

**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): **September 22, 2022**

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	ATXI	Nasdaq Capital Market

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).

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 3.03 Material Modification to Rights of Security Holders.

On September 22, 2022, Avenue Therapeutics, Inc. (the “**Company**”) filed a Certificate of Amendment to its Third Amended and Restated Certificate of Incorporation (the “**Amendment**”) with the Secretary of State of the State of Delaware to (i) effect a 1-for-15 reverse stock split (the ‘**Reverse Stock Split**’) of the Company’s shares of common stock, \$0.0001 par value (the “**Common Stock**”), and (ii) effect a related reduction in the number of the Company’s authorized shares from 50,000,000 to 20,000,000 (the “**Authorized Share Reduction**”).

As previously disclosed in a Definitive Information Statement on Schedule 14C filed with the Securities and Exchange Commission on August 22, 2022 (the “**Information Statement**”), the Company’s stockholders approved the Reverse Stock Split within a range of between 10-for-1 and 20-for-1, such ratio to be determined by the Board of Directors of the Company (the “**Board**”), and the Authorized Share Reduction, each of which the Board also approved. On September 6, 2022, the Board selected the 1-for-15 reverse stock split ratio.

As a result of the Reverse Stock Split, every 15 shares of the Company’s pre-reverse split Common Stock will be combined and reclassified as one share of Common Stock. Proportionate voting rights and other rights of common stockholders will not be affected by the reverse split, other than as a result of the payment for fractional shares. No fractional shares will be issued in connection with the Reverse Stock Split. Stockholders who would otherwise hold a fractional share of Common Stock will receive (upon surrender to the exchange agent of certificates representing such shares), a cash payment in lieu thereof, without interest or deduction, rounded to the nearest cent, in an amount equal to the product obtained by multiplying (a) the closing price per share of our common stock as reported on the Nasdaq Stock Market as of the effective date of the Reverse Stock Split, by (b) the fraction of one share owned by the stockholder.

The Reverse Stock Split became effective on September 22, 2022, and the Common Stock will be quoted on the Nasdaq Stock Market on a post-split basis at the open of business on September 23, 2022. The Company’s post-reverse split Common Stock has a new CUSIP number, 05360L304, but the par value and other terms of the Common

Stock were not affected by the Reverse Stock Split.

The Company's transfer agent, VStock Transfer, LLC, is acting as exchange agent for the Reverse Stock Split and will send instructions to stockholders of record regarding the exchange of certificates for Common Stock.

The foregoing description of the Amendment and the Reverse Stock Split set forth above does not purport to be complete and is qualified in its entirety by reference to the Amendment and the Information Statement. A copy of the Amendment is being filed as Exhibit 3.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year

The disclosures set forth in Item 3.03 of this Current Report on Form 8-K are incorporated into this Item 5.03 by reference.

Item 8.01 Other Events

On September 22, 2022, Avenue Therapeutics, Inc. issued a press release announcing (i) the Reverse Stock Split ratio and (ii) the receipt of official meeting minutes from the U.S. Food and Drug Administration regarding a meeting conducted on August 9, 2022, for intravenous 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 No.	Description
3.1	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc.
99.1	Press Release, dated September 22, 2022
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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: September 22, 2022

By: /s/ David Jin
David Jin
Interim Principal Financial Officer and Chief Operating Officer

**CERTIFICATE OF AMENDMENT
TO
THE THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
AVENUE THERAPEUTICS, INC.**

Avenue Therapeutics, Inc. (the “**Corporation**”), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the “**DGCL**”), does hereby certify:

FIRST. The Certificate of Incorporation of the Corporation is hereby amended by changing ARTICLE IV, so that, as amended, the first paragraph of said Section 5 shall be amended and restated as follows:

Authorized Stock. The total number of shares of all classes of capital stock that the Corporation shall have the authority to issue is (i) twenty million (20,000,000) shares of Common Stock, with \$0.0001 par value, and (ii) 2,000,000 shares of Preferred Stock, with \$.0001 par value (the “**Preferred Stock**”), 250,000 of which are designated as Class A Preferred Stock (the “**Class A Preferred Stock**”) and the remainder are undesignated Preferred Stock.

SECOND. Upon the filing and effectiveness (the “**Effective Time**”) pursuant to the DGCL of this Certificate of Amendment to the Certificate of Incorporation, every fifteen (15) issued and outstanding shares or shares held by the Corporation as treasury stock of the Corporation’s common stock, par value \$.0001 per share, as of the date and time immediately preceding the Effective Time (the “**Old Shares**”), shall automatically be reclassified as and converted into one (1) validly issued, fully paid and non-assessable share of common stock of the Corporation (the “**New Shares**”) without any further action by the Corporation or the holder thereof, subject to the treatment of fractional share interests as described below (the “**Reverse Stock Split**”). Further, every right, option and warrant to acquire Old Shares outstanding immediately prior to the Effective Time shall, as of the Effective Time and without any further action, automatically be reclassified into the right to acquire one (1) New Share based on the conversion ratio of shares of Old Shares to New Shares set forth in the preceding sentence, but otherwise upon the terms of such right, option or warrant (except that the exercise or purchase price of such right, option or warrant shall be proportionately adjusted).

No fractional shares shall be issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive fractional shares of Common Stock shall be entitled to receive cash (without interest or deduction) from the Corporation’s transfer agent in lieu of such fractional share interests upon the submission of a transmission letter by a stockholder holding the shares in book-entry form and, where shares are held in certificated form, upon the surrender of the stockholder’s Old Certificates (as defined below), in an amount equal to the product obtained by multiplying (a) the closing price per share of the Common Stock as reported on the Nasdaq Stock Market as of the date of the Effective Time, by (b) the fraction of one share owned by the stockholder.

