Aquestive Therapeutics Announces Leadership Expansion to Support Growth

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- *Changes strategically aligned to support planned launch of Anaphylm™ (dibutepinephrine) Sublingual Film, if approved by the FDA, and to accelerate the Company's ongoing development initiatives*
- *Matthew Davis, M.D., RPh will join immediately as Chief Development Officer*
- *Gary Slatko, M.D., M.B.A, will become interim Chief Medical Officer*
- *Peter Boyd, M.B.A, has been promoted to Chief People Officer*

WARREN, N.J., Nov. 04, 2025 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive" or the "Company"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced changes to its leadership team to support the launch of Anaphylm™, if approved by the United Stated Food and Drug Administration (FDA), and expansion of its pipeline.

"We remain confident in the potential of our AdrenaVerse™ prodrug epinephrine platform to generate multiple important products starting with Anaphylm," said Dan Barber, President and CEO of Aquestive. "The addition of a seasoned, successful, and innovative leader such as Dr. Matthew Davis gives us an incredible opportunity to accelerate our pipeline efforts. At the same time, strengthening our medical affairs leadership under Dr. Gary Slatko will help expand awareness within the allergy community and support our launch of Anaphylm, if approved by the FDA. Additionally, positioning Peter Boyd to lead our human resources strategy ahead of commercial expansion reinforces our commitment to execution of these planned initiatives. These strategic moves give me great confidence in our ability to succeed in 2026."

"I would like to thank Dr. Carl Kraus for his contributions to Aquestive as our Chief Medical Officer over the last two years and we wish him the best in his future endeavors. I'd like to also take the opportunity to continue to recognize in memoriam Dr. Steve Wargacki, our former Chief Science Officer, for his incredible efforts in developing Anaphylm over the course of almost a decade of research. Thanks to their combined efforts, the Company's product development capabilities are stronger than ever as we approach our upcoming FDA scheduled action date for Anaphylm."

In his new role, Dr. Davis will oversee the Company's research & development and clinical pipeline efforts. Dr. Davis brings more than two decades of experience in drug development and medical leadership, spanning both large pharmaceutical and emerging biotechnology companies. Prior to joining Aquestive, Dr. Davis served as Chief Medical Officer at Neuvivo, where he led clinical development and medical strategy across a portfolio of neurological disorders. Earlier in his career, Dr. Davis held senior leadership roles at Tiziana Life Sciences (NASDAQ:TLSA), Endo Pharmaceuticals, Lupin Pharmaceuticals, United Research Laboratories and Dermik (Aventis), where he played pivotal roles in advancing multiple programs through regulatory approval and commercialization. Dr. Davis has been credited with 17 Orange Book-listed patents, more than 1,100 citations in public literature, and has led 12 FDA approvals and clearances over the course of his career, including six successful product launches such as Lidoderm®. Dr. Davis earned his M.D. from Drexel University College of Medicine, undertook his residency in general surgery at Brown University and received a B.S. in Pharmacy degree from Temple University School of Pharmacy.

Dr. Slatko, who previously served as Aquestive's Chief Medical Officer from 2019 to 2023, returns to the Company to lead medical affairs and pharmacovigilance. He brings over three decades of experience spanning regulatory science, drug safety, and clinical leadership across government, large pharmaceutical, and emerging biotechnology organizations. Dr. Slatko's experience includes three prior CMO medical executive roles over a 15-year period at a biopharmaceutical consulting firm, a specialty pharmaceutical company and a medical device start-up firm. He served over six years as a drug safety regulator at the FDA as a director in the Office of Medication Error Prevention and Risk Management. Earlier in his career, Dr. Slatko held various drug safety, clinical program, new product planning, medical affairs, managed care and executive leadership roles at Bristol Myers Squibb, DuPont Merck Pharmaceuticals, AstraZeneca, and GlaxoSmithKline. Dr. Slatko received a B.A. from Emory University, an M.D. from the University of Miami School of Medicine, and an M.B.A. from West Chester University. He is Board certified in Internal Medicine.

Mr. Boyd joined the Company in August 2013 and has led our Information Technology, Human Resources, and Communications functions since December of 2022. Prior to his current position, Mr. Boyd led Business Process, Manufacturing Operations, and Clinical Operations. Prior to joining us, Mr. Boyd served as Senior Director of Operations for the Americas and APJ Regions at HP Inc. Throughout his 15-year career at HP, Mr. Boyd held a variety of positions in business process improvement and in operations. Mr. Boyd received a B.A. in History from Wittenberg University and an M.B.A in Finance from Seton Hall University. Mr. Boyd also received an M.S. in Management and Urban Policy Analysis from the New School University.

