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

AMENDMENT NO. 3

## FORM S-1 REGISTRATION STATEMENT

**UNDER**THE SECURITIES ACT OF 1933

## Avenue Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

#### Delaware

(State or Other Jurisdiction of Incorporation or Organization)

#### 2834

(Primary Standard Industrial Classification Code Number)

47-4113275

(I.R.S. Employer Identification Number)

2 Gansevoort Street, 9<sup>th</sup> Floor New York, New York 10014 (781) 652-4500

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Lucy Lu, M.D. President & CEO 2 Gansevoort Street, 9<sup>th</sup> Floor New York, New York 10014 (781) 652-4500

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

Copies to:

Mark F. McElreath, Esq. Matthew W. Mamak, Esq. Alston & Bird LLP 90 Park Avenue New York, NY 10016 (212) 210-9400 Ivan Blumenthal, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
666 Third Avenue
New York, NY 10017
(212) 935-3000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.  $\Box$ 

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\square$ 

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\square$ 

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  $\square$ Smaller reporting company  $\square$  Accelerated filer

Non-accelerated filer  $\boxtimes$ Emerging growth company  $\boxtimes$ 

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.  $\Box$ 

#### CALCULATION OF REGISTRATION FEE

Proposed		
Maximum		
Aggregate		
Offering	Amount	Of Registration Fee
Price (1)(3)		(2)(4)
\$ 34,500,000	\$	3,999.00
\$	Maximum Aggregate Offering Price (1)(3)	Maximum Aggregate Offering Amount Price (1)(3)

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.
- (3) Includes the offering price of additional shares that the underwriters have an option to purchase to cover over-allotments, if any.
- (4) Previously paid.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

#### PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution

	A	Amount to
		Be Paid
SEC Registration fee	\$	3,999
Legal fees and expenses	\$	350,000
FINRA filing fee	\$	1,500
NASDAQ listing fee	\$	10,000
Accounting fees and expenses	\$	100,000
Printing expenses	\$	10,000
Transfer agent fees and expenses	\$	5,000
Miscellaneous	\$	19,501
Total	\$	500,000

Each of the amounts set forth above, other than the registration fee, is an estimate.

#### Item 14. Indemnification of Directors and Officers

We have adopted provisions in our Second Amended and Restated Certificate of Incorporation that limit the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the DGCL. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- · any breach of their duty of loyalty to the corporation or the stockholder;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- · unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- · any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Second Amended and Restated Certificate of Incorporation and our Bylaws also provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. We believe that indemnification under our Bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our Bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our Bylaws would permit indemnification. We have secured such insurance

#### Item 15. Recent Sales of Unregistered Securities

On December 30, 2016, we held a closing of the sale of convertible promissory notes. We sold three convertible promissory notes to investors for an aggregate of \$0.2 million. The notes have an initial term of 18 months, which can be extended at the option of the holder, on one or more occasions, for up to 180 days and accrue simple interest at the rate of 5% per annum for the first 12 months and 8% per annum simple interest thereafter. The notes are guaranteed by Fortress. The outstanding principal and interest of the notes automatically converts into the type of equity securities sold by us in the next sale of equity securities in which we realize aggregate gross cash proceeds of at least \$10.0 million (before commissions or other expenses and excluding conversion of the notes) at a conversion price equal to the lesser of (a) the lowest price per share at which equity securities of Avenue are sold in such sale less a 33% discount and (b) a per

share price based on a pre-offering valuation of \$30.0 million divided by the number of common shares outstanding on a fully-diluted basis. The outstanding principal and interest of the notes may be converted at the option of the holder in any sale of equity securities that does not meet the \$10.0 million threshold for automatic conversion using the same methodology. The notes also automatically convert upon a "Sale" of us, defined as (a) a transaction or series of related transactions where one or more non-affiliates acquires (i) capital stock of us or any surviving successor entity possessing the voting power to elect a majority of the board of directors or (ii) a majority of the outstanding capital stock of us or the surviving successor entity (b) the sale, lease or other disposition of all or substantially all of our assets or any other transaction resulting in substantially all of our assets being converted into securities of another entity or cash. Upon a Sale of us, the outstanding principal and interest of the notes automatically converts into common shares at a price equal to the lesser of (a) a discount to the price per share being paid in the Sale of us equal to 33% or (b) the quotient resulting from dividing (x) \$30.0 million by (y) our fully-diluted common stock outstanding immediately prior to the Sale (excluding the notes).

