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): **February 18, 2026**

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: None

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

Title of Class	Trading Symbol(s)
Common Stock	ATXI (OTC Markets Group, Inc.)

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 1.01. Entry into Material Definitive Agreement.

On February 18, 2026, Avenue Therapeutics, Inc. (the "Company") entered into a license agreement (the "License Agreement") with Duke University ("Duke"), whereby the Company obtained from Duke an exclusive, worldwide license to certain patents and know-how for the development and commercialization of products, including ATX-04 (clenbuterol), for the treatment of lysosomal storage diseases, subject to customary retained rights for Duke and other non-profit or governmental institutions to use the licensed technology for non-commercial research and educational purposes. Under the License Agreement, the Company agreed to make an upfront payment and reimburse certain patent expenses to Duke, and to make development, regulatory, and commercial milestone payments upon the achievement of certain milestones. In addition, the Company is obligated to pay a tiered low single-digit royalty on future net sales of licensed products. The Company intends to advance ATX-04 through a late-stage clinical development program leveraging existing human safety and efficacy data, with an initial focus on treating Pompe disease as an adjunct to enzyme replacement therapy ("ERT").

The License Agreement includes customary development and commercialization diligence obligations for the Company, as well as customary termination provisions, including for uncured material breach, certain insolvency-related events and specified patent challenges, and otherwise continues on a product-by-product and country-by-country basis for so long as royalties are payable.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement, which the Company expects to file as an exhibit to a subsequent filing with the Securities and Exchange Commission.

Item 8.01 Other Events.

The Company issued a press release on February 23, 2026 announcing its entry into the License Agreement, a copy of which is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are furnished herewith:

Exhibit Number	Description
99.1	Press Release, dated February 23, 2026
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: February 23, 2026

By: /S/ DAVID JIN
David Jin
Interim Principal Financial Officer and Chief Operating Officer

Exhibit 99.1

Avenue Therapeutics Enters into Exclusive Worldwide License Agreement for ATX-04 for the Treatment of Pompe Disease

ATX-04 is a selective β2-adrenergic agonist with human proof-of-concept data demonstrating improved muscle function and enhanced response to enzyme replacement therapy

MIAMI, February 23, 2026 – Avenue Therapeutics, Inc. (OTC: ATXI) ("Avenue" or the "Company"), a specialty pharmaceutical company focused on the development and commercialization of therapies for rare and neurologic diseases, today announced that it has entered into an exclusive worldwide license agreement with Duke University for patents and know-how pertaining to ATX-04 (clenbuterol), a well-characterized small-molecule β2-adrenergic agonist, in clinical development for the treatment of Pompe disease.

Pompe disease is a rare, inherited lysosomal storage disorder caused by deficiency of the enzyme acid α-glucosidase (GAA), resulting in progressive skeletal and respiratory muscle weakness. The disease presents across a wide clinical spectrum, from severe infantile-onset to later onset forms marked by progressive muscle weakness and respiratory failure, and remains associated with significant morbidity despite available enzyme replacement therapies (ERT).

Clenbuterol is a clinically validated, orally administered selective β2-adrenergic agonist with regulatory approvals outside the United States for the treatment of respiratory diseases. The drug has well-established anabolic effects on skeletal muscle, resulting in increased protein synthesis and muscle fiber size. In addition, clenbuterol enhances lysosomal biogenesis and intracellular trafficking of GAA, the enzyme deficient in Pompe disease, leading to reduced glycogen accumulation in muscle tissue.

A clinical study conducted at Duke University in patients with Pompe disease on baseline ERT, led by Principal Investigator Dwight D. Koeberl, M.D., Ph.D., demonstrated that ATX-04 was associated with meaningful improvements across multiple clinically and biologically relevant domains. Treatment with ATX-04 resulted in improvements in six-minute walk distance, reflecting enhanced functional capacity, as well as increased respiratory muscle strength, including maximal inspiratory pressure. ATX-04 was also associated with reductions in muscle glycogen burden assessed by biopsy, increased GAA activity with improved intracellular trafficking, and broad normalization of disease-relevant gene expression. The therapy was generally well tolerated with chronic, titrated dosing. Collectively, these findings support ATX-04's possible use as a mechanistic potentiator of ERT.

“ATX-04 represents an asset with a favorable risk profile, supported by compelling human clinical data generated at Duke demonstrating functional, biochemical, and molecular benefit in Pompe disease,” said Alexandra MacLean, M.D., Chief Executive Officer of Avenue Therapeutics. “This license allows us to advance a differentiated, mechanism-based therapy with the potential to meaningfully enhance outcomes for patients receiving standard-of-care ERT.”

Avenue plans to advance ATX-04 through a late-stage clinical development program leveraging existing human safety and efficacy data from other jurisdictions, with an initial focus on treating Pompe disease as an adjunct to ERT with the potential to expand into other related indications.

Under the terms of the license, Duke University has granted Avenue an exclusive, worldwide license to develop and commercialize products covered by Duke’s patents and related know-how, including ATX-04 (clenbuterol) for Pompe disease, with the potential to expand into other designated neuromuscular indications. Avenue will also assume control of Duke’s existing clinical and regulatory assets for ATX-04, including the investigational new drug (IND) application and the U.S. Food and Drug Administration (FDA) orphan drug designation for Pompe disease. Duke University will receive an upfront payment, as well as potential development, regulatory and commercial milestone payments, plus royalties on net sales.

About Avenue Therapeutics

Avenue Therapeutics, Inc. (OTC: ATXI) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of rare and neurologic diseases. 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: 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; our ability to realize the anticipated benefits of any exclusive license agreements, including the ability to successfully develop the product candidates licensed and to comply with the diligence, milestone and other obligations under such agreements; 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; uncertainty related to the timing and amounts expected to be realized from future milestone, royalty or similar future revenue streams, if at all; 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; risks 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; 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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