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Avenue Therapeutics Reports Fourth Quarter and Full Year 2017 Financial Results and Recent Corporate Highlights

-- Expect to Report Topline Data from Phase 3 Trial of IV Tramadol in Patients Following Bunionectomy Surgery in 2Q18 --

NEW YORK, March 01, 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 fourth quarter and year ended December 31, 2017.

"2017 was a transformative year for Avenue, as we completed our initial public offering, raising \$38.0 million in gross proceeds, and commenced our pivotal Phase 3 development program for IV tramadol," said Lucy Lu, M.D., Avenue's President and Chief Executive Officer. "We believe IV tramadol, which is widely used outside the U.S., has the potential to be a safe and effective postsurgical treatment option for patients, with less risk of abuse and dependence than conventional narcotics. We are committed to rapidly advancing our pivotal development program in 2018. We look forward to reporting topline data from our Phase 3 trial in patients following bunionectomy surgery in the second quarter, and to initiating a second Phase 3 trial in patients following abdominoplasty surgery in the third quarter of 2018."

2017 Corporate Highlights

Clinical Achievements:

- In December 2017, Avenue dosed the first patient in the Phase 3 safety trial of IV tramadol for the management of moderate to moderately severe pain. This safety study is a key component of Avenue's pivotal Phase 3 development program for IV tramadol.
- In September 2017, Avenue dosed the first patient in the pivotal Phase 3 trial of IV tramadol for the management of moderate to moderately severe pain in patients following bunionectomy surgery. Topline data from the trial are expected in the second quarter of 2018.

Corporate Achievements:

- In August 2017, Avenue appointed Joseph Vazzano as Vice President of Finance and Corporate Controller.
- In June 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 net proceeds of \$34.2 million after deducting underwriting discounts and offering expenses.
- In June 2017, Avenue announced Lucy Lu, M.D., as President and Chief Executive Officer, a position Dr. Lu held on an interim basis since the company's inception.
- In May 2017, Avenue announced a Notice of Allowance from the USPTO 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, which provides certain pharmacokinetic parameters that are similar to those of 100 mg tramadol HCl administered orally every six hours at a steady state. The patent (U.S. Patent No. 9,693,949) was issued in July 2017.
- In February 2017, the U.S. Patent and Trademark Office (USPTO) granted Avenue two continuation patents covering methods of administration for IV tramadol for the treatment of acute pain.

Financial Results:

Full Year 2017 Financial Results:

- **Cash Position:** As of December 31, 2017, Avenue's cash and short-term investments totaled \$21.8 million, compared to \$0.2 million at December 31, 2016, an increase of \$21.6 million as a result our initial public offering partially offset by repayments in full of our outstanding debt and current year cash burn.
- **R&D Expenses:** Research and development expenses for the full year 2017 were \$6.7 million, compared to \$1.3 million in 2016. This increase of \$5.4 million was primarily attributable to the initiation of the bunionectomy study in September 2017 and the initiation of the safety study in December 2017.
- **G&A Expenses:** General and administrative expenses for the full year 2017 were \$3.6 million, compared to \$1.0 million in 2016. This increase of \$2.6 million was primarily attributable to non-cash expenses consisting of our financing fee due to Fortress in connection with our initial public offering and stock compensation. The increase was also attributable to increased personnel costs, market research costs and professional fees.
- **Net Loss:** Net loss attributable to common stockholders for the full year 2017 was \$12.3 million, or \$1.85 per share, compared to a net loss of \$3.2 million, or \$1.11 per share, in 2016.

Three Months Ended December 31, 2017 Financial Results:

- **R&D Expenses:** Research and development expenses for the three months ended December 31, 2017 were \$4.1 million, compared to \$0.2 million in 2016. This increase of \$3.9 million was primarily attributable to the initiation of the bunionectomy study in September 2017 and the initiation of the safety study in December 2017.
- **G&A Expenses:** General and administrative expenses for the three months ended December 31, 2017 were \$1.1 million, compared to \$0.3 million in 2016. This increase of \$0.8 million 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

December 31, 2017 was \$6.2 million, or \$0.63 per share, compared to a net loss of \$0.8 million, or \$0.27 per share, in 2016.

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 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.

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AVENUE THERAPEUTICS, INC.

Balance Sheets

(Unaudited)

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

	December 31, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 11,782	\$ 197
Short-term investments	10,000	-
Prepaid expenses and other current assets	388	-
Total Assets	\$ 22,170	\$ 197
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 2,737	\$ 506
Accounts payable and accrued expenses - related party	53	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	2,790	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	2,790	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 December 31, 2017 and December 31, 2016	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares; 10,265,083 and 3,257,936 shares issued and outstanding as of December 31, 2017 and December 31, 2016, respectively	1	1

Common stock issuable, 273,837 and 83,532 shares as of December 31, 2017 and December 31, 2016, respectively

Additional paid-in capital

Accumulated deficit

Total Stockholders' Equity (Deficit)

Total Liabilities and Stockholders' Equity (Deficit)

1,103	49
38,937	105
(20,661)	(8,403)
19,380	(8,248)
\$ 22,170	\$ 197

AVENUE THERAPEUTICS, INC.

Statements of Operations

(Unaudited)

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

	For the Three Months Ended		For the Twelve Months Ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
Operating expenses:				
Research and development	\$ 4,118	\$ 163	\$ 6,698	\$ 1,331
Research and development - licenses acquired	1,103	49	1,103	49
General and administration	1,104	304	3,620	997
Loss from operations	(6,325)	(516)	(11,421)	(2,377)
Interest income	(82)	-	(88)	-
Interest expense	-	159	294	420
Interest expense - related party	-	60	81	192
Change in fair value of convertible notes payable	-	-	99	-
Change in fair value of warrant liabilities	-	80	451	188
Net Loss	\$ (6,243)	\$ (815)	\$ (12,258)	\$ (3,177)
Net loss per common share outstanding, basic and diluted	\$ (0.63)	\$ (0.27)	\$ (1.85)	\$ (1.11)
Weighted average number of common shares outstanding, basic and diluted	9,968,497	2,975,087	6,634,937	2,860,526



Source: Avenue Therapeutics