

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 13D

(Amendment No. 2)

Under the Securities Exchange Act of 1934

AVENUE THERAPEUTICS, INC.

(Name of Issuer)

Common Stock, \$0.0001 Par Value
(Title of Class of Securities)

05360L205
(CUSIP Number)

Fortress Biotech, Inc.
c/o Lindsay A. Rosenwald, M.D.
1111 Kane Concourse, Suite 301
Bay Harbor Islands, FL 33154
(781) 652-4500

(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications)

December 31, 2022

(Date of Event which Requires Filing of this Statement)

If the filing person has previously filed a statement on Schedule 13G to report the acquisition that is the subject of this Schedule 13D, and is filing this schedule because of §§ 240.13d-1(e), 240.13d-1(f) or 240.13d-1(g), check the following box.

Note: Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. See §240.13d-7 for other parties to whom copies are to be sent.

* The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter disclosures provided in a prior cover page.

The information required on the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

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1. Name of Reporting Person
I.R.S. Identification No. of Above Person (Entities Only)
Fortress Biotech, Inc. 20-5157386
2. Check the Appropriate Box if a Member of a Group
Not Applicable (a)
(b)
3. SEC Use Only
4. Source of Funds (See Instructions)
OO
5. Check if Disclosure of Legal Proceeding Is Required Pursuant to Items 2(d) or 2(e)
Not Applicable.
6. Citizenship or Place of Organization
Delaware
7. Sole Voting Power
8. Shared Voting Power
578,227¹
- Number

of Shares Beneficially Owned By Each Reporting Person with		0
	9.	Sole Dispositive Power
		556,000 ²
	10.	Shared Dispositive Power
		22,222 ³
11.	Aggregate Amount Beneficially Owned by Each Reporting Person	
		578,227 ¹
12.	Check Box if the Aggregate Amount in Row (11) Excludes Certain Shares	
		<input type="checkbox"/>
13.	Percent of Class Represented by Amount in Row (11)	
		11.3% of all outstanding shares of Issuer common stock ⁴
14.	Type of Reporting Person	
		HC, CO

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- ¹ Includes 22,222 shares of Issuer's common stock underlying Warrants and 250,000 shares of the Issuer's Class A preferred stock (both of which are described further below). The Issuer's Class A preferred stock is identical to its common stock other than as to voting rights, conversion rights and the PIK Dividend right. Each share of the Issuer's Class A preferred stock will be entitled to vote the number of shares that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of the Issuer's outstanding common stock and (B) the whole shares of the Issuer's common stock into which any shares of outstanding Class A common shares and Class A preferred stock are convertible and the denominator of which is the number of shares of outstanding Class A preferred stock. Pursuant to a one-for-fifteen reverse stock split of the Issuer's outstanding common stock, which became effective on September 22, 2022, the Class A preferred stock is convertible into 16,666 shares of the Issuer's common stock. Thus, the Class A preferred stock will at all times constitute a voting majority. The Reporting Person owns all outstanding shares of the Issuer's Class A preferred stock. As holders of Class A preferred stock, the Reporting Person will receive on each January 1 (each a "**PIK Dividend Payment Date**") until the date all outstanding Class A preferred stock is converted into common stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and nonassessable shares of Issuer common stock ("**PIK Dividends**") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of the Issuer's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date. An aggregate 22,222 shares of Issuer common stock underlie the Common Stock Warrants dated July 15, 2012, as amended by the Amended and Restated Common Stock Warrant dated December 12, 2016, issued by the Reporting Person to Lindsay A. Rosenwald, M.D., the Reporting Person's Chairman, President and Chief Executive Officer and Michael S. Weiss, the Reporting Person's Executive Vice Chairman, Strategic Development, pursuant to the Fortress Biotech, Inc. Long-Term Incentive Plan (the "**Warrants**"). The Warrants, which have an exercise price of \$0.146 per share, are exercisable until July 15, 2035. The Reporting Person must reserve from its holdings of the Issuer's common stock the shares underlying the Warrants until the Warrants are exercised. The foregoing description of the Warrants is not complete and is qualified in its entirety by reference to the full text of the form of the Amended and Restated Common Stock Warrant which is attached as Exhibit 7.01 and incorporated herein by reference. Mr. Weiss served as a member of the Issuer's Board of Directors from March 2015 until February 8, 2019, and has served as a director and Executive Vice Chairman of the Reporting Person since February 2014. Dr. Rosenwald has been a member of the Board of Directors of the Reporting Person since October 2009 and has served as its Chairman, President and Chief Executive Officer since December 2013.
- ² Excludes the 22,222 shares of Issuer's common stock underlying the Warrants.
- ³ Consists solely of the 22,222 shares of Issuer's common stock underlying the Warrants.
- ⁴ Includes 22,222 shares of Issuer's common stock underlying Warrants described above and 250,000 shares of the Issuer's Class A preferred stock, convertible into 16,666 shares of the Issuer's common stock. Percentage based upon 4,773,316 shares of the Issuer's common stock as reported by the Issuer on its Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on November 18, 2022, and the assumed conversion of the Class A preferred stock.

