

May 3, 2018



# **Avenue Therapeutics Reports First Quarter 2018 Financial Results and Recent Corporate Highlights**

**Completed enrollment in Phase 3 trial of IV tramadol for the treatment of postoperative pain following bunionectomy surgery; topline data expected in second quarter 2018**

NEW YORK, May 03, 2018 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (NASDAQ:ATXI) ("Avenue"), a company focused on the development and commercialization of intravenous (IV) tramadol, today reported financial results and recent corporate highlights for the first quarter ended March 31, 2018.

"We recently completed enrollment in our first pivotal Phase 3 trial of IV tramadol for the treatment of postoperative pain in patients following bunionectomy surgery. Topline data from the trial are anticipated this quarter and, if positive, we expect to initiate our second Phase 3 trial in patients following abdominoplasty surgery in the third quarter of 2018," said Lucy Lu, M.D., Avenue's President and Chief Executive Officer. "Coupled with recent additions to our patent portfolio, which was strengthened by the receipt of Notices of Allowance for three patent applications in the first quarter, we are making progress toward our goal of introducing IV tramadol as a treatment option for use in the management of postoperative pain. Patients and physicians have an increasingly pressing need for medicines that can provide rapid and sustained relief without also introducing the risk of opioid dependence, and we are working hard to advance IV tramadol to address this gap in the acute pain space."

## **First Quarter and Recent Achievements:**

- In April 2018, Avenue completed enrollment in its Phase 3, multicenter, randomized, double-blind, three-arm clinical trial evaluating the efficacy and safety of IV tramadol 50 mg and 25 mg versus placebo for the treatment of moderate to moderately severe pain in patients following bunionectomy surgery. Avenue expects to report topline data in the second quarter of 2018.
- In March 2018, Avenue received Notices of Allowance from the U.S. Patent and Trademark Office (USPTO) for three patent applications covering methods of administration for IV tramadol. Issuance of these patents is expected in the second quarter of 2018.

## Financial Results:

- **Cash Position:** As of March 31, 2018, Avenue's cash, cash equivalents and short-term investments totaled \$15.0 million, compared to \$21.8 million at December 31, 2017. The \$6.8 million decrease was primarily attributable to the continued development of IV tramadol.
- **R&D Expenses:** Research and development expenses for the three months ended March 31, 2018, were \$9.4 million, compared to \$0.1 million for the same quarter in 2017. The \$9.3 million increase was primarily attributable to the ongoing Phase 3 trial of IV tramadol following bunionectomy surgery and to the Phase 3 safety trial of IV tramadol.
- **G&A Expenses:** General and administrative expenses for the three months ended March 31, 2018, were \$1.0 million, compared to \$0.4 million for the same quarter in 2017. The \$0.6 million increase was primarily attributable to increases in non-cash stock compensation, personnel costs, market research costs and professional fees.
- **Net Loss:** Net loss attributable to common stockholders for the three months ended March 31, 2018, was \$10.4 million, or \$1.03 per share, compared to a net loss of \$0.7 million, or \$0.22 per share, for the three months ended March 31, 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](http://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](http://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:**

Jaclyn Jaffe  
Avenue Therapeutics, Inc.  
(781) 652-4500  
[ir@avenuetx.com](mailto:ir@avenuetx.com)

Investor Relations  
Julie Seidel  
Stern Investor Relations, Inc.  
(212) 362-1200  
[julie@sternir.com](mailto:julie@sternir.com)

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

**AVENUE THERAPEUTICS, INC.  
Condensed Balance Sheets**

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

	March 31, 2018 (unaudited)	December 31, 2017
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 14,963	\$ 11,782
Short-term investments	-	10,000
Prepaid expenses and other current assets	310	388
<b>Total Assets</b>	<b>\$ 15,273</b>	<b>\$ 22,170</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,753	\$ 2,737

Accounts payable and accrued expenses - related party	167	53
Total current liabilities	5,920	2,790
<b>Total Liabilities</b>	<b>5,920</b>	<b>2,790</b>

#### 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, 2018 and December 31, 2017, respectively

- -

##### Common Stock (\$0.0001 par value), 50,000,000 shares authorized

- -

Common shares; 10,552,045 and 10,265,083 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively

1 1

Common stock issuable, 0 and 273,837 shares as of March 31, 2018 and December 31, 2017, respectively

- 1,103

Additional paid-in capital

40,390 38,937

Accumulated deficit

(31,038 ) (20,661 )

Total Stockholders' Equity

9,353 19,380

**Total Liabilities and Stockholders' Equity**

**\$ 15,273 \$ 22,170**

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

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

	For the Three Months Ended	
	March 31, 2018	March 31, 2017
Operating expenses:		
Research and development	\$ 9,439	\$ 133
General and administration	986	371
Loss from operations	(10,425 )	(504 )
Interest income	(48 )	-
Interest expense	-	95
Interest expense - related party	-	61
Change in fair value of convertible notes payable	-	4
Change in fair value of warrant liabilities	-	(3 )
<b>Net Loss</b>	<b>\$ (10,377 )</b>	<b>\$ (661 )</b>
Net loss per common share outstanding, basic and diluted	\$ (1.03 )	\$ (0.22 )
Weighted average number of common shares outstanding, basic and diluted	10,099,331	3,022,846



Source: Avenue Therapeutics