

**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): **November 8, 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 2.01 Completion of Acquisition or Disposition of Assets.**

As previously disclosed, on May 11, 2022, Avenue Therapeutics, Inc. (the "Company") entered into a stock contribution agreement (the "Contribution Agreement") with Fortress Biotech, Inc. ("Fortress"), of which the Company is a majority-controlled subsidiary, pursuant to which Fortress agreed to transfer its ownership of a majority of the outstanding shares (common and preferred) (the "Contributed Shares") in a private subsidiary company of Fortress, Baergic Bio, Inc. ("Baergic"), to the Company. Under the Contribution Agreement, Fortress also agreed to assign to the Company certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement was subject to the satisfaction of certain conditions precedent, including, *inter alia*: (i) the closing of an equity financing by the Company resulting in gross proceeds of no less than \$7.5 million, (ii) the agreement by InvaGen Pharmaceuticals Inc. ("InvaGen") to (A) have 100% of its shares in the Company repurchased by the Company and (B) terminate certain of the agreements with the Company and/or Fortress in connection with InvaGen's 2019 equity investment in the Company (including the elimination of certain negative consent rights of InvaGen over the Company and the restoration of certain rights and privileges of Fortress in the Company), and (iii) the Company's shares of common stock, \$0.0001 par value ("Common Stock"), then being listed and trading on the NASDAQ Capital Market without any pending action that would terminate such listing.

On November 8, 2022, following the satisfaction of the closing conditions of the Contribution Agreement, the Company completed the acquisition of a majority of the outstanding shares (common and preferred) of Baergic from Fortress. In exchange for the Contributed Shares, the Company is assuming and becoming solely liable for all obligations, duties, covenants and liabilities arising from, based upon, related to or associated with the Contributed Shares, Fortress' obligations under the contracts being assumed and Fortress' ownership in Baergic. As a result of the closing of the Contribution Agreement, Baergic is now a majority owned subsidiary of the Company. Baergic is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of central nervous system disorders. Baergic's pipeline currently consists of a single compound, BAER-101, a selective GABA-A positive allosteric modulator ("BAER-101"). BAER-101 (formally known as AZD7325) is Baergic's principal asset and was originally developed by AstraZeneca and has an established safety profile in early clinical trials including over 700 patients.

**Item 8.01 Other Events.**

On November 8, 2022, the Company issued a press release announcing the closing of the acquisition of Baergic under the Contribution Agreement. A copy of such press release is being furnished as Exhibit 99.1 to this report.

**Item 9.01 Financial Statements and Exhibits.**

*(a) Financial Statements of Businesses Acquired.*

Baergic's audited balance sheets as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, the related notes, and the report of KPMG LLP, independent registered accounting firm, dated August 31, 2022, included in the Company's Registration Statement on Form S-1 (Reg. 333-267206), declared effective on October 6, 2022 (the "**Registration Statement**"), are (i) incorporated herein by reference, and (ii) incorporated by reference as Exhibit 99.2 to this report.

Baergic's unaudited balance sheet as of June 30, 2022 and December 31, 2021, the related statements of operations and stockholders' equity for each of the three and six months ended June 30, 2022 and 2021, and statements of cash flows for the six months ended June 30, 2022 and 2021, and the related notes, included in the Registration Statement, are (i) incorporated herein by reference, and (ii) incorporated by reference as Exhibit 99.3 to this report.

*(b) Pro Forma Financial Information.*

The unaudited pro forma condensed combined financial information of the Company as of and for the year ended December 31, 2021, giving effect to the acquisition of Baergic, which are included in the Registration Statement in the section titled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 53 of the prospectus included therein, are (i) incorporated herein by reference, and (ii) incorporated by reference as Exhibit 99.4 to this report.

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The unaudited pro forma condensed combined financial information of the Company, giving effect to the acquisition of Baergic, as of and for the six months ended June 30, 2022, which are included in the Registration Statement in the section titled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 53 of the prospectus included therein, are (i) incorporated herein by reference, and (ii) incorporated by reference as Exhibit 99.5 to this report.