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Explanatory Note:

This Amendment No. 2 (the "**Amendment No. 2**") amends and supplements the statement on Schedule 13D and Amendment No. 1 to such Schedule 13D filed respectively on October 19, 2017 and April 19, 2019 (collectively, the "**Schedule 13D**") with the U.S. Securities and Exchange Commission relating to the Common Stock of Avenue Therapeutics, Inc. (the "**Issuer**"), by Fortress Biotech, Inc. (the "**Reporting Person**"). Except as specifically provided herein, this Amendment No. 2 does not modify any of the information previously reported on the Schedule 13D. Capitalized terms used but not defined herein shall have the same meanings as are ascribed to them in the Schedule 13D, as applicable.

Item 1. Security and Issuer

This amendment to a statement on Schedule 13D relates to the common stock of Avenue Therapeutics, Inc. (the "**Issuer**"). The Issuer's principal executive office is located at 2 Gansevoort Street, 9th Floor, New York, New York 10014.

Item 2. Identity and Background

- (a) This Schedule 13D/A is being filed on behalf of Fortress Biotech, Inc. (the “**Reporting Person**” or “**Fortress**”) pursuant to Rule 13d-1 of Regulation D-G under the Act.
- (b) The address of the Reporting Person's principal business and principal office is 1111 Kane Concourse, Suite 301, Bay Harbor Islands, Florida 33154.
- (c) The principal business of the Reporting Person is acquiring, developing and commercializing novel pharmaceutical and biotechnology products both within the Reporting Person and through certain of its subsidiary companies.
- (d)–(e) During the last five years, the Reporting Person: (i) has not been convicted in any criminal proceeding (excluding traffic violations or similar misdemeanors); and (ii) has not been a party to a civil proceeding of a judicial or administrative body of competent jurisdiction resulting in it being subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to, federal or state securities laws or finding any violation with respect to such laws.
- (f) The Reporting Person is organized under the laws of the state of Delaware.

Item 3. Source and Amount of Funds or Other Consideration.

The Reporting Person is filing this amendment to a Schedule 13D as a result of the acquisition of 90,909 shares of Issuer's common stock on December 31, 2022 as an issuance under the Founders Agreement (defined below) and the acquisition of 231,316 shares of Issuer's Common Stock on January 3, 2023 as a PIK Dividend.

The Reporting Person entered into a Founders Agreement with the Issuer in February 2015, which was amended and restated on September 13, 2016 (the “**Founders Agreement**”), pursuant to which the Reporting Person assigned to the Issuer all of its rights and interest under its license agreement with Revogenex for IV Tramadol. As consideration for the Founders Agreement, the Issuer assumed \$3.0 million in debt that the Reporting Person accumulated for expenses and costs of forming the Issuer and obtaining the IV Tramadol license. As additional consideration for the transfer of rights under the Founders Agreement, the Issuer also: (i) issues annually to the Reporting Person, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one-half percent (2.5%) of the fully-diluted outstanding equity of the Issuer at the time of issuance; and (ii) pays an equity fee in shares of the Issuer common stock, payable within five (5) business days of the closing of any equity or debt financing for the Issuer or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement equal to two and one-half percent (2.5%) of the gross amount of any such equity or debt financing.

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Item 5. Interest in Securities of the Issuer.

(a) – (c) The Reporting Person is the beneficial owner of 578,227 shares of the Issuer's common stock (including 250,000 shares of the Issuer's Class A preferred stock, which are convertible into 16,666 shares of the Issuer's common stock). The Reporting Person's shares of the Issuer's common stock represent beneficial ownership of 11.3% of the Issuer's outstanding common stock, based upon 4,773,316 outstanding shares of the Issuer's common stock as reported by the Issuer on its Proxy Statement on Schedule 14A, filed with the Securities and Exchange Commission on November 18, 2022, and the assumed conversion of the Class A preferred stock.

(d) Except with respect to the Warrants described in Footnote 1, no person has the power to direct the receipt of dividends on or the proceeds of sales of, the shares of common stock owned by the Reporting Person.

(e) Not Applicable.

Item 6. Contracts, Arrangements, Understandings or Relationships with Respect to Securities of the Issuer.

Reference is made to the Founders Agreement in Item 3 and the Warrants in Footnote 1 above.

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Item 7. Materials to be Filed as Exhibits.

- Exhibit 7.01 Second Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., dated September 12, 2016, incorporated by reference to Exhibit 3.1 to the Form 10-12G filed by the Issuer with the SEC on January 12, 2017 (File No. 000-55556).*
- Exhibit 7.02 Form of Common Stock Warrant filed as Exhibit 4.2 to Form 10-12G filed by the Issuer with the SEC on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.*
- Exhibit 7.03 Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc., dated September 13, 2016, incorporated by reference to Exhibit 10.2 to the Form 10-12G filed by the Issuer with the SEC on January 12, 2017 (File No. 000-55556).*

* Previously Filed.

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SIGNATURE

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date: January 6, 2023

FORTRESS BIOTECH, INC.

By: /s/ Lindsay A. Rosenwald
Name: Lindsay A. Rosenwald, M.D.
Title: Chairman, President and Chief Executive Officer
