
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13D
(Amendment No. 1)

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.
2 Gansevoort Street, 9th Floor
New York, New York 10014
(212) 554-4366

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

February 17, 2018
(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).

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

Number of Shares Beneficially Owned By Each Reporting Person with	7.	Sole Voting Power
		3, 840,096 ¹
	8.	Shared Voting Power
		0
	9.	Sole Dispositive Power
	3, 506,763 ²	
	10.	Shared Dispositive Power
		333,333 ³

11. Aggregate Amount Beneficially Owned by Each Reporting Person
3, 840,096 ¹

12. Check Box if the Aggregate Amount in Row (11) Excludes Certain Shares

13. Percent of Class Represented by Amount in Row (11)
23.3% of all outstanding shares of Issuer common stock ⁴

14. Type of Reporting Person
HC

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- 1 Includes 333,333 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. 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 (see Item 4 for details on the waiver of the PIK Dividends). An aggregate 333,333 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 333,333 shares of Issuer's common stock underlying the Warrants.
- 3 Consists solely of the 333,333 shares of Issuer's common stock underlying the Warrants.
- 4 Includes 333,333 shares of Issuer's common stock underlying Warrants described above and 250,000 shares of the Issuer's Class A preferred stock. Percentage based upon 16,502,310 shares of the Issuer's common stock as reported by the Issuer on its Form 10-K filed with the Securities and Exchange Commission on March 12, 2019, and the assumed conversion of the Class A preferred stock.
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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 Reporting Person’s business address is 2 Gansevoort Street, 9th Floor, New York, New York 10014.
- (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 273,837 shares of Issuer’s common stock on February 17, 2018 as an issuance under the Founders Agreement (defined below) and to report, in Item 4, the potential sale of the Reporting Person’s interest in the Issuer.

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. The Reporting Person waived these rights under the Founders Agreement in the Waiver Agreement executed on November 12, 2018 (described in Item 4 below).

Item 4. Purpose of Transaction.

Item 4 of the Schedule 13D is hereby amended and restated in its entirety as follows:

The following describes plans or proposals that the Reporting Person may have with respect to the matters set forth in Item 4(a)-(j) of Schedule 13D:

On November 12, 2018, Issuer, a subsidiary of Reporting Person, entered into a Stock Purchase and Merger Agreement (the “SPMA”) with InvaGen Pharmaceuticals Inc. and its subsidiaries (together, “Buyer”), pursuant to which the Buyer will purchase, for \$35 million, common shares representing 33.3% of the fully diluted capitalization of the Issuer (the “Stock Purchase Transaction”) and subsequently acquire the remaining issued and outstanding capital stock of the Issuer for \$180 million, subject to certain reductions, in a reverse subsidiary merger transaction (the “Merger Transaction”). Pursuant to the terms and subject to the conditions set forth in the SPMA, the Buyer will, at second closing, hold 100% of the issued and outstanding equity interests of the Issuer. On February 8, 2019, InvaGen acquired 5,833,333 shares of the Company’s common stock at \$6.00 (“the Stock Purchase Transaction”) per share for net proceeds of \$31.5 million after deducting commission fees and other offering costs, representing a 33.3% stake in the Company’s capital stock on a fully diluted basis.

The aggregate consideration to be paid by the Buyer under the SPMA is \$215 million in cash, subject to certain potential reductions, which Buyer intends to have sufficient immediately available funds to pay. In addition, the Issuer is subject to certain lock-up restrictions and agreed not to (subject to customary exceptions), during the period commencing at the signing of the SPMA until the Merger Transaction, issue, buy, sell, or otherwise subject to a security interest, pledge, hypothecation, mortgage or lien, any securities of the Issuer.

Consummation of the Merger Transaction is conditioned, among other things, upon U.S. Food and Drug Administration (“FDA”) approval of IV Tramadol, its labeling and scheduling and the absence of any Risk Evaluation and Mitigation Strategy restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The SPMA contains customary representations, warranties, covenants and termination rights as well as certain customary closing conditions, including the Issuer’s stockholders approval of the Stock Purchase Transaction and the Merger Transaction.

Stockholders Agreement

Concurrently with the execution and delivery of the SPMA, the Issuer, certain stockholders of the Issuer, including the Reporting Person (the “Stockholders”), and the Buyer entered into a stockholders agreement (the “Stockholders Agreement”), pursuant to which, among other things, the Buyer obtained the right to appoint three directors to the Issuer’s seven member Board of Directors, one of whom must qualify as an independent director, upon the closing of the Stock Purchase Transaction. The Stockholders Agreement also entitles the Buyer to veto rights over certain Issuer actions in the event the Merger Transaction fails to close.

