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

SCHEDULE 13D

**Under the Securities Exchange Act of 1934
(Amendment No. 1)***

AVENUE THERAPEUTICS, INC.

(Name of Issuer)

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

05360L205
(CUSIP Number)

A.S. Kumar
General Counsel, Cipla Limited
c/o

InvaGen Pharmaceuticals Inc.
Site B, 7 Oser Ave.
Hauppauge, New York 11788
Tel: +1 (631) 231-3233

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

February 8, 2019

(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 ("Act") 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 PERSONS I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY) INVAGEN PHARMACEUTICALS INC. 20-1420845 | |
| 2 | CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS) (a) <input type="checkbox"/> (b) <input checked="" type="checkbox"/> | |
| 3 | SEC USE ONLY | |
| 4 | SOURCE OF FUNDS (SEE INSTRUCTIONS) See Item 3 below | |
| 5 | CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO ITEM 2(D) OR 2(E) <input type="checkbox"/> | |
| 6 | CITIZENSHIP OR PLACE OF ORGANIZATION New York | |
| NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH | 7 | SOLE VOTING POWER N/A |
| | 8 | SHARED VOTING POWER 10,060,512 (See Note 1) |
| | 9 | SOLE DISPOSITIVE POWER N/A |
| | 10 | SHARED DISPOSITIVE POWER 10,060,512 |
| 11 | AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON 10,060,512 (See Item 5 below) | |
| 12 | CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS) <input type="checkbox"/> | |
| 13 | PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11) 59.86% (See Note 2) | |
| 14 | TYPE OF REPORTING PERSON (SEE INSTRUCTIONS) CO | |

- (1) Includes 5,833,333 shares of common stock (“Shares”) of Avenue Therapeutics, Inc. (the “Issuer”) owned by InvaGen Pharmaceuticals Inc. (“InvaGen”). In addition, due to the Voting and Support Agreement among InvaGen, Fortress Biotech, Inc. (“Fortress”), and Dr. Lucy Lu (“Dr. Lu”) dated November 12, 2018 (the “Support Agreement”), the Reporting Person may be deemed to have shared voting power to vote, with respect to the matters covered by the Support Agreement, up to an aggregate of 4,227,179 Shares (the “Support Agreement Shares”), and such Shares may be deemed beneficially owned by it pursuant to Rule 13d-3 under the Securities Exchange Act of 1934, as amended (“Rule 13d-3”). Such 4,227,179 Shares include (i) 3,590,096 issued and outstanding Shares held by Fortress, (ii) 191,668 issued and outstanding Shares held by Dr. Lu, (iii) 141,665 unvested restricted Shares of the Issuer held by Dr. Lu, (iv) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (v) 250,000 shares of the Issuer’s class A preferred stock (“Class A Preferred Stock”) held by Fortress that are convertible into Shares. Pursuant to Rule 13d-4 under the Securities Exchange Act of 1934, as amended (“Rule 13d-4”), neither this Schedule 13D nor any of its content shall be deemed to constitute an admission by the Reporting Person that it is a beneficial owner of the Support Agreement Shares, and the Reporting Person expressly disclaims any such beneficial ownership.
 - (2) Calculation of percentage is based on a total of 16,805,435 Shares, comprised of (i) 16,141,368 issued and outstanding Shares, (ii) 360,317 unvested restricted Shares of the Issuer, (iii) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (iv) 250,000 shares Class A Preferred Stock held by Fortress that are convertible into Shares, based on information provided to InvaGen by the Issuer as of February 8, 2019.
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| 1 | NAME OF REPORTING PERSONS I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY) CIPLA (EU) LIMITED | |
| 2 | CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS) (a) <input type="checkbox"/> (b) <input checked="" type="checkbox"/> | |
| 3 | SEC USE ONLY | |
| 4 | SOURCE OF FUNDS (SEE INSTRUCTIONS) Not Applicable (see Item 3 below) | |
| 5 | CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO ITEM 2(D) OR 2(E) <input type="checkbox"/> | |
| 6 | CITIZENSHIP OR PLACE OF ORGANIZATION United Kingdom | |
| NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH | 7 | SOLE VOTING POWER N/A |
| | 8 | SHARED VOTING POWER 10,060,512 (See Note 1) |
| | 9 | SOLE DISPOSITIVE POWER N/A |
| | 10 | SHARED DISPOSITIVE POWER 10,060,512 |
| 11 | AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON 10,060,512 (See Item 5 below) | |
| 12 | CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS) <input type="checkbox"/> | |
| 13 | PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11) 59.86% (See Note 2) | |
| 14 | TYPE OF REPORTING PERSON (SEE INSTRUCTIONS) CO | |

