
**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): **May 13, 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ATXI	Nasdaq Capital Market

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2019, Avenue Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the first quarter ended March 31, 2019. A copy of such press release is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	Description
99.1	Press release issued by Avenue Therapeutics, Inc., dated May 13, 2019.

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: May 13, 2019

By: /s/ Lucy Lu, M.D.
Lucy Lu, M.D.
President and Chief Executive Officer



Avenue Therapeutics Reports First Quarter 2019 Financial Results and Recent Corporate Highlights

Safety study completed; Expect to report data from 2nd pivotal Phase 3 trial by the end of second quarter 2019

New York, NY – May 13, 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 first quarter ended March 31, 2019.

“We recently completed the safety study for IV tramadol and expect to report data by the end of this quarter from our pivotal Phase 3 trial of IV tramadol for the management of postoperative pain in patients following abdominoplasty surgery,” said Lucy Lu, M.D., Avenue’s President and Chief Executive Officer. “We look forward to the results from this important study, as it not only compares IV tramadol to placebo, but also includes an active-comparator arm of IV morphine.”

Recent Achievements:

- The Company has completed the open-label, single-arm safety study of IV tramadol in post-surgical pain. The results show that IV tramadol is well-tolerated with a side effect profile consistent with known pharmacology.
- In April 2019, Avenue announced the appointment of Dr. Thomas G. Moore to its Board of Directors.

Financial Results:

- **Cash Position:** As of March 31, 2019, Avenue’s cash and cash equivalents totaled \$29.4 million, compared to \$2.7 million at December 31, 2018. The \$26.7 million increase was primarily attributable to the stock purchase by InvaGen Pharmaceuticals Inc. (“InvaGen”) in connection with the first stage closing of the agreement between InvaGen and Avenue.
 - **R&D Expenses:** Research and development expenses for the three months ended March 31, 2019, were \$10.2 million, compared to \$9.4 million for the same quarter in 2018. The \$0.8 million increase was primarily attributable to the ongoing Phase 3 trial of IV tramadol following abdominoplasty surgery and to the Phase 3 safety trial of IV tramadol.
 - **G&A Expenses:** General and administrative expenses for the three months ended March 31, 2019, were \$1.1 million, compared to \$1.0 million for the same quarter in 2018. The \$0.1 million increase was primarily attributable to an increase in non-cash stock compensation offset by reductions in market research costs and professional fees.
 - **Net Loss:** Net loss attributable to common stockholders for the three months ended March 31, 2019, was \$11.3 million, or \$0.82 per share, compared to a net loss of \$10.4 million, or \$1.03 per share, for the three months ended March 31, 2018.
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About Avenue Therapeutics

Avenue 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 and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.avenuetx.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.
Condensed Balance Sheets
(\$ in thousands, except for share and per share amounts)

	March 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 29,448	\$ 2,671
Deferred financing costs	61	1,702
Prepaid expenses and other current assets	254	152
Total Assets	\$ 29,763	\$ 4,525
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 9,326	\$ 4,669
Accounts payable and accrued expenses - related party	86	487
Total current liabilities	9,412	5,156
Total Liabilities	9,412	5,156
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 March 31, 2019 and December 31, 2018	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares; 16,557,122 and 10,667,714 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	2	1
Additional paid-in capital	73,827	41,577
Accumulated deficit	(53,478)	(42,209)
Total Stockholders' Equity (Deficit)	20,351	(631)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 29,763	\$ 4,525

AVENUE THERAPEUTICS, INC.
Condensed Statements of Operations
(Unaudited)

(\$ in thousands, except for share and per share amounts)

	For the Three Months Ended	
	March 31,	March 31,
	2019	2018
Operating expenses:		
Research and development	\$ 10,241	\$ 9,439
General and administrative	1,119	986
Loss from operations	<u>(11,360)</u>	<u>(10,425)</u>
Interest income	(91)	(48)
Net Loss	<u>\$ (11,269)</u>	<u>\$ (10,377)</u>
Net loss per common share outstanding, basic and diluted	\$ (0.82)	\$ (1.03)
Weighted average number of common shares outstanding, basic and diluted	13,742,649	10,099,331
