November 13, 2023

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

- Phase 1b/2a clinical trial of AJ201 remains on track to report topline data in second quarter of 2024 -

- Positive BAER-101 preclinical data accepted for presentation at American Epilepsy Society (AES) Annual Meeting -

- Agreement reached with U.S. FDA on study design and analysis approach for Phase 3 safety study of IV tramadol -

- Raised $5 million in gross proceeds from public equity offering -

MIAMI, Nov. 13, 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 third quarter ended September 30, 2023.

"In the third quarter, Avenue continued to successfully execute across our pipeline of innovative CNS treatments," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue. "We presented trial-in-progress posters for our lead product candidate, AJ201 for the treatment of spinal and bulbar muscular atrophy ("SBMA"), at important medical meetings attended by the neurology scientific community in recent months, and we are pleased to report that enrollment continues to progress on-track in the Phase 1b/2a clinical trial of AJ201, with initial clinical results anticipated in the second quarter of 2024. Turning to BAER-101, we look forward to presenting the full dataset of August's promising preclinical results at the American Epilepsy Society Annual Meeting in December, further showcasing this novel drug's robust anti-seizure activity in a translational animal model of absence epilepsy. This quarter, we also reached alignment with the U.S. Food and Drug Administration ("FDA") on the key aspects of the Phase 3 safety study design for IV tramadol, a crucial milestone for the program as positive study results have the potential to support an approval in acute post-operative pain. Importantly, we closed a public offering of common stock and warrants, resulting in $5 million in gross proceeds, to strengthen Avenue's balance sheet and continue to fund our clinical and corporate progress. We look forward to providing updates in the quarters to come as we work to deliver near-term value

for Avenue shareholders and realize our mission of providing impactful therapies to patients suffering from neurologic diseases."

Recent Corporate Highlights:

AJ201 *(Nrf1 and Nrf2 activator, androgen receptor degradation enhancer for SBMA)*

- Avenue presented trial-in-progress posters for the Phase 1b/2a clinical trial of AJ201 for the treatment of SBMA, also known as Kennedy's Disease, at three scientific congresses, including the 2023 Neuromuscular Study Group Annual Scientific Meeting in Orlando, World Muscle Society in Charleston and the European Neuro Muscular Centre (ENMC) Meeting on SBMA in Amsterdam. The 12-week, multicenter, randomized, double-blind Phase 1b/2a clinical trial of AJ201 is expected to enroll approximately 24 patients, randomly assigned to AJ201 (600 mg/day) or placebo. Topline data for the Phase 1b/2a clinical trial of AJ201 in SBMA are expected in the second quarter of 2024. More information about this study can be found at ClinicalTrials.gov (Identifier: NCT05517603).

BAER-101 *(GABA$_A$ α2/3 positive allosteric modulator)*

- In August 2023, Avenue reported preclinical results for BAER-101, a potentially best-in-class selective GABA-A α2,3 positive allosteric modulator, demonstrating that it significantly suppressed seizures in a translational animal model of absence epilepsy. In an *in vivo* evaluation using the SynapCell's Genetic Absence Epilepsy Rat from Strasbourg ("GAERS") model of absence epilepsy, BAER-101 fully suppressed seizure activity with a minimal effective dose of 0.3 mg/kg, PO. The effect was fast in onset and stable throughout the duration of testing. The detailed preclinical results were accepted to be presented in a poster presentation at the American Epilepsy Society (AES) Annual Meeting taking place December 1-5th in Orlando. The combination of safety and tolerability in hundreds of patients and the preclinical efficacy data support BAER-101's continued development in a Phase 2a trial.

IV Tramadol

- In July 2023, Avenue reached agreement with the FDA on key elements of the Phase 3 safety study, including the primary endpoint and statistical analysis approach for intravenous ("IV") tramadol, which is in development for the treatment of acute postoperative pain in a medically supervised setting. The non-inferiority study is designed to assess the theoretical risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine. The study will randomize post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. Patients will have access to IV hydromorphone for rescue of breakthrough pain. The full study protocol, including the statistical plan, has been submitted to the FDA for final review. Pending additional financing or partnering, Avenue aims to initiate the Phase 3 safety study as soon as feasible.

Financial Results:

- **Cash Position:** As of September 30, 2023, our cash and cash equivalents totaled $0.2 million, compared to $6.7 million at December 31, 2022, a decrease of $6.5 million. In

November 2023, we completed a follow-on public offering of our common stock and warrants, raising approximately $5.0 million in gross proceeds.

- **R&D Expenses:** Research and development expenses for the third quarter of 2023 were $0.9 million, compared to $0.2 million for the third quarter of 2022.
- **G&A Expenses:** General and administrative expenses for the third quarter of 2023 were $1.2 million, compared to $0.5 million for the third quarter of 2022.
- **Net Income (Loss):** Net income attributable to common stockholders for the third quarter of 2023 was $0.5 million, or $0.06 per share, compared to a net loss of $0.7 million, or $0.45 per share, for the third 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. The Company 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 acute postoperative 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.
Unaudited Condensed Consolidated Balance Sheets
($ in thousands, except for share and per share amounts)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 161	$ 6,708
Other receivables - related party	13	—
Deferred financing costs	310	—
Prepaid expenses and other current assets	18	137
Total assets	$ **502**	$ **6,845**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,460	$ 949
Accounts payable and accrued expenses - related party	264	21
Warrant liability	3,300	2,609
Total current liabilities	5,024	3,579
Total liabilities	**5,024**	**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 September 30, 2023 and December 31, 2022	—	—
Common stock ($0.0001 par value), 75,000,000 shares authorized		
Common shares, 8,964,222 and 4,773,841 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	—
Additional paid-in capital	87,917	84,456
Accumulated deficit	(91,568)	(80,551)
Total stockholders' equity attributed to the Company	(3,650)	3,905
Non-controlling interests	(872)	(639)

Total stockholders' equity (deficit)	(4,522)	3,266
Total liabilities and stockholders' equity	$ **502**	$ **6,845**

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 907	$ 194	$ 5,149	$ 2,153
Research and development – licenses acquired	—	—	4,230	—
General and administrative	1,161	469	3,042	1,978
Loss from operations	(2,068)	(663)	(12,421)	(4,131)
Other income (expense)				
Interest income	9	1	104	4
Financing costs – warrant liabilities	—	—	(332)	—
Change in fair value of warrant liabilities	2,572	—	1,544	—
Total other income (expense)	2,581	1	1,316	4
Net income (loss)	**$ 513**	**$ (662)**	**$ (11,105)**	**$ (4,127)**
Net loss attributable to non-controlling interests	(13)	—	(88)	—
Net loss attributable to common stockholders	**$ 526**	**$ (662)**	**$ (11,017)**	**$ (4,127)**
Net income (loss) per common share attributable to common stockholders:				
Basic	$ 0.06	$ (0.45)	$ (1.54)	$ (2.86)
Diluted	$ 0.06	$ (0.45)	$ (1.54)	$ (2.86)
Weighted average number of common shares outstanding:				
Basic	8,114,155	1,465,691	7,155,050	1,441,542
Diluted	8,200,069	1,465,691	7,155,050	1,441,542

Source: Avenue Therapeutics