
**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 11, 2017**

Avenue Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-55558
(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 11, 2017, 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, 2017. 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 11, 2017.

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: August 11, 2017

AVENUE THERAPEUTICS, INC.

(Registrant)

By: /s/ Lucy Lu, M.D.

Name: Lucy Lu, M.D.

Title: President and Chief Executive Officer



Avenue Therapeutics Reports Second Quarter 2017 Financial Results and Recent Corporate Highlights

New York, NY – August 11, 2017 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) (“Avenue”), a Fortress Biotech (NASDAQ: FBIO) Company, today announced financial results and recent corporate highlights for the second quarter ended June 30, 2017.

“We are thrilled to have completed our initial public offering. The initiation of the Phase 3 bunionectomy trial is planned for the third quarter of 2017, and we anticipate announcing topline data from the study as early as the second quarter of 2018,” said Lucy Lu, MD, Avenue’s Chief Executive Officer. Dr. Lu continued, “I am also excited to take on an official leadership role at Avenue, and look forward to delivering value for our shareholders.”

Financial Results:

- As of June 30, 2017, Avenue’s cash totaled \$34.7 million compared to \$0.2 million at December 31, 2016, an increase of \$34.5 million year-to-date.
- Research and development expenses were \$0.4 million for the second quarter of 2017, compared to \$0.4 million for the second quarter of 2016.
- General and administrative expenses were \$1.3 million for the second quarter of 2017, compared to \$0.2 million for the second quarter of 2016.
- Net loss attributable to common stockholders was \$2.4 million, or \$0.70 per share, for the second quarter of 2017. This compares to a net loss attributable to common stockholders of \$0.8 million, or \$0.28 per share, for the second quarter of 2016.

Recent Corporate Highlights:

- In May 2017, Avenue received a Notice of Allowance from the U.S. Patent and Trademark Office for a new patent application (U.S. Application No. 15/163,111) titled “Intravenous Administration of Tramadol.” The patent application describes and claims a dosing regimen of IV 50 mg tramadol that provides certain pharmacokinetic parameters that are similar to those of 100 mg tramadol HCl administered orally every six hours at a steady state. Issuance of the patent (U.S. Patent No. 9,693,949) occurred in July 2017. This patent application falls under Avenue’s licensing agreement with Revogenex Ireland Ltd.
- On June 30, 2017, Avenue completed its initial public offering of 6,325,000 shares of common stock, at a public offering price of \$6.00 per share, resulting in gross proceeds of approximately \$38 million. Avenue’s common stock began trading on The NASDAQ Capital Market under the ticker symbol “ATXI”.
- Also in June 2017, Dr. Lu was named President and Chief Executive Officer of Avenue, a position she held on an interim basis since the company’s inception.

About Avenue Therapeutics

Avenue Therapeutics, Inc., a Fortress Biotech Company, is a specialty pharmaceutical company focused on the development and commercialization of an intravenous formulation of tramadol HCl (“IV tramadol”) 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 licensings, 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 any such statement is based, except as required by law.

Contacts:

Joseph Vazzano, VP, Finance and Corporate Controller
Avenue Therapeutics, Inc.
(781) 652-4500
ir@avenuetx.com

Media Relations
Sarah Hall
Phase IV Communications
(215) 313-5638
sarah@phaseivcommunications.com

AVENUE THERAPEUTICS, INC.
UNAUDITED CONDENSED BALANCE SHEETS
(\$ in thousands, except for share and per share amounts)

	June 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash	\$ 34,683	\$ 197
Prepaid expenses	22	-
Total Assets	\$ 34,705	\$ 197
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 826	\$ 506
Accrued expenses - related party	167	1,348
Interest payable	56	57
Accrued interest - related party	120	346
Notes payable - related party	3,486	2,848
NSC notes payable, short-term	2,500	1,000
Derivative warrant liability	-	314
Total current liabilities	7,155	6,419
Convertible notes payable, at fair value	-	200
NSC notes payable, long-term (net of debt discount of \$106 and \$174, respectively)	394	1,826
Total Liabilities	7,549	8,445
Commitments and Contingencies		
-		
Stockholders' Deficit		
Preferred Stock (\$0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 83,333 shares issued and outstanding as of June 30, 2017 and December 31, 2016	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares; 10,041,008 and 3,257,936 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	1	1
Common stock issuable, 0 and 83,532 shares as of June 30, 2017 and December 31, 2016, respectively	-	49
Additional paid-in capital	38,625	105
Accumulated deficit	(11,470)	(8,403)
Total Stockholders' Deficit	27,156	(8,248)
Total Liabilities and Stockholders' Deficit	\$ 34,705	\$ 197

AVENUE THERAPEUTICS, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS

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

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Operating expenses:				
Research and development	\$ 447	\$ 421	\$ 580	\$ 985
General and administration	1,297	217	1,668	493
Loss from operations	<u>(1,744)</u>	<u>(638)</u>	<u>(2,248)</u>	<u>(1,478)</u>
Interest expense	93	87	188	172
Interest expense - related party	20	46	81	79
Change in fair value of convertible notes payable	95	-	99	-
Change in fair value of warrant liabilities	454	-	451	89
Net Loss	<u>\$ (2,406)</u>	<u>\$ (771)</u>	<u>\$ (3,067)</u>	<u>\$ (1,818)</u>
Net loss per common share outstanding, basic and diluted	\$ (0.70)	\$ (0.28)	\$ (0.95)	\$ (0.66)
Weighted average number of common shares outstanding, basic and diluted	3,459,942	2,785,865	3,242,602	2,761,367