
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 11, 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:

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

- 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 May 11, 2020, 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, 2020. 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 11, 2020.

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 11, 2020

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



Avenue Therapeutics Reports First Quarter 2020 Financial Results and Recent Corporate Highlights

New York, NY – May 11, 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 first quarter ended March 31, 2020.

“In the first quarter of 2020, the U.S. Food and Drug Administration (“FDA”) accepted our IV tramadol New Drug Application (“NDA”) submission for review and set a Prescription Drug User Fee Act (“PDUFA”) goal action date of October 10, 2020,” stated Lucy Lu, M.D., Avenue’s President and CEO. “2020 is gearing up to be an exciting year for Avenue as we anticipate that the merger with InvaGen Pharmaceuticals Inc., a subsidiary of Cipla Limited, will be completed shortly after the PDUFA date, pending a positive outcome and other certain conditions being satisfied.”

Recent Corporate Highlights:

- In February 2020, the FDA accepted Avenue’s IV tramadol NDA for review with a PDUFA goal action date of October 10, 2020.
- In April 2020, we announced that two e-posters highlighting efficacy and safety results from our Phase 3 program are available for online viewing from the cancelled Annual Regional Anesthesiology and Acute Pain Medicine Meeting hosted by the American Society of Regional Anesthesia and Pain Medicine (“ASRA”).
 - o The e-poster (816) titled “Intravenous Tramadol is Effective in Management of Postoperative Pain Following Abdominoplasty: A 3-arm Randomized Controlled Trial” presents data from the Phase 3 abdominoplasty study and can be found here: <https://epostersonline.com/ASRASPRING20/node/65>
 - o The e-poster (1001) titled “IV tramadol – A New Treatment Option for Management of Post-Operative Pain: A Safety Trial Including Various Types of Surgery” presents data from the Phase 3 safety study and can be found here: <https://epostersonline.com/ASRASPRING20/node/68>

2020 Financial Results:

- **Cash Position:** As of March 31, 2020, our cash and cash equivalents totaled \$6.6 million, compared to \$8.7 million at December 31, 2019, a decrease of \$2.1 million.
- **R&D Expenses:** Research and development expenses for the first quarter of 2020 were \$0.7 million, compared to \$10.2 million in the first quarter of 2019. This decrease of \$9.5 million was primarily attributable to the completion of our abdominoplasty and safety studies in 2019.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2020 were \$0.6 million, compared to \$1.1 million in the first quarter of 2019. This decrease of \$0.5 million was primarily attributable to decreases in non-cash stock compensation expenses and professional fees.
- **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2020 was \$1.2 million, or \$0.08 per share, compared to a net loss of \$11.3 million, or \$0.82 per share, in the first quarter of 2019.

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 the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner, 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, 2020 (unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 6,574	\$ 8,745
Prepaid expenses and other current assets	122	170
Total Assets	\$ 6,696	\$ 8,915
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 790	\$ 1,101
Accounts payable and accrued expenses - related party	133	14
Licenses payable	-	1,000
Total current liabilities	923	2,115
Total Liabilities	923	2,115
Commitments and Contingencies		
Stockholders' Equity		
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, 2020 and December 31, 2019, respectively	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares, 16,682,803 and 16,682,190 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	2	2
Additional paid-in capital	75,130	74,915
Accumulated deficit	(69,359)	(68,117)
Total Stockholders' Equity	5,773	6,800
Total Liabilities and Stockholders' Equity	\$ 6,696	\$ 8,915

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

	For the Three Months Ended	
	March 31, 2020	March 31, 2019
Operating expenses:		
Research and development	\$ 697	\$ 10,241
General and administrative	577	1,119
Loss from operations	(1,274)	(11,360)
Interest income	(32)	(91)
Net Loss	\$ (1,242)	\$ (11,269)
Net loss per common share outstanding, basic and diluted	\$ (0.08)	\$ (0.82)
Weighted average number of common shares outstanding, basic and diluted	16,474,655	13,742,649