November 6, 2025

Avenue Therapeutics Announces Acquisition of Subsidiary Baergic Bio by Axsome Therapeutics

Baergic shareholders eligible to receive up to approximately $82 million in potential development, regulatory, and sales milestones plus a tiered mid-to-high single digit royalty on global net sales from Axsome

MIAMI, Nov. 06, 2025 (GLOBE NEWSWIRE) -- Avenue Therapeutics, Inc. (OTC: ATXI) ("Avenue" or the "Company"), a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases, and its majority-owned subsidiary, Baergic Bio, Inc. ("Baergic"), today announced that Avenue has entered into an agreement for Baergic to be acquired by Axsome Therapeutics, Inc. (NASDAQ: AXSM) ("Axsome"), including the global rights to BAER-101 (also known as AZD7325), a novel oral $GABA_A$ α2,3 subtype-selective receptor positive allosteric modulator (PAM). BAER-101 was originally licensed by Baergic from AstraZeneca AB ("AstraZeneca") and will be referred to as AXS-17 by Axsome going forward. Axsome intends to evaluate AXS-17 as a potential treatment for epilepsy.

"This acquisition by Axsome will enable the efficient progression of this potentially best-in-class targeted therapy for epilepsy. By leveraging Axsome's expertise, we hope that the development of the therapy can be accelerated for the benefit of patients suffering from epilepsy. We believe the potential potency, tolerability and efficacy of BAER-101 is exciting, as it creates an opportunity to improve the treatment of seizures in a field where there remains high unmet need for novel therapies. This partnership further validates our model of sourcing and developing high-impact therapies that address large unmet needs, while creating meaningful opportunities for long-term shareholder value," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue.

In clinical studies in over 700 patients, BAER-101 has demonstrated an attractive and potentially differentiated safety and tolerability profile. Axsome plans to advance AXS-17 in epilepsy, based on anti-convulsant effects observed in multiple preclinical seizure models.

Transaction Details

- Axsome will receive worldwide commercial, development, and manufacturing rights to BAER-101, including all available nonclinical and clinical data. The transaction was effectuated through Axsome's acquisition of 100% of the equity interests in Baergic, a subsidiary of Avenue, and concurrent amendment to the License Agreement between Baergic and AstraZeneca.
- Under the terms of the purchase agreement, Baergic Bio shareholders will receive a $0.3 million upfront payment (less transaction expenses) and are eligible to receive

milestone payments of up to $2.5 million upon the occurrence of certain development and regulatory events for the first indication and $1.5 million for each indication thereafter, up to $79 million in potential sales-based milestones, and a tiered mid-to-high single-digit royalty on potential global net sales of AXS-17.
- Avenue expects to receive ~74% of all future payments and royalties payable under the agreement.

About Avenue Therapeutics

Avenue Therapeutics, Inc. (OTC: ATXI) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. 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; 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; uncertainty related to the timing and amounts expected to be realized from future milestone, royalty or similar future revenue streams, if at all; 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; risks 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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Source: Avenue Therapeutics