- (1) Includes 5,833,333 Shares owned by InvaGen. Because of the relationship between the Reporting Persons, as described in Item 2 of the Original Schedule 13D, Cipla (EU) Limited may be deemed to beneficially own such Shares pursuant to Rule 13d-3 . In addition, due to the Support Agreement, the Reporting Person may be deemed to have shared voting power to vote, with respect to the matters covered by the Support Agreement, up to an aggregate of 4,227,179 Shares, and such Shares may be deemed beneficially owned by it pursuant to Rule 13d-3. Such 4,227,179 Shares include (i) 3,590,096 issued and outstanding Shares held by Fortress, (ii) 191,668 issued and outstanding Shares held by Dr. Lu, (iii) 141,665 unvested restricted Shares of the Issuer held by Dr. Lu, (iv) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (v) 250,000 shares of the Issuer's Class A Preferred Stock held by Fortress that are convertible into Shares. Pursuant to Rule 13d-4, neither this Schedule 13D nor any of its content shall be deemed to constitute an admission by the Reporting Person that it is a beneficial owner of the Support Agreement Shares, and the Reporting Person expressly disclaims any such beneficial ownership.
 - (2) Calculation of percentage is based on a total of 16,805,435 Shares, comprised of (i) 16,141,368 issued and outstanding Shares, (ii) 360,317 unvested restricted Shares of the Issuer, (iii) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (iv) 250,000 shares Class A Preferred Stock held by Fortress that are convertible into Shares, based on information provided to InvaGen by the Issuer as of February 8, 2019.
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| 1 | NAME OF REPORTING PERSONS I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY) CIPLA LIMITED | |
| 2 | CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP (SEE INSTRUCTIONS) (a) <input type="checkbox"/> (b) <input checked="" type="checkbox"/> | |
| 3 | SEC USE ONLY | |
| 4 | SOURCE OF FUNDS (SEE INSTRUCTIONS) See Item 3 below | |
| 5 | CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO ITEM 2(D) OR 2(E) <input type="checkbox"/> | |
| 6 | CITIZENSHIP OR PLACE OF ORGANIZATION India | |
| NUMBER OF SHARES BENEFICIALLY OWNED BY EACH REPORTING PERSON WITH | 7 | SOLE VOTING POWER N/A |
| | 8 | SHARED VOTING POWER 10,060,512 (See Note 1) |
| | 9 | SOLE DISPOSITIVE POWER N/A |
| | 10 | SHARED DISPOSITIVE POWER 10,060,512 |
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| 12 | CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES (SEE INSTRUCTIONS) <input type="checkbox"/> | |
| 13 | PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11) 59.86% (See Note 2) | |
| 14 | TYPE OF REPORTING PERSON (SEE INSTRUCTIONS) CO | |

- (1) Includes 5,833,333 Shares owned by InvaGen. Because of the relationship between the Reporting Persons, as described in Item 2 of the Original Schedule 13D, Cipla Limited may be deemed to beneficially own such Shares pursuant to Rule 13d-3 . In addition, due to the Support Agreement, the Reporting Person may be deemed to have shared voting power to vote, with respect to the matters covered by the Support Agreement, up to an aggregate of 4,227,179 Shares, and such Shares may be deemed beneficially owned by it pursuant to Rule 13d-3. Such 4,227,179 Shares include (i) 3,590,096 issued and outstanding Shares held by Fortress, (ii) 191,668 issued and outstanding Shares held by Dr. Lu, (iii) 141,665 unvested restricted Shares of the Issuer held by Dr. Lu, (iv) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (v) 250,000 shares of the Issuer's Class A Preferred Stock held by Fortress that are convertible into Shares. Pursuant to Rule 13d-4, neither this Schedule 13D nor any of its content shall be deemed to constitute an admission by the Reporting Person that it is a beneficial owner of the Support Agreement Shares, and the Reporting Person expressly disclaims any such beneficial ownership.
 - (2) Calculation of percentage is based on a total of 16,805,435 Shares, comprised of (i) 16,141,368 issued and outstanding Shares, (ii) 360,317 unvested restricted Shares of the Issuer, (iii) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (iv) 250,000 shares Class A Preferred Stock held by Fortress that are convertible into Shares, based on information provided to InvaGen by the Issuer as of February 8, 2019.
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This Amendment No. 1 (this “Amendment”) to Schedule 13D (as so amended, “Schedule 13D”) amends the statement on Schedule 13D (the “Original Schedule 13D”) which was filed by the Reporting Persons on November 23, 2018, with respect to shares of common stock (“Shares”) of Avenue Therapeutics, Inc., a Delaware corporation (the “Issuer”). Unless otherwise defined herein, capitalized terms used but not defined in this Amendment have the respective meanings ascribed to them in the Original Schedule 13D.

