
**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): **November 4, 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.

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	ATXI	Nasdaq Capital Market

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 November 4, 2019, Avenue Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 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 November 4, 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.

Date: November 4, 2019

Avenue Therapeutics, Inc.
(Registrant)

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



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

New York, NY – November 4, 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 third quarter ended September 30, 2019.

“We are pleased with the progress made during the third quarter of 2019, especially with the fact that our partner company, Cipla Limited, brought on Ms. Garrett Ingram as head of their U.S. specialty hospital business to lead the potential commercialization of IV tramadol,” said Lucy Lu, M.D., Avenue’s President and Chief Executive Officer. “Looking ahead, we are on track to submit a New Drug Application for IV tramadol to the U.S. Food and Drug Administration by year-end 2019.”

Recent Achievements:

- In August 2019, Avenue announced the appointment of Ms. Garrett Ingram to its Board of Directors.
- In October 2019, an eAbstract was presented at ANESTHESIOLOGY® 2019, the Annual Meeting of the American Society of Anesthesiologists in Orlando, FL, highlighting the Phase 3 data for IV tramadol in the management of post-surgical pain in patients undergoing bunionectomy, an orthopedic model. As previously announced, IV tramadol 50 mg met the primary endpoint, as well as all of the key secondary endpoints.
- Also in October 2019, Avenue announced the publication of IV tramadol Phase 1 clinical data in the peer-reviewed journal *Clinical Pharmacology in Drug Development*. The paper titled “Comparing the Pharmacokinetics of 2 Novel Intravenous Tramadol Dosing Regimens to Oral Tramadol: A Randomized 3-Arm Crossover Study” can be accessed [here](#).

Financial Results:

- **Cash Position:** As of September 30, 2019, Avenue’s cash and cash equivalents and short-term investments totaled \$13.7 million, compared to \$15.5 million at June 30, 2019.
- **R&D Expenses:** Research and development expenses for the three months ended September 30, 2019, were \$1.7 million, relatively flat compared to \$1.8 million for the same quarter in 2018.
- **G&A Expenses:** General and administrative expenses for the three months ended September 30, 2019, were \$0.6 million, compared to \$0.8 million for the same quarter in 2018. The \$0.2 million decrease was primarily attributable to decreased market research costs and non cash stock compensation.
- **Net Loss:** Net loss attributable to common stockholders for the three months ended September 30, 2019, was \$2.2 million, or \$0.14 per share, compared to a net loss of \$2.6 million, or \$0.25 per share, for the three months ended September 30, 2018.

About Avenue Therapeutics

Avenue Therapeutics is a specialty pharmaceutical company whose mission is to develop intravenous IV tramadol, a potential alternative that could reduce the use of conventional opioids, for patients suffering from acute pain in the U.S. 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)

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,741	\$ 2,671
Short-term investments	5,000	-
Deferred financing costs	61	1,702
Prepaid expenses and other current assets	76	152
Total Assets	<u>\$ 13,878</u>	<u>\$ 4,525</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,901	\$ 4,669
Accounts payable and accrued expenses - related party	16	487
Total current liabilities	1,917	5,156
Total Liabilities	<u>1,917</u>	<u>5,156</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 September 30, 2019 and December 31, 2018	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares, 16,661,355 and 10,667,714 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	2	1
Additional paid-in capital	74,661	41,577
Accumulated deficit	(62,702)	(42,209)
Total Stockholders' Equity (Deficit)	11,961	(631)
Total Liabilities and Stockholders' Equity (Deficit)	<u>\$ 13,878</u>	<u>\$ 4,525</u>

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

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

	For the Three Months Ended		For the Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Operating expenses:				
Research and development	\$ 1,706	\$ 1,788	\$ 18,339	\$ 14,981
General and administrative	617	820	2,452	2,733
Loss from operations	(2,323)	(2,608)	(20,791)	(17,714)
Interest income	(81)	(13)	(298)	(85)
Net Loss	\$ (2,242)	\$ (2,595)	\$ (20,493)	\$ (17,629)
Net loss per common share outstanding, basic and diluted	\$ (0.14)	\$ (0.25)	\$ (1.32)	\$ (1.73)
Weighted average number of common shares outstanding, basic and diluted	16,376,204	10,295,958	15,487,519	10,216,466