*(d) Exhibits*

The following exhibit is furnished herewith:

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>23.1</u></a>	<a href="#"><u>Consent of KPMG LLP</u></a>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press release dated November 8, 2022</u></a>
<a href="#"><u>99.2</u></a>	<a href="#"><u>Baergic audited balance sheets as of December 31, 2021 and 2020, the related statements of operations, stockholders' equity and cash flows for the years then ended, the related notes, and the report of KPMG LLP, independent registered accounting firm, dated August 31, 2022, incorporated by reference to the Registration Statement on Form S-1 (Reg. 333-267206), filed by the registrant with the SEC on October 6, 2022</u></a>
<a href="#"><u>99.3</u></a>	<a href="#"><u>Baergic unaudited balance sheet as of June 30, 2022 and December 31, 2021, the related statements of operations and stockholders' equity for each of the three and six months ended June 30, 2022 and 2021, and statements of cash flows for the six months ended June 30, 2022 and 2021, and the related notes, incorporated by reference to the Registration Statement on Form S-1 (Reg. 333-267206), filed by the registrant with the SEC on October 6, 2022</u></a>
<a href="#"><u>99.4</u></a>	<a href="#"><u>Unaudited pro forma condensed combined financial information of the Company as of and for the year ended December 31, 2021, incorporated by reference to the Registration Statement on Form S-1 (Reg. 333-267206), filed by the registrant with the SEC on October 6, 2022</u></a>
<a href="#"><u>99.5</u></a>	<a href="#"><u>Unaudited pro forma condensed combined financial information, as of and for the six months ended June 30, 2022, and notes to the unaudited pro forma condensed combined financial information, incorporated by reference to the Registration Statement on Form S-1 (Reg. 333-267206), filed by the registrant with the SEC on October 6, 2022</u></a>
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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**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: November 8, 2022

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

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**Consent of Independent Auditors**

We consent to the incorporation by reference in the registration statements on Form S-1 (No. 333-267206), Form S-3 (No. 333-259850 and No. 333-261520) and Form S-8 (No. 333-219972 and No. 333-261710) of Avenue Therapeutics, Inc. of our report dated August 31, 2022, with respect to the financial statements of Baergic Bio, Inc., which report appears in the Form 8-K of Avenue Therapeutics, Inc. dated November 8, 2022.

/s/ KPMG LLP

New York, New York  
November 8, 2022

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## **Avenue Therapeutics Completes the Acquisition of Baergic Bio and its Selective GABA-A $\alpha$ 2/3 Receptor Positive Allosteric Modulator for the Treatment of Central Nervous System Disorders**

**New York, NY – November 8, 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 (“CNS”) diseases, today announced the closing of the acquisition of Baergic Bio, Inc. (“Baergic Bio”) pursuant to the previously disclosed Share Contribution Agreement with its parent company, Fortress Biotech, Inc.

Founded in December 2019, Baergic Bio, now a subsidiary of Avenue, is a clinical-stage pharmaceutical company that focuses on the development of a pharmaceutical product for the treatment of CNS disorders. Its pipeline currently includes a single compound, BAER-101, an oral small molecule selective GABA-A  $\alpha$ 2/3 receptor positive allosteric modulator, which was in-licensed from AstraZeneca Plc.

The potential therapeutic value of selective modulators of GABA-A receptors has recently been recognized, with multiple assets moving forward since the 2019 U.S. Food and Drug Administration approval of brexanolone. These compounds are being developed for a host of therapeutic indications including epilepsy, anxiety, pain, depression and other related conditions. Preclinical data have substantiated the efficacy of BAER-101 as a novel anxiolytic and antiepileptic.

Benzodiazepines interact non-selectively with GABA-A receptor (GABA-AR) subunits, especially the  $\alpha$ 1 subunit. By selectively targeting the  $\alpha$ 2/3 subunits of the GABA-A receptor, BAER-101 may spare the adverse effects associated with benzodiazepine use. Consistent with its selectivity over  $\alpha$ 1-preferring GABA-ARs, BAER-101 may have a reduced propensity to produce sedation and memory impairment. To date, clinical experience in over 700 patients has shown that BAER-101 is safe and side effects were mild to moderate.

Alexandra MacLean, M.D., Chief Executive Officer of Avenue, said, “The acquisition of Baergic Bio is a step forward in our plan to build Avenue into a leader in the development of drugs targeting unmet needs in the CNS field. BAER-101 has the potential to address various orphan indications as well as larger markets with a favorable profile relative to current therapeutic options. Combined with our recent capital raise and potential regulatory path forward for IV tramadol, we believe Avenue has the foundational portfolio to continue to deliver and expand meaningful therapies for patients with CNS diseases.”

### **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 and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit [www.avenuetx.com](http://www.avenuetx.com).

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### **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; ability to successfully integrate Baergic Bio in the Company’s operations; 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.

### **Contact:**

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