
**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 30, 2020**

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.)

1140 Avenue of the Americas, Floor 9
New York, New York 10036
(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 Each Class	Trading Symbol(s)	Name of each exchange on which registered
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 March 30, 2020, 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, 2019. 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 30, 2020.</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 30, 2020

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



Avenue Therapeutics Reports Full Year 2019 Financial Results and Recent Corporate Highlights

New York, NY – March 30, 2020 – 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, 2019.

“2019 was a tremendous year for Avenue. In February 2019, we closed the first stage of a two-stage equity investment and contingent acquisition transaction with InvaGen Pharmaceuticals Inc. (“InvaGen”), a subsidiary of Cipla Limited,” said Lucy Lu, MD, Avenue’s President and Chief Executive Officer. “In June, we announced positive data from our second pivotal Phase 3 trial evaluating IV tramadol in patients following abdominoplasty surgery. The year culminated with the filing of a New Drug Application (“NDA”) with the FDA for IV tramadol in December, and we recently learned that the FDA accepted the submission for review and set a Prescription Drug User Fee Act (“PDUFA”) goal action date of October 10, 2020. We look forward to working with the FDA during their review process with a goal of bringing IV tramadol to patients suffering from acute pain in the U.S. as soon as possible.”

2019 and Recent Corporate Highlights:

- The stock purchase stage of the strategic transaction between InvaGen and Avenue closed in February 2019. InvaGen acquired approximately 5.8 million shares of Avenue Therapeutics’ common stock at \$6.00 per share for total gross consideration of \$35.0 million, representing a 33.3% stake in Avenue’s capital stock on a fully-diluted basis. Avenue anticipates that the merger with InvaGen will be completed shortly after the PFUDA date of October 10, 2020, if IV tramadol is approved by the FDA.
- In June 2019, Avenue announced that the second pivotal Phase 3 trial of IV tramadol achieved the primary endpoint of a statistically significant improvement in Sum of Pain Intensity Difference over 24 hours (SPID24) compared to placebo in patients with postoperative pain following abdominoplasty surgery. In addition, the trial met all of its key secondary endpoints. The study also included a standard-of-care IV opioid as an active comparator, IV morphine 4 mg. In this study, IV tramadol also demonstrated similar efficacy and safety to that of IV morphine.
- In October 2019, an eAbstract was presented at ANESTHESIOLOGY 2019, the American Society of Anesthesiologists’ annual meeting highlighting the Phase 3 data for IV tramadol in the management of post-surgical pain in patients undergoing bunionectomy, an orthopedic model.
- Also in October 2019, IV tramadol Phase 1 clinical data were published 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. We are not including the information in the paper on our website as a part of, or incorporating it by reference into, this press release.
- In December 2019, Avenue submitted its NDA to the FDA for IV tramadol for managing moderate to moderately severe pain in adults in a medically supervised health care setting. The FDA accepted the IV tramadol NDA for review in February 2020 with a PDUFA goal action date of October 10, 2020.

2019 Financial Results:

- **Cash Position:** As of December 31, 2019, our cash and cash equivalents totaled \$8.7 million, compared to \$2.7 million at December 31, 2018, an increase of \$6.0 million.
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- **R&D Expenses:** Research and development expenses for the full year 2019 were \$22.2 million, compared to \$17.7 million in 2018. This increase of \$4.5 million was primarily attributable to the completion of our abdominoplasty study as well as NDA submission costs.
- **R&D Expenses – Licenses Acquired:** Research and development expenses - licenses acquired for the full year 2019 were \$1.0 million, compared to \$0 in 2018. The 2019 expense was related to the milestone payment due to our licensor in connection with the submission of our NDA for IV tramadol.
- **G&A Expenses:** General and administrative expenses for the full year 2019 were \$3.1 million, compared to \$4.1 million in 2018. This decrease of \$1.0 million was primarily attributable to decreases 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 2019 was \$25.9 million, or \$1.65 per share, compared to a net loss of \$21.5 million, or \$2.10 per share, in 2018.

About Avenue Therapeutics

Avenue Therapeutics is a specialty pharmaceutical company whose mission is to develop 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 related to us obtaining regulatory approval from the FDA for our product candidate, 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; risks relating to the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner; 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)

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,745	\$ 2,671
Deferred financing costs	-	1,702
Prepaid expenses and other current assets	170	152
Total Assets	\$ 8,915	\$ 4,525
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,101	\$ 4,669
Accounts payable and accrued expenses - related party	14	487
Licenses payable	1,000	-
Total current liabilities	2,115	5,156
Total Liabilities	2,115	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 December 31, 2019 and 2018	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares, 16,682,190 and 10,667,714 shares issued and outstanding as of December 31, 2019 and 2018, respectively	2	1
Additional paid-in capital	74,915	41,577
Accumulated deficit	(68,117)	(42,209)
Total Stockholders' Equity (Deficit)	6,800	(631)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 8,915	\$ 4,525

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

	For the Years Ended	
	December 31, 2019	December 31, 2018
Operating expenses:		
Research and development	\$ 22,194	\$ 17,696
Research and development - licenses acquired	1,000	-
General and administrative	3,071	4,120
Loss from operations	(26,265)	(21,816)
Interest income	(357)	(93)
Other income	-	(175)
Net Loss	\$ (25,908)	\$ (21,548)
Net loss per common share outstanding, basic and diluted	\$ (1.65)	\$ (2.10)
Weighted average number of common shares outstanding, basic and diluted	15,721,619	10,239,169