postoperative regimen of IV tramadol 50 mg, placebo or IV morphine 4 mg. The primary endpoint of the study assessed the analgesic efficacy of IV tramadol compared to placebo as measured by SPID24 (sum of pain intensity differences through 24 hours post first dose). The key secondary endpoints included SPID48 (sum of pain intensity differences through 48 hours post first dose), total consumption of rescue medicine and Patient Global Assessment. IV tramadol 50 mg was statistically significantly superior to placebo for the primary efficacy endpoint and all three key secondary efficacy endpoints. In addition, IV tramadol demonstrated a similar efficacy profile to that of IV morphine 4 mg, a standard-of-care active comparator in this study. Topline results from this study were announced in June 2019.

The e-poster (1001) titled "IV tramadol – A New Treatment Option for Management of Post-Operative Pain: A Safety Trial Including Various Types of Surgery", presents data from the Phase 3 safety study and can be found here.

The Phase 3 safety study was a single-arm open label study that enrolled patients undergoing a range of surgical procedures including both orthopedic and soft tissue surgeries. IV tramadol 50 mg was administered at Hours 0, 2, 4, and every 4 hours thereafter for up to 7 days of treatment. Patients were allowed to use non-opioid medications per treating physicians' discretion if additional pain relief was needed. While efficacy was not a primary objective of the study, patient satisfaction with treatment was measured with Patient Global Assessment.

IV tramadol 50 mg was well tolerated in this real-world trial, with only 4% of patients discontinuing for adverse events. The most commonly observed adverse events were nausea and vomiting, which is consistent with known tramadol pharmacology. At the end of treatment, 95% of patients reported that study medication was good, very good, or excellent for controlling pain. No patients discontinued the study due to a lack of efficacy.

"The results of these two studies indicate that IV tramadol may become a useful option in patients where exposure to conventional opioids is not desired," said Harold Minkowitz, M.D., an anesthesiologist at Memorial Hermann Memorial City Medical Center in Houston, TX. "IV tramadol, with its dual mechanisms of action, may fill a gap between IV non-opioid medicine and conventional opioids. The availability of IV tramadol as an alternative to conventional opioid analgesics should be a valuable option for U.S. clinicians who treat pain in the hospital setting."

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.

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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