

**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 7, 2023**

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.)

1111 Kane Concourse, Suite 301
Bay Harbor Islands, Florida 33154
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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)	Name of each exchange on which registered
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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On March 7, 2023, the Board of Directors (the "Board") of Avenue Therapeutics, Inc. (the "Company") voted to expand the size of the Board from five to six members, effective immediately, and appointed Alexandra MacLean, M.D., Chief Executive Officer of the Company, to the Board as a director, effective immediately, with a term expiring at the 2023 Annual Meeting of Stockholders of the Company (the "Annual Meeting") or until her successor is elected and qualified, or, if earlier, her death, disability, resignation, disqualification or removal from the Board.

Dr. MacLean, due to her position of Chief Executive Officer of the Company, will not be independent under rules and regulations of the Securities and Exchange Commission (the "SEC") and the listing requirements of The Nasdaq Stock Market and will not be permitted to sit on any of the committees of the Board. Consistent with the Company's current policies, she will receive no compensation for her service as a director. There are no arrangements or understandings between Dr. MacLean and any other person pursuant to which Dr. MacLean was selected as a director and there are no transactions in which Dr. MacLean has an interest requiring disclosure under Item 404(a) of Regulation S-K.

Also on March 7, 2023, the Board appointed Jay Kranzler, M.D., Ph.D. to serve as Chairman of the Board, effective immediately, in place of Lindsay A. Rosenwald, M.D. Dr. Rosenwald will remain a member of the Board.

Item 5.08 Shareholder Director Nominations.

To the extent applicable, the information in Item 8.01 of this Current Report on Form 8-K is incorporated by reference into this Item 5.08.

Item 8.01 Other Events.

2023 Annual Meeting of Stockholders

On March 7, 2023, the Board determined that the Annual Meeting will be held on June 22, 2023. The Board also approved April 25, 2023 as the record date for the Annual Meeting. Only stockholders of record at the close of business on that date may attend and vote at the meeting or any adjournment or postponement thereof.

Because the date of the Annual Meeting has changed by more than 30 days from the anniversary of the Company's 2022 annual meeting of stockholders, the Company has set a new deadline for the receipt of stockholder proposals. In accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), any stockholder proposal intended to be considered for inclusion in the Company's proxy materials for the Annual Meeting must be delivered to, or mailed to and received at, the Company's executive offices located at Avenue Therapeutics, Inc., 1111 Kane Concourse, Suite 301, Bay Harbor Islands, Florida 33154, Attn: David Jin, Corporate Secretary, on or before the close of business on March 24, 2023, which the Company has determined to be a reasonable time before it expects to begin to print and distribute its proxy materials for the Annual Meeting. In addition to complying with this deadline, stockholder proposals intended to be considered for inclusion in the Company's proxy materials for the Annual Meeting must also comply with all applicable SEC rules, including Rule 14a-8 of the Exchange Act, and the Company's Amended and Restated Bylaws (the "Bylaws").

To comply with the universal proxy rules under Rule 14a-19 of the Exchange Act, stockholders who intend to solicit proxies in support of director nominees other than the Company's nominees must provide notice that sets forth the information required by Rule 14a-19 under the Exchange Act no later than May 3, 2023.

Under the Company's Bylaws, stockholders may also present a proposal or director nomination at the Annual Meeting if advance written notice is timely given to the Company, in accordance with the Bylaws. Because the date of the 2023 Annual Meeting will now be held more than 30 days before the anniversary of the 2022 annual meeting of stockholders, the Company is establishing March 24, 2023 as the date by which notice by a stockholder of any such proposal or nomination must be received by the Company.

Press Release

On March 8, 2023, the Company issued a press release announcing (i) the expansion of the Board and appointment of Dr. MacLean to the Board and the appointment of Dr. Kranzler as Chairman of the Board, (ii) that it plans to hold the Annual Meeting of the Company on June 22, 2023, and (iii) that it will participate in a Type C meeting with the Food and Drug Administration on March 9, 2023 to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on intravenous tramadol relative to an approved opioid analgesic. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are furnished herewith:

Exhibit Number	Description
99.1	Press Release dated March 8, 2023
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.