Voting and Support Agreement

Concurrently with the execution and delivery of the SPMA, the Issuer, the Stockholders and the Buyer entered into a voting and support agreement (the “Voting Agreement”), pursuant to which, among other things, the Stockholders will (i) be present at any meeting of the Issuer’s stockholders, in person or represented by proxy, or otherwise cause all of their voting securities to be counted as present for purposes of calculating a quorum, and (ii) vote or cause to be voted (including by proxy or written consent, if applicable) all of their securities in favor of the Proposals (as defined in the SPMA), adjourning or postponing the stockholders meeting to a later date if there are not sufficient votes for the requisite stockholder approval, electing the Buyer Directors (as defined in the Stockholders Agreement) as members of the board of directors of the Issuer or any other matter necessary for the consummation of the Stock Purchase Transaction, Merger Transaction and any other transactions contemplated by the SPMA or the ancillary agreements. Further, pursuant to the Voting Agreement, the Stockholders will vote against any Takeover Proposal (as defined in the SPMA), any other action made in opposition to adoption of the SPMA or the ancillary agreements, any action reasonably expected to materially impede any of the transactions contemplated by the SPMA or the ancillary agreements or any action reasonably expected to result in a breach in any respect of any covenant, representation or warranty or any other obligation or agreement of the Issuer contained in the SPMA, or of the Stockholders contained in the Voting Agreement. In addition, the Stockholders agreed not to transfer any Issuer securities held by them until the earlier of the Merger Transaction and the termination of the SPMA.

Waiver Agreement

Concurrently with the execution and delivery of the SPMA, the Issuer, the Reporting Person and the Buyer entered into a waiver agreement (the “Waiver Agreement”), pursuant to which the Reporting Person irrevocably waived its right to receive the annual dividend of the Issuer’s common shares under the terms of the Class A preferred stock and any fees, payments, reimbursements or other distributions under a certain management services agreement between the Reporting Person and the Issuer and the Founders Agreement, for the period from the effective date of the Waiver Agreement to the termination of the Buyer’s rights under Section 4 of the Stockholders Agreement. Pursuant to the Waiver Agreement, immediately prior to the closing of the Merger Transaction, the Reporting Person will convert all of its preferred shares into common shares pursuant to the terms of the certificate of incorporation of the Issuer, as amended from time to time.

If the Merger Transaction is effected, it would result in one or more of the actions specified in clauses (a) through (j) of Item 4 of the Schedule 13D, including, without limitation, a merger or other extraordinary transaction involving the Issuer, the delisting of the Common Stock from the Nasdaq Global Select Market and the Common Stock becoming eligible for termination from registration pursuant to Section 12(b) of the Act.

Item 5. Interest in Securities of the Issuer.

(a) – (c) The Reporting Person is the beneficial owner of 3,840,096 shares of the Issuer’s common stock (including 250,000 shares of the Issuer’s Class A preferred stock, which are convertible into common stock). The Reporting Person’s shares of the Issuer’s common stock represent beneficial ownership of 23.3% of the Issuer’s outstanding common stock, based upon 16,502,310 outstanding shares of the Issuer’s common stock as reported by the Issuer on its Form 10-K, filed with the Securities and Exchange Commission on March 12, 2019, 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 and the Waiver Agreement in Item 3, the SPMA, the Stockholders Agreement, the Voting Agreement and the Waiver Agreement in Item 4, and the Warrants in Footnote 1 above.

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).*
- Exhibit 7.04 Stock Purchase and Merger Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc., InvaGen Pharmaceuticals Inc. and Madison Pharmaceuticals Inc., incorporated by reference to Exhibit 10.1 to the Form 8-K filed by the Reporting Person with the SEC on November 16, 2018 (File No. 001-35366).*
- Exhibit 7.05 Stockholders Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc., Avenue Therapeutics, Inc., Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc., incorporated by reference to Exhibit 10.2 to the Form 8-K filed by the Reporting Person with the SEC on November 16, 2018 (File No. 001-35366).*
- Exhibit 7.06 Voting and Support Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc., Avenue Therapeutics, Inc., Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc., incorporated by reference to Exhibit 10.5 to the Form 8-K filed by the Reporting Person with the SEC on November 16, 2018 (File No. 001-35366).*
- Exhibit 7.07 Waiver Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc., Avenue Therapeutics, Inc. and InvaGen Pharmaceuticals Inc., incorporated by reference to Exhibit 10.6 to the Form 8-K filed by the Reporting Person with the SEC on November 16, 2018 (File No. 001-35366).*

* Previously Filed.

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: April 19, 2019

FORTRESS BIOTECH, INC.

By: /s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald, M.D.

Title: Chairman, President and Chief Executive Officer
