May 15, 2024

Avenue Therapeutics Reports First Quarter 2024 Financial Results and Recent Corporate Highlights

– Raised a total of $9.4 million in gross proceeds from warrant exercise transactions since January 2024 –

MIAMI, May 15, 2024 (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, 2024.

"The first quarter was incredibly productive for Avenue, as we've successfully executed on key milestones across our pipeline of CNS treatments," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue. "We made significant strides advancing our lead clinical program, AJ201, in spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease and look forward to reporting topline data in the middle of 2024. Additionally, this quarter we continued to showcase the potential of BAER-101 for the treatment of epilepsy with preclinical data at the American Society for Experimental Neurotherapeutics (ASENT) Annual Meeting and in the publication, *Drug Development Research*. We believe that with the proper financing or a partnership, BAER-101 has the potential to make a meaningful difference for patients facing great unmet need. Finally, we reached agreement with the U.S. FDA on the safety study design and statistical analysis approach for IV tramadol, setting this program up for a successful Phase 3 study as soon as the necessary funding is acquired. We look forward to progressing our pipeline in the quarters to come as we seek to bring long-term value to our shareholders and provide impactful therapies to patients suffering from neurologic diseases."

Recent Corporate Highlights:

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

- In April, Avenue hosted a virtual key opinion leader ("KOL") event highlighting expert perspectives on SBMA. The event featured Christopher Grunseich, M.D., Lasker Clinical Research Scholar and Investigator and Head of the Inherited Neuromuscular Diseases Unit at the National Institute of Neurological Disorders and Stroke, and Tahseen Mozaffar, M.D., Professor of Neurology, Pathology and Laboratory Medicine,

Director of the Division of Neuromuscular Diseases and Director of the ALS and Neuromuscular Center at the University of California, Irvine. The two featured speakers discussed the characteristics and treatment landscape of SBMA, as well as the trial design and potential of AJ201 in SBMA. A replay of the event can be accessed here.

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

- Avenue presented preclinical results for BAER-101, a potentially best-in-class selective GABA$_A$ α2,3 positive allosteric modulator, in the publication Drug Development Research in February 2024 and the ASENT Annual Meeting in March 2024. The *in vivo* data showcase BAER-101's ability to significantly suppress seizures using the SynapCell's Genetic Absence Epilepsy Rat from Strasbourg ("GAERS") model of epilepsy. BAER-101 fully suppressed seizure activity in the GAERS model with a minimal effective dose of 0.3 mg/kg, PO, and the effect was fast in onset and stable throughout the duration of testing. The data also demonstrated BAER-101's ability to selectively target GABA$_A$ α2 and α3 subtypes more than α1 and α5, potentially improving anti-convulsant and anxiolytic activity while minimizing the risk of tolerance and abuse associated with existing treatments in this drug class. Subject to obtaining the necessary financing, which could be provided through a strategic partnership, Avenue plans to initiate a Phase 2a clinical trial of BAER-101 to further study its anti-seizure properties in patients with common or rare epilepsies.

IV Tramadol

- In January, Avenue reached final agreement with the FDA on the safety study protocol and statistical analysis approach for the Phase 3 study of intravenous ("IV") tramadol, which is being developed for the treatment of acute post-operative pain in a medically supervised setting. The proposed study will randomize approximately 300 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, a Schedule II opioid, for rescue of breakthrough pain. Avenue aims to initiate the Phase 3 safety study as soon as feasible. The Company believes that the study can be completed and submitted to the FDA within 12 months of the study's initiation.

Corporate Highlights

- In January and May 2024, Avenue raised a total of approximately $9.4 million in gross proceeds from warrant exercise transactions.
- In April 2024, the Company effected a 1-for-75 reverse stock split of its issued and outstanding common stock which we expect will bring the Company into compliance with Nasdaq's $1.00 per share minimum bid price requirement for continued listing.

Financial Results:

- **Cash Position:** As of March 31, 2024, cash and cash equivalents totaled $3.2 million, compared to $1.8 million at December 31, 2023, an increase of $1.4 million. In May 2024, the Company completed a warrant inducement transaction for $4.4 million in gross proceeds.
- **R&D Expenses:** Research and development expenses for the first quarter of 2024

were $2.4 million, compared to $1.2 million for the first quarter of 2023. Additionally, there was $4.2 million in expense for the acquisition of the AJ201 license in the first quarter of 2023.

- **G&A Expenses:** General and administrative expenses for the first quarter of 2024 were $1.3 million, compared to $1.0 million for the first quarter of 2023.
- **Net Loss:** Net loss attributable to common stockholders for the first quarter of 2024 was $4.3 million, or $15.40 per share, compared to a net loss of $7.5 million, or $101.57 per share, for the first quarter of 2023.

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, α3 receptor positive allosteric modulator for CNS diseases, and IV tramadol, which is in Phase 3 clinical development for the management of acute post-operative 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: the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized; the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates; our ability to successfully develop, partner, or commercialize any of our current or future product candidates including AJ201, IV tramadol, and BAER-101; the substantial doubt raised about our ability to continue as a going concern, which may hinder our ability to obtain future financing; the significant losses we have incurred since inception and our expectation that we will continue to incur losses for the foreseeable future; our need for substantial additional funding, which may not be available to us on acceptable terms, or at all, which unavailability of could force us to delay, reduce or eliminate our product development programs or commercialization efforts; our reliance on

third parties for several aspects of our operations; our reliance on clinical data and results obtained by third parties that could ultimately prove to be inaccurate, or unreliable, or unacceptable to regulatory authorities; the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons; the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny; the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations; the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications; the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products; our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates; our exposure to potential product liability claims; related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products; our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business; the fact that Fortress Biotech, Inc. controls a majority of the voting power of our outstanding capital stock and has rights to receive significant share grants annually; 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.

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

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

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,194	$ 1,783
Prepaid expenses and other current assets	116	67
Total assets	**$ 3,310**	**$ 1,850**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 647	$ 287
Accounts payable and accrued expenses - related party	352	323
Warrant liability	413	586
Total current liabilities	1,412	1,196
Total liabilities	**1,412**	**1,196**

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 December 31, 2023 and 2022, respectively	—	—
Common stock ($0.0001 par value) 200,000,000 and 75,000,000 shares authorized as of March 31, 2024 and December 31, 2023, respectively		
Common shares, 590,188 and 341,324 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	3
Additional paid-in capital	98,104	92,507
Accumulated deficit	(95,268)	(90,928)
Total stockholders' equity attributed to the Company	2,836	1,582
Non-controlling interests	(938)	(928)
Total stockholders' equity	1,898	654
Total liabilities and stockholders' equity	$ **3,310**	$ **1,850**

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

	For the Three Months Ended March 31,	
	2024	**2023**
Operating expenses		
Research and development	$ 2,392	$ 1,215
Research and development - licenses acquired	—	4,230
General and administrative	1,316	984
Loss from operations	(3,708)	(6,429)
Interest income	49	37
Financing costs – warrant liabilities	—	(332)
Loss on settlement of common stock warrant liabilities	(574)	—
Change in fair value of warrant liabilities	(116)	(878)
Net loss	$ **(4,349)**	$ **(7,602)**
Net loss attributable to non-controlling interests	(9)	(66)
Net loss attributable to common stockholders	$ **(4,340)**	$ **(7,536)**
Net loss per common share attributable to common stockholders, basic and diluted	$ (15.40)	$ (101.57)
Weighted average number of common shares outstanding, basic and diluted	562,031	74,198

Source: Avenue Therapeutics