Date: March 8, 2023

AVENUE THERAPEUTICS, INC.
(Registrant)

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



Avenue Therapeutics Provides Regulatory Update on IV Tramadol and Other Corporate Updates

Company to participate in Type C meeting for IV Tramadol with FDA on March 9, 2023

Miami, FL – March 8, 2023 – 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 rare and neurologic diseases, today announced that it will participate in a Type C meeting with the FDA on March 9, 2023 to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on intravenous tramadol (“IV Tramadol”) relative to an approved opioid analgesic. The Company expects to provide an update on the outcome of the meeting in April 2023, after receipt of the meeting minutes from the FDA.

As disclosed in September 2022, Avenue received meeting minutes from the FDA regarding a Type A meeting conducted on August 9, 2022, for IV Tramadol. 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 and the FDA stated that the proposed study design appeared 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.

Subsequent to the August 9 meeting, the Company incorporated the FDA’s suggestions from the meeting minutes and submitted a Type C Meeting Request and a briefing book that included a detailed study protocol for further discussion with the FDA.

Board Appointments

On March 7, 2023, Alexandra MacLean, M.D., the Chief Executive Officer of Avenue, was appointed to the Board of Directors. In addition, Jay Kranzler, M.D., Ph.D., a current Director of Avenue, was appointed as the Chairman, true to Dr. Kranzler’s expertise in the neurosciences. Lindsay Rosenwald, M.D. will remain a Director of the Company.

Dr. Rosenwald commented, “I am very excited to have Dr. Kranzler become Chairman of Avenue. Deep training, knowledge and experience in the neurological sciences and drug development will be very important as Avenue continues to develop and expand its portfolio.”

2023 Annual Meeting

Today, the Company also announced its 2023 Annual Meeting of Stockholders will be held on June 22, 2023 and that stockholders of record as of the close of business on April 25, 2023 will be entitled to notice of, and to vote at, the annual meeting and any adjournment or postponement thereof. The 2023 Annual Meeting will be a virtual meeting conducted via webcast.

Because the date of the Annual Meeting has changed by more than 30 days from the anniversary of the Company’s 2022 annual meeting of stockholders, the Company has set a new deadline for the receipt of stockholder proposals. In accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), any stockholder proposal intended to be considered for inclusion in the Company’s proxy materials for the 2023 Annual Meeting must be delivered to, or mailed to and received at, the Company’s executive offices located at Avenue Therapeutics, Inc., 1111 Kane Concourse, Suite 301, Bay Harbor Islands, Florida 33154, Attn: David Jin, Corporate Secretary, on or before the close of business on March 24, 2023, which the Company has determined to be a reasonable time before it expects to begin to print and distribute its proxy materials for the 2023 Annual Meeting. In addition to complying with this deadline, stockholder proposals intended to be considered for inclusion in the Company’s proxy materials for the 2023 Annual Meeting must also comply with all applicable SEC rules, including Rule 14a-8 of the Exchange Act. To comply with the universal proxy rules under Rule 14a-19 of the Exchange Act, stockholders who intend to solicit proxies in support of director nominees other than the Company’s nominees must provide notice that sets forth the information required by Rule 14a-19 under the Exchange Act no later than May 3, 2023.

Under the Company’s Bylaws, stockholders may also present a proposal or director nomination at the Annual Meeting if advance written notice is timely given to the Company, in accordance with the Bylaws. Because the date of the 2023 Annual Meeting will now be held more than 30 days before the anniversary of the 2022 annual meeting of stockholders, notice by a stockholder of any such proposal or nomination must be provided no later than the close of business on March 24, 2023.

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 neurologic and rare diseases. It is currently developing three assets including AJ201, a first-in-class asset for spinal and bulbar muscular atrophy, BAER-101, an oral small molecule selective GABA-A $\alpha 2/3$ receptor positive allosteric modulator for CNS diseases, and IV Tramadol, which is in Phase 3 clinical development for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting. Avenue is headquartered in Miami, FL and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). 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; 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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