May 12, 2023

Avenue Therapeutics Reports First Quarter 2023 Financial Results and Recent Corporate Highlights

MIAMI, May 12, 2023 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue" or the "Company"), a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases, today reported financial results and recent corporate highlights for the first quarter ended March 31, 2023.

"Avenue is progressing its neuro-focused clinical stage pipeline and 2023 is off to a strong start with AJ201, a first in class small molecule for the treatment of Spinal and Bulbar Muscular Atrophy ("SBMA"), now in an ongoing Phase 1b/2a clinical trial, and BAER-101, a potentially more tolerable drug for the treatment of epilepsy and acute anxiety, advancing toward Phase 1b studies in each indication. We also held collaborative discussions with the Food and Drug Administration ("FDA") regarding a safety confirmatory trial protocol for IV Tramadol in the first quarter," said Alexandra MacLean, M.D., Avenue's Chief Executive Officer. "With this foundational portfolio, we believe Avenue will achieve critical milestones this year and has the potential to provide impactful therapies to treat patients with neurologic diseases."

Recent Corporate Highlights:

AJ201

- In March 2023, Avenue announced that it entered into an exclusive license agreement with AnnJi Pharmaceutical Co., Ltd., to acquire rights to AJ201, a first-in-class clinical asset in a Phase 1b/2a study in the U.S. for the treatment of SBMA, which currently has no FDA approved therapy. AJ201 completed a Phase 1 clinical trial in 2021, which demonstrated the safety of the molecule. The Phase 1b/2a multicenter, randomized, double-blind clinical trial is being conducted in six clinical sites across the U.S., and screening of patients with SBMA has begun. This study aims to evaluate the safety and clinical response of AJ201 in patients suffering from SBMA. AJ201 has been granted Orphan Drug Designation by the FDA for the indications of SBMA, Huntington's Disease and Spinocerebellar Ataxia.

IV Tramadol

- In March 2023, Avenue participated in a Type C meeting with the FDA to discuss the proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV Tramadol compared to IV morphine. The Type C meeting minutes from the FDA indicate that the FDA and Avenue are in agreement with a majority of the proposed protocol items and are in active discussion about remaining open items. The minutes indicate that the FDA also agrees that a successful study will support the submission of a complete response to the second Complete Response Letter for IV Tramadol pending final agreement on a statistical analysis plan and a full review of the submitted data in the complete response, as well as concurrence from the Division of Anesthesia, Analgesia and Addiction Products.

General Corporate

- In January 2023, Avenue completed a registered direct offering and concurrent private placement to an institutional accredited investor priced at the market under Nasdaq rules for total gross proceeds of approximately $3.25 million.
- In March 2023, Alexandra MacLean, M.D., Chief Executive Officer of Avenue, was appointed to Avenue's Board of Directors. In addition, Jay Kranzler, M.D., Ph.D., a current Director of Avenue, was appointed as the Chairman of Avenue. Lindsay Rosenwald, M.D., will remain a Director of Avenue.

Financial Results:

- **Cash Position:** As of March 31, 2023, our cash and cash equivalents totaled $8.2 million, compared to $6.7 million at December 31, 2022, an increase of $1.5 million.
- **R&D Expenses:** Research and development expenses for the first quarter of 2023 were $1.2 million, compared to $1.8 million for the first quarter of 2022.
- **R&D – Licenses Acquired Expenses:** Research and development – licenses acquired expenses for the first quarter of 2023 were $4.2 million, compared to $0 for the first quarter of 2022.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2023 were $1.0 million, compared to $1.0 million for the first quarter of 2022.
- **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2023 was $7.5 million, or $1.37 per share, compared to a net loss of $2.9 million, or $2.05 per share, for the first quarter of 2022.

About Avenue Therapeutics

Avenue Therapeutics, Inc. (Nasdaq: ATXI) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. It is currently developing three assets including AJ201, a first-in-class asset for spinal and bulbar muscular atrophy, BAER-101, an oral small molecule selective GABA-A α2/3 receptor positive allosteric modulator for CNS diseases, and IV Tramadol, which is in Phase 3 clinical development for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting. Avenue is headquartered in Miami, FL and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.avenuetx.com.

Forward-Looking Statements

This press release contains predictive or "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of

current or historical fact contained in this press release, including statements that express our intentions, plans, objectives, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “should,” “would” and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in, or implied by, the forward-looking statements due to numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from: expectations for increases or decreases in expenses; expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidate or any other products we may acquire or in-license; our use of clinical research centers and other contractors; expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities; expectations for generating revenue or becoming profitable on a sustained basis; expectations or ability to enter into marketing and other partnership agreements; expectations or ability to enter into product acquisition and in-licensing transactions; expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidates; acceptance of our products by doctors, patients or payors; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our products; estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments; the volatility of our stock price; expected losses; expectations for future capital requirements; and those risks discussed in our filings which we make with the SEC. Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this press release, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

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AVENUE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
($ in thousands, except for share and per share amounts)
(Unaudited)

	March 31, 2023	December 31, 2022
ASSETS		

Current assets:		
Cash and cash equivalents	$ 8,236	$ 6,708
Other receivables - related party	13	—
Prepaid expenses and other current assets	198	137
Total assets	$ **8,447**	$ **6,845**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,838	$ 949
Accrued licenses acquired	3,000	—
Accounts payable and accrued expenses - related party	44	21
Warrant liability	5,722	2,609
Total current liabilities	10,604	3,579
Total liabilities	10,604	3,579
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 March 31, 2023 and December 31, 2022	—	—
Common stock ($0.0001 par value), 75,000,000 shares authorized		
Common shares, 6,828,186 and 4,773,841 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	1	—
Additional paid-in capital	86,634	84,456
Accumulated deficit	(88,087)	(80,551)
Total stockholders' equity attributed to the Company	(1,452)	3,905
Non-controlling interests	(705)	(639)
Total stockholders' equity (deficit)	(2,157)	3,266
Total liabilities and stockholders' equity	$ **8,447**	$ **6,845**

AVENUE THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
($ in thousands, except for share and per share amounts)
(Unaudited)

	For the Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 1,215	$ 1,808
Research and development - licenses acquired	4,230	—
General and administrative	984	1,055
Loss from operations	(6,429)	(2,863)
Other income (expense)		
Interest income	37	2
Financing costs – warrant liabilities	(332)	—
Change in fair value of warrant liabilities	(878)	—
Total other income (expense)	(1,173)	2
Net loss	$ **(7,602)**	$ **(2,861)**
Net loss attributable to non-controlling interests	66	—
Net loss attributable to common stockholders	**$ (7,536)**	**$ (2,861)**
Net loss per common share attributable to common stockholders, basic and diluted	$ (1.37)	$ (2.05)

Weighted average number of common shares outstanding, basic and diluted	5,564,830	1,397,145

Source: Avenue Therapeutics