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, 2025**

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.)

1111 Kane Concourse, Suite 301
Bay Harbor Islands, FL 33154
(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 each 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 8.01 Other Events.

Nasdaq Stock Market Panel Hearing Results

As previously disclosed, on November 26, 2024, Avenue Therapeutics, Inc. (the "Company") received a delist letter (the "Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was not in compliance with Nasdaq Listing Rule 5550(b)(1), the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market (the "Stockholders' Equity Requirement"). In the Letter, the Staff formally notified the Company that it would move to delist the Company's securities from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing, which was held on January 30, 2025.

On March 7, 2025, the Company announced that it received a letter from Nasdaq advising the Company that the Panel had granted the Company's request for an exception to permit the continued listing of the Company's common stock on the Nasdaq Capital Market, subject to certain conditions. The Panel's grant of the Company's request for continued listing is subject to the conditions that (i) on or before March 14, 2025, the Company must make public disclosure describing any transactions undertaken by the Company to increase its equity and provide an indication of its equity following those transactions, (ii) on or before March 14, 2025, the Company must provide the Panel with an update on its fundraising plans and updated income projections for the next 12 months, with all underlying assumptions clearly stated, and (iii) on or before April 15, 2025, the Company must file a Current Report on Form 8-K announcing the results of the read out from the clinical trial for the Company's AJ201 program assessing the product candidate's efficacy in treating patients with spinal bulbar and muscular atrophy. During the exception period, the Company must promptly notify the Panel of any significant events that occur.

The Company is considering all options available to it to regain compliance with the Stockholders' Equity Requirement; however, there can be no assurance that the Company will be able to do so.

License Agreement with AnnJi Pharmaceutical Co.

As previously disclosed, on February 28, 2023, the Company entered into a license agreement with AnnJi Pharmaceutical Co. Ltd., a Taiwanese company ("AnnJi"), whereby the Company obtained an exclusive license (the "License Agreement") from AnnJi to intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the U.S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's Disease.

AnnJi has communicated to the Company its intent to unblind clinical data from the recently-concluded Phase 1b/2a clinical trial for AJ201 employing an assay measuring mutant androgen receptor protein levels (a key secondary endpoint) in the primary and backup clinical samples of skeletal muscle. These samples are irreplaceable and limited in quantity. AnnJi proposes to do this in a manner that Avenue believes is materially defective. AnnJi's deployment of such assay on the remaining clinical samples in connection with the unblinding will exhaust the samples, thereby permanently and irreparably impairing the future proper measurement of such samples and will yield data that Avenue believes will be unreliable. On February 28, 2025, Avenue submitted a Request for Emergency Measures with the International Court of Arbitration seeking to prevent the deployment of such assay.

On March 3, 2025, the Company received a notice of AnnJi's intent to terminate the License Agreement (the "Purported Termination Notice") in which AnnJi purports to assert its right to terminate the License Agreement due to alleged material breaches by the Company of various provisions the License Agreement for (i) failure to use its commercially reasonable efforts to develop and commercialize AJ201, (ii) failure to negotiate and execute a clinical supply agreement by March 31, 2024, and (iii) the anticipated failure of the Company to meet a diligence milestone of first patient dosing in a Phase 2/3 clinical trial by February 28, 2027.

The Company firmly believes that the grounds for termination of the License Agreement stated in the Purported Termination Notice are without merit and intends to pursue all rights provided to it under the License Agreement and by law. Accordingly, the Company believes that the purported termination of the License Agreement in the Purported Termination Notice is invalid and of no force and effect, and that the License Agreement remains a valid and binding agreement.

Under the terms of the License Agreement, the Company or AnnJi may terminate the License Agreement upon a material breach by the other party upon written notice to the breaching party, provided that the breaching party has not cured such breach within sixty (60) calendar days after the date such written notice was received (such period, the "Cure Period"), provided that if the breaching party is exercising commercially reasonable efforts to cure the breach, the Cure Period is automatically extended for so long as such breaching party is exercising such efforts, but in no event no more than ninety (90) calendar days in the aggregate from the date of a written termination notice. The License Agreement further provides that if the parties disagree as to whether there has been a material breach (including whether the breach is material), the disputing party may contest the allegation in accordance with the applicable provisions of the License Agreement, and the Cure Period for any dispute must run through the date of resolution of such dispute. During the pendency of any such dispute, all terms and conditions of the License Agreement remain in effect, and the parties are required to continue to perform their respective obligations under the License Agreement. In sending the Purported Termination Notice, AnnJi did not observe these dispute resolution provisions in the License Agreement.

The foregoing summary of the material terms of the License Agreement is qualified in its entirety by the complete terms and conditions of the License Agreement, which was filed with the Securities and Exchange Commission on May 12, 2023 as Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are furnished herewith:

Exhibit Number	Description
10.1	AnnJi License Agreement by and between the Company and AnnJi Pharmaceutical Co. Ltd., dated February 28, 2023, filed as Exhibit 10.9 to Form 10-Q filed on May 12, 2023 (File No. 001-38114) and incorporated herein by reference.
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

Forward-Looking Statements

This Current Report on Form 8-K 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 Current Report on Form 8-K, 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: the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized; the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates; our ability to successfully develop, partner, or commercialize any of our current or future product candidates including AJ201, IV tramadol, and BAER-101; additional costs and uncertainties caused by the purported attempts to terminate our license agreement for our AJ201 product candidate; the substantial doubt raised about our ability to continue as a going concern, which may hinder our ability to obtain future financing; the significant losses we have incurred since inception and our expectation that we will continue to incur losses for the foreseeable future; our need for substantial additional funding, which may not be available to us on acceptable terms, or at all, which unavailability could force us to delay, reduce or eliminate our product development programs or commercialization efforts; our reliance on third parties for several aspects of our operations; our reliance on clinical data and results obtained by third parties that could ultimately prove to be inaccurate, unreliable, or unacceptable to regulatory authorities; the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons; the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny; the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations; the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications; the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products; our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates; our exposure to potential product liability claims; related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products; our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business; the fact that Fortress Biotech, Inc. controls a majority of the voting power of our outstanding capital stock and has rights to receive significant share grants annually; our failure to satisfy applicable listing standards of the Nasdaq Capital Market resulting in a potential delisting of our common stock; 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 Current Report on Form 8-K, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

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 7, 2025

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