THIRD. Each holder of record of a certificate which immediately prior to the last trading day preceding the date of the Split Effective Time (the ‘**Split Effective Date**’) represents Old Shares (the “**Old Certificates**”) shall be entitled to receive upon surrender of such Old Certificates to the Corporation’s transfer agent for cancellation, a certificate (the “**New Certificates**”) representing the number of whole shares of common stock into and for which the shares formerly represented by such Old Certificates so surrendered are exchangeable. From and after the Effective Date, Old Certificates shall represent only the right to receive New Certificates pursuant to the provisions hereof.

FOURTH. That a resolution was duly adopted by unanimous written consent of the directors of the Corporation, pursuant to Section 242 of the General Corporation Law of the State of Delaware, setting forth the above mentioned amendment to the Certificate of Incorporation and declaring said amendment to be advisable.

FIFTH. That this amendment was duly authorized by the holders of a majority of the voting stock of the Corporation by written consent of the stockholders of the Corporation. Said amendment was duly adopted in accordance with the provisions of the General Corporation Law.

IN WITNESS WHEREOF, this Certificate of Amendment of the Certificate of Incorporation has been signed by the Chief Executive Officer of the Corporation this 22nd day of September, 2022.

AVENUE THERAPEUTICS, INC.

By: /s/ Alexandra MacLean
Name: Alexandra MacLean
Title: Chief Executive Officer



Avenue Therapeutics Announces Reverse Stock Split and Provides Regulatory Update for IV Tramadol Including Receipt of Type A Meeting Minutes from the FDA

New York, NY – September 22, 2022 – Avenue Therapeutics, Inc. (Nasdaq: ATXI) (“Avenue” or the “Company”), a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of central nervous system diseases, today announced that it will effect a 1-for-15 reverse split of its common stock, which will be effective for trading purposes on the Nasdaq Capital Market as of the commencement of trading on September 23, 2022, and also provided a regulatory update related to its intravenous (“IV”) Tramadol product candidate.

Reverse Stock Split

The reverse stock split was approved on July 25, 2022 by stockholders representing approximately 73% of the voting power of the outstanding voting stock of the Company, with authorization to determine the final ratio having been granted to the Company’s Board of Directors.

Avenue’s common stock will continue to trade on the Nasdaq Capital Market under the symbol “ATXI” following the reverse stock split, with a new CUSIP number of 05360L304. After the effectiveness of the reverse stock split, we expect that the number of outstanding shares of common stock will be reduced from approximately 22.7 million to approximately 1.5 million, subject to adjustment to give effect to the treatment of any fractional shares that stockholders would have received in the reverse stock split. No fractional shares will be issued in connection with the reverse stock split and stockholders who would otherwise be entitled to a fractional share will receive a proportional cash payment.

The reverse stock split is primarily intended to bring the Company into compliance with Nasdaq’s \$1.00 per share minimum bid price requirement for continued listing. The Company is simultaneously effecting a reduction in the number of authorized shares of common stock from 50,000,000 to 20,000,000.

Avenue’s transfer agent, VStock Transfer, LLC, which is also acting as the exchange and paying agent for the reverse stock split, will provide instructions to stockholders regarding the process for exchanging physical share certificates. We do not expect that stockholders holding their shares in book-entry form or through a bank, broker or other nominee need to take any action in connection with the reverse stock split. Beneficial holders are encouraged to contact their bank, broker or other nominee with any procedural questions. Additional information concerning the reverse stock split can be found in the Company’s definitive Information Statement on Schedule 14C filed with the Securities and Exchange Commission on August 22, 2022.

IV Tramadol Regulatory Update

Avenue received the official meeting minutes from the FDA regarding a meeting conducted on August 9, 2022, for IV Tramadol. Avenue submitted the Type A Meeting Request and related briefing documents to the FDA on June 17, 2022, and included a proposed study design to address the concerns around the safety risk of IV Tramadol in combination with other opioid analgesics for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting that was discussed in detail at the previously disclosed Advisory Committee meeting on February 15, 2022 and in the Appeal Denied letter received on March 18, 2022.

At the meeting, Avenue presented a study design for a single safety clinical trial that the Company believes could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to Avenue upon review of a more detailed study protocol. The Company intends to incorporate the FDA’s suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.

About Avenue Therapeutics

Avenue Therapeutics, Inc. (Nasdaq: ATXI) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of central nervous system diseases. Avenue is headquartered in New York City. For more information, visit www.avenuetx.com.

Forward-Looking Statements

This press release contains predictive or “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of current or historical fact contained in this press release, including statements that express our intentions, plans, objectives, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “should,” “would” and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in, or implied by, the forward-looking statements due to numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from: expectations for increases or decreases in expenses; expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidate or any other products we may acquire or in-license; our use of clinical research centers and other contractors; expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities; expectations for generating revenue or becoming profitable on a sustained basis; expectations or ability to enter into marketing and other partnership agreements; expectations or ability to enter into product acquisition and in-licensing transactions; expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidate; acceptance of our products by doctors, patients or payors; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our products; estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments; the volatility of our stock price; expected losses expectations for future capital requirements; uncertainty surrounding the Baergic Bio acquisition; ability to effectuate the reverse stock split; and those risks discussed in our filings which we make with the SEC. Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this press release, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

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