
**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, 2018**

Avenue Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-55556
(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.

Item 8.01. Other Events.

On August 14, 2018, 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, 2018. 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
99.1	Press release issued by Avenue Therapeutics, Inc., dated August 14, 2018.

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, 2018

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



Avenue Therapeutics Reports Second Quarter 2018 Financial Results and Recent Corporate Highlights

Company reported positive Phase 3 data in patients with post-surgical pain following bunionectomy

Initiation of second pivotal Phase 3 trial expected in the second half of 2018

New York, NY – August 14, 2018 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) (“Avenue”), a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) tramadol, today reported financial results and recent corporate highlights for the second quarter ended June 30, 2018.

“In May, we reported that IV tramadol achieved primary and key secondary endpoints and demonstrated a clear dose response in a Phase 3 trial for the management of postoperative pain following bunionectomy surgery,” said Lucy Lu, M.D., Avenue’s President and Chief Executive Officer. “IV tramadol was well tolerated, with no reports of drug-related serious adverse events. IV tramadol has the potential to change the acute pain treatment paradigm by providing doctors with an option that can provide effective pain relief in place of Schedule II intravenous narcotics. Moreover, IV tramadol may play a key role in multimodal treatment regimens and enhance recovery, returning patients to baseline more quickly and leave the hospital sooner. We plan to initiate our second Phase 3 trial in the second half of this year that will evaluate IV tramadol in patients following abdominoplasty surgery.”

Financial Results:

- **Cash Position:** As of June 30, 2018, Avenue’s cash, cash equivalents and short-term investments totaled \$8.9 million, compared to \$15.0 million at March 31, 2018, and \$21.8 million at December 31, 2017, a decrease of \$6.1 million in the quarter and a decrease of \$12.9 million year to date. The decreases were primarily attributable to the continued Phase 3 development of IV tramadol.
- **R&D Expenses:** Research and development expenses for the three months ended June 30, 2018, were \$3.8 million, compared to \$0.4 million for the same quarter in 2017. The \$3.4 million increase was attributable to the completion of the Phase 3 trial of IV tramadol following bunionectomy surgery and to the ongoing Phase 3 safety trial of IV tramadol.
- **G&A Expenses:** General and administrative expenses for the three months ended June 30, 2018, were \$0.9 million, compared to \$1.3 million for the same quarter in 2017. The \$0.4 million decrease was primarily attributable to decreased stock compensation expense related to Avenue’s initial public offering in June 2017, and partially offset by increases in market research and personnel costs.
- **Net Loss:** Net loss attributable to common stockholders for the three months ended June 30, 2018, was \$4.7 million, or \$0.45 per share, compared to a net loss of \$2.4 million, or \$0.70 per share, for the three months ended June 30, 2017.

About Avenue Therapeutics

Avenue Therapeutics, Inc. (“Avenue”), a Fortress Biotech (NASDAQ: FBIO) Company, is a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) tramadol for the management of moderate to moderately severe postoperative 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 postoperative pain. Avenue is headquartered in New York City. For more information, visit www.avenuetx.com.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.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 such statement is based, except as required by law.

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AVENUE THERAPEUTICS, INC.
Condensed Balance Sheets
(\$ in thousands, except for share and per share amounts)

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 8,940	\$ 11,782
Short-term investments	-	10,000
Prepaid expenses and other current assets	496	388
Total Assets	\$ 9,436	\$ 22,170
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 4,234	\$ 2,737
Accounts payable and accrued expenses - related party	185	53
Total current liabilities	4,419	2,790
Total Liabilities	4,419	2,790
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, 2018 and December 31, 2017, respectively	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares; 10,554,170 and 10,265,083 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	1	1
Common stock issuable, 0 and 273,837 shares as of June 30, 2018 and December 31, 2017, respectively	-	1,103
Additional paid-in capital	40,711	38,937
Accumulated deficit	(35,695)	(20,661)
Total Stockholders' Equity	5,017	19,380
Total Liabilities and Stockholders' Equity	\$ 9,436	\$ 22,170

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

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

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2018	June 30, 2017	June 30, 2018	June 30, 2017
Operating expenses:				
Research and development	\$ 3,754	\$ 447	\$ 13,193	\$ 580
General and administrative	927	1,297	1,913	1,668
Loss from operations	(4,681)	(1,744)	(15,106)	(2,248)
Interest income	(24)	-	(72)	-
Interest expense	-	93	-	188
Interest expense - related party	-	20	-	81
Change in fair value of convertible notes payable	-	95	-	99
Change in fair value of warrant liabilities	-	454	-	451
Net Loss	\$ (4,657)	\$ (2,406)	\$ (15,034)	\$ (3,067)
Net loss per common share outstanding, basic and diluted	\$ (0.45)	\$ (0.70)	\$ (1.48)	\$ (0.95)
Weighted average number of common shares outstanding, basic and diluted	10,251,950	3,459,942	10,176,062	3,242,602