

September 22, 2022



Avenue Therapeutics Announces Reverse Stock Split and Provides Regulatory Update for IV Tramadol Including Receipt of Type A Meeting Minutes from the FDA

NEW YORK, Sept. 22, 2022 (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 central nervous system diseases, today announced that it will effect a 1-for-15 reverse split of its common stock, which will be effective for trading purposes on the Nasdaq Capital Market as of the commencement of trading on September 23, 2022, and also provided a regulatory update related to its intravenous ("IV") Tramadol product candidate.

Reverse Stock Split

The reverse stock split was approved on July 25, 2022 by stockholders representing approximately 73% of the voting power of the outstanding voting stock of the Company, with authorization to determine the final ratio having been granted to the Company's Board of Directors.

Avenue's common stock will continue to trade on the Nasdaq Capital Market under the symbol "ATXI" following the reverse stock split, with a new CUSIP number of 05360L304. After the effectiveness of the reverse stock split, we expect that the number of outstanding shares of common stock will be reduced from approximately 22.7 million to approximately 1.5 million, subject to adjustment to give effect to the treatment of any fractional shares that stockholders would have received in the reverse stock split. No fractional shares will be issued in connection with the reverse stock split and stockholders who would otherwise be entitled to a fractional share will receive a proportional cash payment.

The reverse stock split is primarily intended to bring the Company into compliance with Nasdaq's \$1.00 per share minimum bid price requirement for continued listing. The Company is simultaneously effecting a reduction in the number of authorized shares of common stock from 50,000,000 to 20,000,000.

Avenue's transfer agent, VStock Transfer, LLC, which is also acting as the exchange and paying agent for the reverse stock split, will provide instructions to stockholders regarding the process for exchanging physical share certificates. We do not expect that stockholders holding their shares in book-entry form or through a bank, broker or other nominee need to take any action in connection with the reverse stock split. Beneficial holders are encouraged to contact their bank, broker or other nominee with any procedural questions. Additional information concerning the reverse stock split can be found in the Company's definitive Information Statement on Schedule 14C filed with the Securities and Exchange Commission

on August 22, 2022.

IV Tramadol Regulatory Update

Avenue received the official meeting minutes from the FDA regarding a meeting conducted on August 9, 2022, for IV Tramadol. Avenue submitted the Type A Meeting Request and related briefing documents to the FDA on June 17, 2022, and included a proposed study design to address the concerns around the safety risk of IV Tramadol in combination with other opioid analgesics for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting that was discussed in detail at the previously disclosed Advisory Committee meeting on February 15, 2022 and in the Appeal Denied letter received on March 18, 2022.

At the meeting, Avenue presented a study design for a single safety clinical trial that the Company believes could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to Avenue upon review of a more detailed study protocol. The Company intends to incorporate the FDA's suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.

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 central nervous system diseases. Avenue is headquartered in New York City. 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 candidate; 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; uncertainty surrounding the Baergic Bio acquisition; ability to effectuate the reverse stock split; 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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