
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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, 9th 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, 9th 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 PC
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: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☒ (File No. 333-217552)

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. ☐

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 ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☐

Emerging growth company ☒

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 to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title Of Each Class Of Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount Of Registration Fee(2)
Common Stock, par value \$0.0001 per share	\$3,450,000	\$399.86

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes shares of our common stock that the underwriters have the option to purchase to cover over-allotments, if any.
- (2) The registration fee is calculated pursuant to Rule 457(o) under the Securities Act. The \$3,450,000 proposed maximum aggregate offering price is in addition to the \$34,500,000 proposed maximum aggregate offering price registered pursuant to the Registrant's registration statement on Form S-1 (File No. 333-217552). A registration fee was previously paid in connection with that registration statement.

This registration statement shall become effective upon filing with the Securities and Exchange Commission in accordance with Rule 462(b) under the Securities Act of 1933, as amended.

EXPLANATORY NOTE AND INCORPORATION BY REFERENCE

This registration statement is being filed with respect to the registration of additional securities pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and includes the registration statement facing page, this page, the signature page, the exhibit index and exhibits. Pursuant to Rule 462(b), the contents of the registration statement on Form S-1 (File No. 333-217552), including all amendments and exhibits thereto, which was declared effective by the Commission on June 26, 2017, are incorporated herein by reference into this registration statement and this registration statement is being filed solely for the purpose of registering an increase in the maximum aggregate offering price of \$3,450,000.

SIGNATURES

Pursuant to the requirements of the Securities Act, 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 26th 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 Act, 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
* _____ Lindsay A. Rosenwald, M.D.	Executive Chairman of the Board	June 26, 2017
<u>/s/ Lucy Lu, M.D.</u> Lucy Lu, M.D.	President, Chief Executive and Director	June 26, 2017
* _____ Scott A. Reines, M.D., Ph.D.	Interim Chief Medical Officer	June 26, 2017
<u>/s/ David J. Horin</u> David J. Horin	Interim Chief Financial Officer	June 26, 2017
* _____ Michael S. Weiss	Director	June 26, 2017
* _____ Neil Herskowitz	Director	June 26, 2017
* _____ Jeffrey Paley, M.D.	Director	June 26, 2017
* _____ Akhtar Samad, M.D., PhD.	Director	June 26, 2017
* _____ Jay Kranzler, M.D., PhD	Director	June 26, 2017
*By: <u>/s/ Lucy Lu, M.D.</u> Lucy Lu, M.D. Attorney-in-Fact		

EXHIBIT INDEX

Exhibit Number	Description
5.1	Opinion of Alston & Bird LLP. *
23.1	Consent of BDO USA, LLP. *
23.2	Consent of Alston & Bird LLP (included in Exhibit 5.1).
24.1	Power of Attorney (incorporated by reference to the signature page of the Registrant's registration statement on Form S-1 (File No. 333-217552), filed with the SEC on April 28, 2017).

* Filed herewith.

ALSTON & BIRD

90 Park Avenue
New York, NY 10016
212-210-9400 | Fax: 212-210-9444

Mark F. McElreath

Direct Dial: 212-210-95955

Email: mark.mcelreath@alston.com

June 26, 2017

Avenue Therapeutics, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

We are acting as counsel to Avenue Therapeutics, Inc., a Delaware corporation (the “Company”). We have represented the Company in connection with the Company’s filing of a registration statement on Form S-1 (File No. 333-217552) (the “Initial Registration Statement”) filed by the Company with the Securities and Exchange Commission (the “Commission”) pursuant to the Securities Act of 1933, as amended (the “Securities Act”), on April 28, 2017 (and amended on May 22, 2017 and June 23, 2017) and declared effective by the Commission on June 26, 2017, as well as this registration statement filed in connection thereto under Rule 462(b) of the Securities Act (the “Rule 462(b) Registration Statement”). The Rule 462(b) Registration Statement was filed by the Company with the Commission pursuant to the Securities Act, for the registration of shares of Common Stock, \$0.0001 par value per share, with a proposed maximum aggregate offering price of \$3,450,000 (the “Shares”), including Shares issuable upon the exercise of an option granted by the Company to the underwriters to purchase additional shares. This opinion is furnished to you at your request in accordance with the requirements of Item 16 of the Commission’s Form S-1 and Item 601(b)(5) of Regulation S-K promulgated under the Securities Act.

The Shares are being sold by the Company to the several underwriters named in, and pursuant to, an underwriting agreement among the Company and such underwriters, a form of which has been filed as Exhibit 1.1 to the Initial Registration Statement (the “Underwriting Agreement”).

We have examined the Amended and Restated Certificate of Incorporation of the Company, the Bylaws of the Company, records of proceedings of the Board of Directors of the Company (the “Board of Directors”), or committees thereof, and records of proceedings of the stockholders, deemed by us to be relevant to this opinion letter. We also have made such further legal and factual examinations and investigations as we deemed necessary for purposes of expressing the opinion set forth herein.

Alston & Bird LLP

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As to certain factual matters relevant to this opinion letter, we have relied conclusively upon originals or copies, certified or otherwise identified to our satisfaction, of such records, agreements, documents and instruments, including certificates or comparable documents of officers of the Company and of public officials, as we have deemed appropriate as a basis for the opinion hereinafter set forth. Except to the extent expressly set forth herein, we have made no independent investigations with regard to matters of fact, and, accordingly, we do not express any opinion as to matters that might have been disclosed by independent verification.

In our examination of the foregoing, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

Based upon the foregoing and subject to the limitations, qualifications, exceptions and assumptions set forth herein, we are of the opinion that the Shares have been duly authorized by all necessary corporate action of the Company and, when issued and paid for in accordance with the terms and conditions of the Underwriting Agreement, will be validly issued, fully paid and nonassessable.

Our opinion set forth herein is limited to the General Corporation Law of the State of Delaware, the laws of the State of New York, and the federal law of the United States, and we do not express any opinion herein concerning any other laws.

This opinion letter is provided to the Company for its use solely in connection with the transactions contemplated by the Underwriting Agreement and may not be used, circulated, quoted or otherwise relied upon for any other purpose without our express written consent. The only opinion rendered by us consists of that set forth in the sixth paragraph of this letter, and no opinion may be implied or inferred beyond the opinion expressly stated. Our opinion expressed herein is as of the date hereof, and we undertake no obligation to advise you of any changes in applicable law or any other matters that may come to our attention after the date hereof that may affect our opinion expressed herein.

We consent to the filing of this opinion letter with the Commission as an exhibit to the Rule 462(b) Registration Statement and the use of our name in the Initial Registration Statement and in the related Prospectus under the heading "Legal Matters". In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

ALSTON & BIRD LLP

By: /s/ Mark F. McElreath
Mark F. McElreath
Partner

Consent of Independent Registered Public Accounting Firm

Avenue Therapeutics, Inc.

New York, New York

We hereby consent to the use of our report dated March 6, 2017, except for Note 11 which is as of June 22, 2017, relating to the financial statements of Avenue Therapeutics, Inc., which appears in the registration statement (Form S-1 No. 333-217552) and related Prospectus of Avenue Therapeutics, Inc. dated June 23, 2017, in this registration statement on Form S-1 filed pursuant to Rule 462(b) of the Securities Act of 1933. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/BDO USA, LLP

Boston, Massachusetts

June 26, 2017