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

Item 3 of the Original Schedule 13D is hereby supplemented by adding the following:

InvaGen paid the consideration payable in connection with the closing of the Stock Purchase Transaction in part out of its generally available funds and in part through issuance of further securities to its parent Cipla EU.

Item 4. Purpose of Transaction.

Item 4 of the Original Schedule 13D is hereby supplemented by adding the following:

On February 8, 2019, InvaGen and the Issuer completed the First Stage Closing under the SPMA. In connection with the First Stage Closing, InvaGen paid the Issuer \$35 million and received 5,833,333 Shares representing 33.3% of the fully diluted capitalization of the Issuer.

Item 5. Interest in Securities of the Issuer.

Item 5 of the Original Schedule 13D is hereby amended and restated as follows:

- (a)-(b) The information contained in rows 7 through 13 on each of the cover pages of the Amendment and the information contained in Items 1, 2 and 4 of Schedule 13D, as amended, are incorporated by reference.

InvaGen owns 5,833,333 Shares (the “InvaGen Shares”). Because of the relationship between the Reporting Persons, as described in Item 2 of the Original Schedule 13D, each Reporting Person may be deemed to beneficially own such Shares pursuant to Rule 13d-3. The Reporting Persons have shared voting and dispositive power over the InvaGen Shares.

In addition, due to the Support Agreement, the Reporting Persons may be deemed to have shared voting power to vote, with respect to the matters covered by the Support Agreement, up to an aggregate of 4,227,179 Shares (the “Support Agreement Shares”), and such Shares may be deemed beneficially owned pursuant to Rule 13d-3 under the Securities Exchange Act of 1934, as amended. Such 4,227,179 Shares include (i) 3,590,096 issued and outstanding Shares held by Fortress, (ii) 191,668 issued and outstanding Shares held by Dr. Lu, (iii) 141,665 unvested restricted Shares of the Issuer held by Dr. Lu, (iv) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (v) 250,000 shares of the Issuer’s class A preferred stock (“Class A Preferred Stock”) held by Fortress that are convertible into Shares. Pursuant to Rule 13d-4 under the Securities Exchange Act of 1934, as amended, neither the filing of the Schedule 13D nor any of its content shall be deemed to constitute an admission by any of the Reporting Persons that it is a beneficial owner of the Support Agreement Shares, and the Reporting Persons expressly disclaim any such beneficial ownership.

The Shares which the Reporting Persons may be deemed to beneficially own represent 59.86% of the outstanding Shares of the Issuer. The calculation of such percentage is based on a total of 16,805,435 Shares, comprised of (i) 16,141,368 issued and outstanding Shares, (ii) 360,317 unvested restricted Shares of the Issuer, (iii) 53,750 vested restricted stock units of the Issuer held by Dr. Lu that are convertible into Shares, and (iv) 250,000 shares Class A Preferred Stock held by Fortress that are convertible into Shares, based on information provided to InvaGen by the Issuer as of February 8, 2019.

- (c) Except as set forth in Item 4 and Item 6 of Schedule 13D, as amended, none of the Reporting Persons nor, to the Reporting Persons' knowledge, any of the persons listed in Annex A hereto, has effected any transaction in the Shares during the past 60 days.
- (d) No other person has the power to direct the receipt of dividends from, or the proceeds from the sale of, the InvaGen Shares. The Reporting Persons have no right to receive dividends from, or the proceeds from the sale of, the Support Agreement Shares.
- (e) Not applicable.

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

InvaGen Directors

Effective February 8, 2019, in connection with the First Stage Closing, Dr. Akhtar Samad and Michael S. Weiss each resigned as a member of the Board of Directors of the Issuer (the "Board"), and, immediately thereafter, the Board elected Dr. Jaideep Gogtay and Nishant Saxena as new members of the Board. On November 12, 2018, in connection with the execution and delivery of the SPMA, the Issuer, certain stockholders of the Issuer including Fortress, and InvaGen, entered into a stockholders agreement (the "Stockholders Agreement"), pursuant to which, among other things, InvaGen obtained the right to nominate three directors to the Issuer's seven member Board (the "InvaGen Directors"), one of whom must qualify as an independent director, upon the First Stage Closing. At this time, InvaGen exercised its right to nominate two directors to the Board, Dr. Gogtay and Mr. Saxena (neither of which qualifies as an independent director). The above description is qualified in its entirety by the full text of the Stockholders Agreement which was incorporated by reference into the Original Schedule 13D.

