
**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): **August 14, 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:

| <u>Title of Class</u> | <u>Trading Symbol(s)</u> | <u>Exchange Name</u> |
|-----------------------|--------------------------|-----------------------|
| 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 August 14, 2020, Avenue Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 30, 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 August 14, 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: August 14, 2020

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



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

New York, NY – August 14, 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 second quarter ended June 30, 2020.

“We were pleased to announce several publications pertaining to IV tramadol in peer-reviewed journals recently. These publications highlight the positive data and accomplishments from our Phase 3 program,” said Lucy Lu, M.D., Avenue’s President and CEO. “We look forward to an eventful second half of 2020 as we approach IV tramadol’s Prescription Drug User Fee Act (“PDUFA”) date of October 10, 2020.”

Recent Corporate Highlights:

- In April 2020, Avenue announced that two e-posters highlighting efficacy and safety results from its Phase 3 program were 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.
 - 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.
 - 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.
- In June 2020, Avenue announced the following clinical study publications in peer-reviewed journals.
 - o The publication titled “Intravenous Tramadol is Effective in the Management of Postoperative Pain Following Abdominoplasty: A Three-Arm Randomized Placebo- and Active-Controlled Trial” was published in *Drugs in R&D* and can be accessed here.
 - o The publication titled “IV Tramadol – A New Treatment Option for Management of Post-Operative Pain in the U.S: An Open-Label, Single-Arm, Safety Trial Including Various Types of Surgery” was published in *Journal of Pain Research* and can be accessed here.
- In July 2020, Avenue announced the following publication of its Phase 3 bunionectomy study.
 - o The publication titled “Efficacy and Safety of Intravenously Administered Tramadol in Patients with Moderate to Severe Pain Following Bunionectomy: A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study” was published in *Pain and Therapy* and can be accessed here.

2020 Financial Results:

- **Cash Position:** As of June 30, 2020, Avenue’s cash and cash equivalents totaled \$5.3 million, compared to \$6.6 million at March 31, 2020 and \$8.7 million at December 31, 2019, a decrease of \$1.3 million for the quarter and a decrease of \$3.4 million year-to-date.
 - **R&D Expenses:** Research and development expenses for the second quarter of 2020 were \$1.2 million, compared to \$6.4 million in the second quarter of 2019. This decrease of \$5.2 million was primarily attributable to the completion of the abdominoplasty and safety studies in 2019.
 - **G&A Expenses:** General and administrative expenses for the second quarters of 2020 and 2019 were flat at approximately \$0.7 million, each.
 - **Net Loss:** Net loss attributable to common stockholders for the second quarter of 2020 was \$1.9 million, or \$0.11 per share, compared to a net loss of \$7.0 million, or \$0.43 per share, in the second quarter of 2019.
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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)

| | June 30, 2020 (unaudited) | December 31, 2019 |
|--|---------------------------------|----------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 5,257 | \$ 8,745 |
| Prepaid expenses and other current assets | 74 | 170 |
| Total Assets | \$ 5,331 | \$ 8,915 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | \$ 1,193 | \$ 1,101 |
| Accounts payable and accrued expenses - related party | 37 | 14 |
| Licenses payable | - | 1,000 |
| Total current liabilities | 1,230 | 2,115 |
| Total Liabilities | 1,230 | 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 June 30, 2020 and December 31, 2019, respectively | - | - |
| Common Stock (\$0.0001 par value), 50,000,000 shares authorized | | |
| Common shares, 16,702,803 and 16,682,190 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively | 2 | 2 |
| Additional paid-in capital | 75,346 | 74,915 |
| Accumulated deficit | (71,247) | (68,117) |
| Total Stockholders' Equity | 4,101 | 6,800 |
| Total Liabilities and Stockholders' Equity | \$ 5,331 | \$ 8,915 |

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

| | For the Three Months Ended | | For the Six Months Ended | |
|---|-----------------------------------|--------------------------|---------------------------------|--------------------------|
| | June 30, 2020 | June 30, 2019 | June 30, 2020 | June 30, 2019 |
| Operating expenses: | | | | |
| Research and development | \$ 1,219 | \$ 6,392 | \$ 1,916 | \$ 16,633 |
| General and administrative | 684 | 716 | 1,261 | 1,835 |
| Loss from operations | (1,903) | (7,108) | (3,177) | (18,468) |
| Interest income | (15) | (126) | (47) | (217) |
| Net Loss | \$ (1,888) | \$ (6,982) | \$ (3,130) | \$ (18,251) |
| Net loss per common share outstanding, basic and diluted | \$ (0.11) | \$ (0.43) | \$ (0.19) | \$ (1.21) |
| Weighted average number of common shares outstanding, basic and diluted | 16,474,655 | 16,314,763 | 16,474,655 | 15,035,811 |