In the closing, we realized net proceeds of \$142,000 after paying WestPark Capital, Inc., the placement agent, placement agent fees of \$30,000 and escrow fees of \$4,000. Additionally, WestPark received a warrant ("Avenue Warrant") to purchase the number of shares of our common stock equal to \$10,000 divided by the price per share at which any note sold to investors first converts into our common stock. The Avenue Warrant has a ten-year term and has a per share exercise price equal to the price per share at which any note sold to investors first converts into our common stock.

#### Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

(b) Financial Statements Schedules:

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto included elsewhere in this registration statement.

#### Item 17. Undertakings

- (a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

- (c) The undersigned registrant hereby undertakes that:
- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

## **SIGNATURES**

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of New York, State of New York, on this 23<sup>rd</sup> day of June, 2017.

## Avenue Therapeutics, Inc.

By: /s/ Lucy Lu, M.D.

Name: Lucy Lu, M.D.

Title: President, Chief Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this registration statement has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
*	Executive Chairman of the Board	June 23, 2017
Lindsay A. Rosenwald, M.D.		
/s/ Lucy Lu, M.D.	President,	June 23, 2017
Lucy Lu, M.D.	Chief Executive and Director	
*	Interim Chief Medical Officer	June 23, 2017
Scott A. Reines, M.D., Ph.D.		
/s/ David J. Horin	Interim Chief Financial Officer	June 23, 2017
David J. Horin		
*	Director	June 23, 2017
Michael S. Weiss		
*	Director	June 23, 2017
Neil Herskowitz		
*	Director	June 23, 2017
Jeffrey Paley, M.D.		
*	Director	June 23, 2017
Akhtar Samad, M.D., PhD.		
*	Director	June 23, 2017
Jay Kranzler, M.D., PhD		
*/s/ Lucy Lu, M.D.		
Attorney in Fact		
Attorney in ract		

#### EXHIBIT INDEX

#### Exhibit No. Description

- Form of Underwriting Agreement.\*\*\* 1.1
- 3.1 Second Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- 3.2 Bylaws of Avenue Therapeutics, Inc., filed as Exhibit 3.2 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- 4.1 Specimen certificate evidencing shares of Common Stock, filed as Exhibit 4.1 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- Form of warrant agreement, filed as Exhibit 4.2 to Form 10-12G filed on January 12, 2017 (File No. 000-4.2 55556) and incorporated herein by reference.
- 5.1 Opinion of Alston & Bird LLP.\*\*
- 10.1 Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated February 17, 2015, filed as Exhibit 10.1 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by reference.\*
- 10.2 First Amendment to Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated June 23, 2016, filed as Exhibit 10.11 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by reference.
- Second Amendment to Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated May 4, 2017.\*\*\*
- 10.4 Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. dated September 13, 2016, filed as Exhibit 10.2 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- Promissory Note from Avenue Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC, effective as of October 31, 2015, filed as Exhibit 10.3 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- 10.6 Promissory Note from Avenue Therapeutics, Inc. to Fortress Biotech, Inc., effective as of March 15, 2015, filed as Exhibit 10.4 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- 10.7 Management Services Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. effective as of February 17, 2015, filed as Exhibit 10.5 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- 10.8 Employment Agreement with Dr. Lucy Lu, MD, dated June 10, 2015, filed as Exhibit 10.6 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.#
- 109 Avenue Therapeutics, Inc. 2015 Incentive Plan, filed as Exhibit 10.7 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
- Consulting Agreement with Dr. Scott A. Reines, dated July 22, 2015, filed as Exhibit 10.8 to Form 10-12G 10.10 filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.#
- First Amendment to Consulting Agreement with Dr. Scott A. Reines, dated January 25, 2016, filed as Exhibit 10.9 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by
- 10.12 Second Amendment to Consulting Agreement with Dr. Scott A. Reines, dated August 2, 2016, filed as Exhibit 10.10 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by reference.#

Exhibit No.	Description
10.13	Third Amendment to Consulting Agreement with Dr. Scott A. Reines, dated February 28, 2017, filed as
	Exhibit 10.12 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by
	reference.#
23.1	Consent of BDO USA, LLP.***
23.2	Consent of Alston & Bird LLP (included in Exhibit 5.1).
24.1	Power of Attorney.***

- \* Subject to a Confidential Treatment Order.
- # Management Compensation Arrangement.
- + To be filed by amendment.
- \*\* Filed herewith.
- \*\*\* Previously filed.