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Avenue Therapeutics Reports Second Quarter 2019 Financial Results and Recent Corporate Highlights

NEW YORK, Aug. 14, 2019 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a company focused on the development of intravenous ("IV") tramadol for the U.S. market, today reported financial results and recent corporate highlights for the second quarter ended June 30, 2019.

"We recently reported positive data from our second pivotal Phase 3 trial of IV tramadol for the management of postoperative pain in patients following abdominoplasty surgery, which compared IV tramadol to placebo and an active-comparator arm of IV morphine," said Lucy Lu, M.D., Avenue's President and Chief Executive Officer. "We have successfully completed our Phase 3 program of IV tramadol for the management of postoperative pain and we are on track to submit a New Drug Application to the U.S. Food and Drug Administration by year-end."

Recent Achievements:

- In the second quarter of 2019, Avenue completed the open-label, single-arm safety study of IV tramadol in post-surgical pain. The results showed that IV tramadol is well-tolerated with a side effect profile consistent with known pharmacology.
- In April 2019, Avenue announced the appointment of Dr. Thomas G. Moore to its Board of Directors.
- In June 2019, Avenue announced that its second pivotal Phase 3 trial of IV tramadol achieved the primary endpoint of a statistically significant improvement in Sum of Pain Intensity Difference over 24 hours (SPID24) compared to placebo in patients with postoperative pain following abdominoplasty surgery. In addition, the trial met all of its key secondary endpoints. The study also included a standard-of-care IV opioid as an active comparator: IV morphine 4 mg. In this study, IV tramadol also demonstrated similar efficacy and safety to that of IV morphine.
- In August 2019, Avenue announced the appointment of Ms. Garrett Ingram to its Board of Directors.

Financial Results:

- **Cash Position:** As of June 30, 2019, Avenue's cash and cash equivalents and short-term investments totaled \$15.5 million, compared to \$29.4 million at March 31, 2019. This decrease reflects the completion of the abdominoplasty and safety studies in the second quarter of 2019. Based on its current development plans, Avenue expects that its existing cash and cash equivalents and short-term investments and line of credit related to the InvaGen agreement, will enable it to fund its operations into the Second Stage Closing with InvaGen.

- **R&D Expenses:** Research and development expenses for the three months ended June 30, 2019, were \$6.4 million, compared to \$3.8 million for the same quarter in 2018. The \$2.6 million increase was primarily attributable to the completion of the Phase 3 trial of IV tramadol following abdominoplasty surgery, partially offset by the completion of the Phase 3 trial of IV tramadol following bunionectomy in the same quarter last year.
- **G&A Expenses:** General and administrative expenses for the three months ended June 30, 2019, were \$0.7 million, compared to \$0.9 million for the same quarter in 2018. The \$0.2 million decrease was primarily attributable to a decrease in market research costs and professional fees.
- **Net Loss:** Net loss attributable to common stockholders for the three months ended June 30, 2019, was \$7.0 million, or \$0.43 per share, compared to a net loss of \$4.7 million, or \$0.45 per share, for the three months ended June 30, 2018.

About Avenue Therapeutics

Avenue 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 has completed its Phase 3 program of IV tramadol for the management of postoperative pain and plans to submit a New Drug Application to the U.S. Food and Drug Administration by year-end. Avenue is headquartered in New York City and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.avenuetx.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.
Condensed Balance Sheets
(\$ in thousands, except for share and per share amounts)

	June 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 10,455	\$ 2,671
Short-term investments	5,000	-
Deferred financing costs	61	1,702
Prepaid expenses and other current assets	161	152
Total Assets	\$ 15,677	\$ 4,525
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 1,728	\$ 4,669
Accounts payable and accrued expenses - related party	45	487
Total current liabilities	1,773	5,156
Total Liabilities	1,773	5,156
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 June 30, 2019 and December 31, 2018	-	-
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares; 16,559,747 and 10,667,714 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	2	1
Additional paid-in capital	74,362	41,577
Accumulated deficit	(60,460)	(42,209)
Total Stockholders' Equity (Deficit)	13,904	(631)
Total Liabilities and Stockholders' Equity (Deficit)	\$ 15,677	\$ 4,525

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, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Operating expenses:				
Research and development	\$ 6,392	\$ 3,754	\$ 16,633	\$ 13,193
General and administrative	716	927	1,835	1,913
Loss from operations	(7,108)	(4,681)	(18,468)	(15,106)
Interest income	(126)	(24)	(217)	(72)
Net Loss	\$ (6,982)	\$ (4,657)	\$ (18,251)	\$ (15,034)
Net loss per common share outstanding, basic and diluted	\$ (0.43)	\$ (0.45)	\$ (1.21)	\$ (1.48)
Weighted average number of common shares outstanding, basic and diluted	16,314,763	10,251,950	15,035,811	10,176,062



Source: Avenue Therapeutics