
**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): **November 9, 2017**

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 November 9, 2017, Avenue Therapeutics, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 2017. 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 November 9, 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.

AVENUE THERAPEUTICS, INC.
(Registrant)

Date: November 9, 2017

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



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

New York, NY – November 9, 2017 – Avenue Therapeutics, Inc. (NASDAQ: ATXI) (“Avenue”), a Fortress Biotech (NASDAQ: FBIO) Company, today announced financial results and recent corporate highlights for the third quarter ended September 30, 2017.

“We are excited to have dosed the first patient with IV Tramadol in our Phase 3 bunionectomy trial this quarter, and we look forward to reporting topline data from the study in the second quarter of 2018,” said Lucy Lu, MD, Avenue’s President and Chief Executive Officer. “If successful in our clinical trials and approved by the FDA, IV Tramadol would be the only intravenous Schedule IV opioid in the U.S. IV Tramadol fits into and facilitates the trend to minimize usage of conventional narcotics in the post-surgical setting.”

Financial Results:

- As of September 30, 2017, Avenue’s cash and short-term investments (certificates of deposit) totaled \$26.1 million compared to \$0.2 million at December 31, 2016, an increase of \$25.9 million year-to-date.
- Research and development expenses were \$2.0 million for the third quarter of 2017, compared to \$0.2 million for the third quarter of 2016.
- General and administrative expenses were \$0.8 million for the third quarter of 2017, compared to \$0.2 million for the third quarter of 2016.
- Net loss attributable to common stockholders was \$2.9 million, or \$0.30 per share, for the third quarter of 2017. This compares to a net loss attributable to common stockholders of \$0.5 million, or \$0.19 per share, for the third quarter of 2016.

Recent Corporate Highlights:

- In September 2017, Avenue announced that the first patient has been dosed in the pivotal Phase 3 clinical trial of intravenous (IV) tramadol for the management of moderate to moderately severe pain in patients following bunionectomy surgery.
- In August 2017, Avenue appointed Joseph Vazzano as Vice President of Finance and Corporate Controller (principal financial and accounting officer).

About Avenue Therapeutics

Avenue Therapeutics, Inc. (“Avenue”), a Fortress Biotech 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 trial for the management of postoperative pain following bunionectomy surgery. 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:

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

	September 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 16,050	\$ 197
Short-term investments	10,000	-
Prepaid expenses	126	-
Total Assets	\$ 26,176	\$ 197
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,914	\$ 506
Accounts payable and accrued expenses - related party	76	1,348
Interest payable	-	57
Accrued interest - related party	-	346
Notes payable - related party	-	2,848
NSC notes payable, short-term	-	1,000
Derivative warrant liability	-	314
Total current liabilities	1,990	6,419
Convertible notes payable, at fair value	-	200
NSC notes payable, long-term (net of debt discount of \$0 and \$174, respectively)	-	1,826
Total Liabilities	1,990	8,445
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 September 30, 2017 and December 31, 2016	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares; 10,265,174 and 3,257,936 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	1	1
Common stock issuable, 0 and 83,532 shares as of September 30, 2017 and December 31, 2016, respectively	-	49
Additional paid-in capital	38,603	105
Accumulated deficit	(14,418)	(8,403)
Total Stockholders' Equity (Deficit)	24,186	(8,248)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 26,176	\$ 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 Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Operating expenses:				
Research and development	\$ 2,000	\$ 183	\$ 2,580	\$ 1,168
General and administration	848	200	2,516	693
Loss from operations	<u>(2,848)</u>	<u>(383)</u>	<u>(5,096)</u>	<u>(1,861)</u>
Interest income	(6)	-	(6)	-
Interest expense	106	89	294	261
Interest expense - related party	-	53	81	132
Change in fair value of convertible notes payable	-	-	99	-
Change in fair value of warrant liabilities	-	19	451	108
Net Loss	<u>\$ (2,948)</u>	<u>\$ (544)</u>	<u>\$ (6,015)</u>	<u>\$ (2,362)</u>
Net loss per common share outstanding, basic and diluted	\$ (0.30)	\$ (0.19)	\$ (1.09)	\$ (0.85)
Weighted average number of common shares outstanding, basic and diluted	9,972,663	2,848,651	5,514,988	2,790,674