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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **March 12, 2019**

Avenue Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38114
(Commission File Number)

47-4113275
(IRS Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 12, 2019, Avenue Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the fiscal year ended December 31, 2018. A copy of such press release is being furnished as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

| Exhibit Number | Description |
|-----------------------------|---|
| <u>99.1</u> | <u>Press release issued by Avenue Therapeutics, Inc., dated March 12, 2019.</u> |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVENUE THERAPEUTICS, INC.
(Registrant)

Date: March 12, 2019

By: /s/ Lucy Lu, M.D.
Name: Lucy Lu, M.D.
Title: President & Chief Executive Officer



Avenue Therapeutics Reports Full Year 2018 Financial Results and Recent Corporate Highlights

-- Expects to Report Topline Data from Phase 3 Trial of IV Tramadol in Patients Following Abdominoplasty Surgery in mid-2019 --

New York, NY – March 12, 2019 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) (“Avenue”), a company focused on the development of intravenous (“IV”) tramadol for the U.S. market, today reported financial results and recent corporate highlights for the year ended December 31, 2018.

“2018 was an exciting year for Avenue. We announced positive data from our first pivotal Phase 3 trial evaluating IV tramadol in patients following bunionectomy surgery in May, and signed a two-stage equity investment and contingent acquisition agreement with InvaGen Pharmaceuticals Inc. (“InvaGen”), a subsidiary of Cipla Limited, in November,” said Lucy Lu, MD, Avenue’s President and Chief Executive Officer. “The first stage of the transaction closed in February of 2019 and we look forward to reporting topline data from our second Phase 3 trial in patients following abdominoplasty surgery in the coming months.”

2018 and Recent Corporate Highlights:

- In May 2018, we announced that our first pivotal Phase 3 trial of IV tramadol achieved the primary endpoint of a statistically significant improvement in Sum of Pain Intensity Difference over 48 hours compared to placebo in patients with moderate to moderately severe postoperative pain following bunionectomy surgery. In addition, the trial met its key secondary endpoints and demonstrated a clear dose response.
- In November 2018, we announced definitive agreements regarding an equity investment and contingent acquisition of Avenue by InvaGen, a subsidiary of Cipla Limited, a leading pharmaceutical company. The first stage of the transaction closed in February 2019, and InvaGen acquired 5,833,333 shares of our common stock at \$6.00 per share for total gross proceeds of \$35.0 million, representing a 33.3% stake in Avenue’s capital stock on a fully diluted basis.
- In December 2018, we announced that the first patient has been dosed in a pivotal Phase 3 clinical trial of IV tramadol for the management of moderate to moderately severe pain in patients following abdominoplasty surgery. Topline data is expected to be available in mid-2019.

2018 Financial Results:

- **Cash Position:** As of December 31, 2018, our cash and short-term investments totaled \$2.7 million, compared to \$21.8 million at December 31, 2017, a decrease of \$19.1 million. However, on February 8, 2019, we completed the first stage of the Acquisition agreement and we sold 5,833,333 shares of our common stock to InvaGen for total gross proceeds of \$35.0 million.
 - **R&D Expenses:** Research and development expenses for the full year 2018 were \$17.7 million, compared to \$6.7 million in 2017. This increase of \$11.0 million was primarily attributable to the completion of our bunionectomy study, continuation of our safety study and the initiation of our abdominoplasty study.
 - **G&A Expenses:** General and administrative expenses for the full year 2018 were \$4.1 million, compared to \$3.6 million in 2017. This increase of \$0.5 million was primarily attributable to increases in legal costs and other professional fees partially offset by non-cash stock compensation expenses.
 - **Net Loss:** Net loss attributable to common stockholders for the full year 2018 was \$21.5 million, or \$2.10 per share, compared to a net loss of \$12.3 million, or \$1.85 per share, in 2017.
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About Avenue Therapeutics

Avenue, a company founded by Fortress Biotech, is a specialty pharmaceutical company focused on the development and commercialization of IV Tramadol for the management of moderate to moderately severe post-operative pain. IV Tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAIDs and IV conventional narcotics. Avenue is currently evaluating IV Tramadol in a pivotal Phase 3 program for the management of post-operative pain. Avenue is headquartered in New York City. For more information, visit www.avenuetx.com.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") (NASDAQ: FBIO) is an innovative biopharmaceutical company focused on identifying, in-licensing and developing high-potential clinical-stage assets. The company has over 25 programs in clinical development at Fortress, at its majority-owned and majority-controlled subsidiaries and at entities it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market therapeutic areas, including oncology, rare diseases and gene therapy, which allow it to create value while mitigating risk for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company's portfolio of product opportunities. Fortress has established partnerships with some of the world's leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion Pharmaceuticals, Inc., City of Hope, Fred Hutchinson Cancer Research Center, InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Limited), St. Jude Children's Research Hospital and UCL Business PLC. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

Contacts:

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AVENUE THERAPEUTICS, INC.
Balance Sheets
(\$ in thousands, except for share and per share amounts)

| | <u>December 31,</u> <u>2018</u> | <u>December 31,</u> <u>2017</u> |
|---|------------------------------------|------------------------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 2,671 | \$ 11,782 |
| Short-term investments | - | 10,000 |
| Deferred financing costs | 1,702 | - |
| Prepaid expenses and other current assets | 152 | 388 |
| Total Assets | <u>\$ 4,525</u> | <u>\$ 22,170</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | \$ 4,669 | \$ 2,737 |
| Accounts payable and accrued expenses - related party | 487 | 53 |
| Total current liabilities | 5,156 | 2,790 |
| Total Liabilities | <u>5,156</u> | <u>2,790</u> |
| Commitments and Contingencies | | |
| Stockholders' Equity (Deficit) | | |
| Preferred Stock (\$0.0001 par value), 2,000,000 shares authorized | | |
| Class A Preferred Stock, 250,000 shares issued and outstanding as of December 31, 2018 and 2017, respectively | - | - |
| Common Stock (\$0.0001 par value), 50,000,000 shares authorized | | |
| Common shares; 10,667,714 and 10,265,083 shares issued and outstanding as of December 31, 2018 and 2017, respectively | 1 | 1 |
| Common stock issuable, 0 and 273,837 shares as of December 31, 2018 and 2017, respectively | - | 1,103 |
| Additional paid-in capital | 41,577 | 38,937 |
| Accumulated deficit | (42,209) | (20,661) |
| Total Stockholders' Equity (Deficit) | (631) | 19,380 |
| Total Liabilities and Stockholders' Equity (Deficit) | <u>\$ 4,525</u> | <u>\$ 22,170</u> |

AVENUE THERAPEUTICS, INC.
Statements of Operations
(\$ in thousands, except for share and per share amounts)

| | For the Year Ended | |
|---|----------------------|----------------------|
| | December 31, 2018 | December 31, 2017 |
| Operating expenses: | | |
| Research and development | \$ 17,696 | \$ 6,698 |
| Research and development - licenses acquired | - | 1,103 |
| General and administrative | 4,120 | 3,620 |
| Loss from operations | (21,816) | (11,421) |
| Interest income | (93) | (88) |
| Interest expense | - | 294 |
| Interest expense - related party | - | 81 |
| Change in fair value of convertible notes payable | - | 99 |
| Change in fair value of warrant liabilities | - | 451 |
| Other income | (175) | - |
| Net Loss | \$ (21,548) | \$ (12,258) |
| Net loss per common share outstanding, basic and diluted | \$ (2.10) | \$ (1.85) |
| Weighted average number of common shares outstanding, basic and diluted | 10,239,169 | 6,634,937 |