November 14, 2024

# Avenue Therapeutics Reports Third Quarter 2024 Financial Results and Recent Corporate Highlights

## - Topline data in Phase 1b/2a clinical trial of AJ201 for spinal and bulbar muscular atrophy anticipated around year-end 2024

MIAMI, Nov. 14, 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 third quarter ended September 30, 2024.

"We have generated considerable momentum this past quarter in advancing our pipeline of innovative treatments for neurologic diseases," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue. "AJ201 is a potential best-in-class asset that would bring a disease-modifying therapeutic option to patients with significant unmet medical need in Kennedy's Disease. Since dosing the last patient in the study in May, we continue to work diligently to move the study forward. We are looking forward to sharing topline clinical data in the coming months and building upon our progress of delivering impactful therapies to patients suffering from neurologic diseases."

**Recent Corporate Highlights:**

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

- In May 2024, Avenue announced the last patient visit was complete in the Phase 1b/2a clinical trial of AJ201 for the treatment of spinal and bulbar muscular atrophy (SBMA), marking the final clinical milestone ahead of the anticipated topline data announcement around year-end 2024. The 12-week, multicenter, randomized, double-blind Phase 1b/2a clinical trial of AJ201 enrolled 25 patients randomly assigned to AJ201 (600 mg/day) or placebo. The primary endpoint of the study is to assess safety and tolerability of AJ201 in subjects with clinically and genetically defined SBMA. Secondary endpoints include pharmacokinetic and pharmacodynamic data measuring change from baseline in mutant AR protein levels in skeletal muscle and changes from baseline in expression of Nrf2-activated genes in skeletal muscle. Exploratory objectives of the study include changes in the fat and muscle composition as seen on MRI scans. These endpoints are believed to be biomarkers indicating likelihood for

longer term clinical improvement. Further details about this study can be found at ClinicalTrials.gov (Identifier: NCT05517603).

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

- Subject to the receipt of additional financing, Avenue plans to initiate a Phase 2a clinical trial of BAER-101 in patients with focal epilepsy and other seizure disorders. Preclinical mouse models have demonstrated BAER-101 as a therapeutic option with the ability to fully suppress seizure activity, with the effect being fast in onset and stable throughout the duration of testing.

**IV Tramadol**

- Avenue has reached final agreement with the U.S. Food and Drug Administration ("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 pending additional financing or a partnership. The Company believes that the study can be completed and submitted to the FDA within 12 months of the study's initiation.

**Financial Results:**

- **Cash Position:** As of September 30, 2024, cash and cash equivalents totaled $2.6 million, compared to $4.9 million at June 30, 2024 and $1.8 million at December 31, 2023, a decrease of $2.3 million compared to the prior quarter and an increase of $0.8 million year-to-date.
- **R&D Expenses:** Research and development expenses for the third quarter of 2024 were $2.3 million, compared to $0.9 million for the third quarter of 2023.
- **G&A Expenses:** General and administrative expenses for the third quarter of 2024 were $0.8 million, compared to $1.2 million for the third quarter of 2023.
- **Net Loss:** Net loss attributable to common stockholders for the third quarter of 2024 was $(3.1) million, or $(1.92) per share, compared to net income of $0.5 million, or $4.86 per share, for the third 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 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: 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 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, 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.

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,597 | $ 1,783 |
| Prepaid expenses and other current assets | 28 | 67 |
| **Total assets** | $ **2,625** | $ **1,850** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 427 | $ 287 |
| Accounts payable and accrued expenses - related party | 517 | 323 |
| Warrant liability | 29 | 586 |
| Total current liabilities | 973 | 1,196 |
| **Total liabilities** | **973** | **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 September 30, 2024 and December 31, 2023 | — | — |
| **Common stock ($0.0001 par value) 200,000,000 and 75,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively** | | |
| Common shares, 1,604,158 and 341,324 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | — | 3 |
| Additional paid-in capital | 103,646 | 92,507 |
| Accumulated deficit | (101,036) | (90,928) |
| Total stockholders' equity attributed to the Company | 2,610 | 1,582 |
| Non-controlling interests | (958) | (928) |
| Total stockholders' equity | 1,652 | 654 |
| **Total liabilities and stockholders' equity** | $ **2,625** | $ **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 September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Operating expenses: | | | | |
| Research and development | $ 2,327 | $ 907 | $ 6,080 | $ 5,149 |
| Research and development - licenses acquired | — | — | — | 4,230 |
| General and administrative | 829 | 1,161 | 3,607 | 3,042 |
| Loss from operations | (3,156) | (2,068) | (9,687) | (12,421) |
| | | | | |
| Other income (expense) | | | | |
| Interest income | 51 | 9 | 152 | 104 |
| Financing costs – warrant liabilities | — | — | — | (332) |
| Loss on settlement of common stock warrant liabilities | — | — | (759) | — |
| Change in fair value of warrant liabilities | 18 | 2,572 | 157 | (1,544) |
| Total other income (expense) | 69 | 2,581 | (450) | 1,316 |
| Net (loss) income | $ (3,087) | $ 513 | $ (10,137) | $ (11,105) |
| | | | | |
| Net loss attributable to non-controlling interests | (11) | (13) | (29) | (88) |
| Net (loss) income attributable to Avenue | $ (3,076) | $ 526 | $ (10,108) | $ (11,017) |
| | | | | |
| Net (loss) income attributable to common stockholders | $ (3,076) | $ 526 | $ (18,918) | $ (11,017) |
| | | | | |
| Net (loss) income per common share attributable to common stockholders, basic and diluted | $ (1.92) | $ 4.86 | $ (17.27) | $ (115.55) |
| | | | | |
| Weighted average number of common shares outstanding, basic and diluted | 1,600,189 | 108,210 | 1,095,180 | 95,348 |

Source: Avenue Therapeutics