Registration Rights Agreement

Effective February 8, 2019, in connection with the First Stage Closing, the Issuer and InvaGen entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which, among other things, InvaGen has the right to deliver to the Issuer a written notice requiring the Issuer to prepare and file with the U.S. Securities and Exchange Commission, a registration statement with respect to resales of some or all registrable securities held by InvaGen. The above description is qualified in its entirety by the full text of the Registration Rights Agreement which was filed as Exhibit D to the Original Schedule 13D.

Amendment and Restatement of Issuer's Bylaws

Effective February 8, 2019, in connection with the First Stage Closing, the Board approved and adopted the Revised Bylaws as the amended and restated bylaws of the Issuer, effective immediately. Among other things, the Board amended Section 3 of the Issuer's bylaws to include InvaGen's right to nominate the InvaGen Directors and so that InvaGen's consent would be required to change the size of the Board. The above description is qualified in its entirety by the full text of the Revised Bylaws which was filed as Exhibit E to the Original Schedule 13D.

SIGNATURE

After reasonable inquiry and to the best of his or her knowledge and belief, the undersigned certifies that the information set forth in this statement is true, complete and correct.

Dated: February 11, 2019

INVAGEN PHARMACEUTICALS INC.

By: /s/ Deepak Agarwal

Name: Deepak Agarwal

Title: Director

CIPLA (EU) LIMITED

By: /s/ Christos Kartalis

Name: Christos Kartalis

Title: Director

CIPLA LIMITED

By: /s/ A.S. Kumar

Name: A.S. Kumar

Title: Global General Counsel and Executive Vice President

Annex A
Directors and Executive Officers of the Reporting Persons

InvaGen Pharmaceuticals Inc.

The name, business address, present principal occupation and citizenship of each director and executive officer of InvaGen Pharmaceuticals Inc. (“InvaGen”) are set forth below. If no address is given, the business address of each person listed below is 7 Oser Avenue, Hauppauge, New York 11788.

| <u>Name</u> | <u>Present Principal Occupation and Business Address</u> | <u>Citizenship</u> |
|------------------|--|--------------------|
| Umang Vohra | Director | India |
| Samina Vaziralli | Director | India |
| Peter Lankau | Director | United States |
| Nikhil Lalwani | Director, President and Chief Executive Officer of InvaGen | India |
| Deepak Agarwal | Director, Chief Financial Officer of InvaGen | India |
| Mohit Mundra | Secretary and Treasurer of InvaGen | India |

Cipla (EU) Limited

The name, business address, present principal occupation and citizenship of each director and executive officer of Cipla (EU) Limited (“Cipla EU”) are set forth below. If no address is given, the business address of each person listed below is Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey, KT15 2LE, United Kingdom.

| <u>Name</u> | <u>Present Principal Occupation and Business Address</u> | <u>Citizenship</u> |
|-------------------|--|--------------------|
| Gillian Latham | Director | United Kingdom |
| Christos Kartalis | Director | Greece |
| Samina Vaziralli | Director | India |
| Anchal Sultania | Director | India |

Cipla Limited

The name, business address, present principal occupation and citizenship of each director and executive officer of Cipla Limited (“Cipla Limited”) are set forth below. If no address is given, the business address of each person listed below is Cipla House, Peninsula Business Park, Ganapatrao Kadam Marg, Lower Parel West, Mumbai, Maharashtra 400013, India.

| Name | Present Principal Occupation and Business Address | Citizenship |
|-------------------|---|--------------------|
| Y. K. Hamied | Non-Executive Chairman of Cipla Limited | India |
| M.K. Hamied | Non-Executive Vice-Chairman of Cipla Limited | India |
| Samina Vaziralli | Executive Vice-Chairperson of Cipla Limited | India |
| Umang Vohra | Managing Director and Global Chief Executive Officer of Cipla Limited | India |
| S. Radhakrishnan | Director of Cipla Limited | India |
| Ashok Sinha | Director of Cipla Limited | India |
| Dr. Peter Mugenyi | Director of Cipla Limited | Uganda |
| Adil Zainulbhai | Director of Cipla Limited | United States |
| Punita Lal | Director of Cipla Limited | India |
| Naina Lal Kidwai | Director of Cipla Limited | India |
| Ireena Vittal | Director of Cipla Limited | India |
| Peter Lankau | Director of Cipla Limited | United States |