Inducement Grant under Nasdaq Listing Rule 5635(c)(4)

Under the Company's 2022 Equity Inducement Plan, Dr. Davis will receive an equity award of 50,000 Restricted Stock Units (the "Inducement RSUs") and an equity award of 50,000 non-qualified common stock options (the "Inducement Options"), each award to be granted on the second full trading date following the date of the next public release of quarterly or annual financial results. The Inducement RSUs and the Inducement Options will vest 25% after each of the first and second anniversaries of the grant date, and 50% on the third anniversary of the grant date, subject to continued employment through the applicable grant date. The Inducement Options will have a term of ten years and an exercise price per share equal to the closing price of Aquestive's common stock on the Nasdaq Global Market on November 10, 2025, the scheduled grant date of the award. The Inducement RSUs and the Inducement Options are being granted in reliance on the employment inducement exemption provided under Nasdaq Listing Rule 5635(c)(4), and these awards were approved by the independent Compensation Committee of the Board of Directors of the Company as a material inducement for Dr. Davis acceptance of employment with Aquestive. The Inducement RSUs and the Inducement Options were granted outside of the Company's 2018 Equity Incentive Plan.

About Anaphylm™ (dibutepinephrine) Sublingual Film

Anaphylm™ (dibutepinephrine) Sublingual Film is a polymer matrix-based epinephrine prodrug product candidate. Anaphylm is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a phone or wallet, and is designed to withstand weather excursions such as exposure to rain and/or sunlight. If approved by the FDA, Anaphylm would be the first and only oral medication for the rescue treatment of severe allergic reactions, including anaphylaxis. The Anaphylm trade name for AQST-109 has been conditionally approved by the FDA. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

About Aquestive Therapeutics

Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has four commercialized products marketed by its licensees in the U.S. and around the world, and is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product candidate for the treatment of severe allergic reactions, including anaphylaxis, and an earlier stage epinephrine prodrug topical gel product candidate for possible various dermatology conditions, including alopecia areata. For more information, visit Aquestive.com and follow us on LinkedIn.

Forward-Looking Statement

Certain statements in this press release include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the advancement and related timing of our product candidate Anaphylm™ (dibutepinephrine) Sublingual Film through clinical development and approval by the FDA and the following commercial launch of Anaphylm, if approved by the FDA; the potential for Anaphylm to be the first and only orally delivered epinephrine product, if approved by the FDA, and the Company's ability to expand awareness of Anaphylm in the allergy community; the advancement, growth and related timing of our AdrenaVerse™ pipeline of epinephrine prodrug product candidates through clinical development and approval by the FDA, including AQST-108 (epinephrine) Topical Gel for possible various dermatology conditions, including alopecia areata; the potential benefits our products and product candidates could bring to patients; the potential of the AdrenaVerse prodrug epinephrine platform to generate multiple new important products; the future strength of the Company to advance its key initiatives; and business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm, AQST-108, and our other product candidates; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including for Anaphylm and AQST-108, or failure to receive FDA approval at all of these product candidates; risk of government shutdown on the ability of the FDA to act on the approval of our product candidates, including Anaphylm and AQST-108; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our pharmacokinetic and pharmacodynamic (PK/PD) comparability submission for FDA approval of Anaphylm; risks associated with our ability to address the FDA's comments on our NDA, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risks associated with the success of any competing products, including generics; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of our product candidates, including Anaphylm and AQST-108; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product and product candidates, including Anaphylm and other product candidates; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Notes in 2026, and to fund future clinical development and commercial activities for our product candidates, including Anaphylm ; risk of the impact of our obligations under the Company's Purchase Agreement and the Royalty Rights

Agreement with third parties, each of which agreements requires the Company to make payments to each counterparty thereof, respectively, of a portion of our revenues, on our ability to contribute to the funding of our operations and the payment of principal and interest on our debt; the risk of our obligations under such Purchase Agreement and Royalty Rights Agreement impacting our ability to refinance our 13.5% Notes; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates in the U.S. and abroad, if such product candidates should be approved by the FDA and other regulatory authorities, and our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunsetting product, which accounts for a substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance in the U.S. and abroad of Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA and other regulatory authorities, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets; risk associated with our compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm and AQST-108, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office or, if issued, will be sufficient to provide long-term commercial success of these product candidates; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and product candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against us including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and changing interest rates; risks related to the impact of other pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business, including imposition of tariffs and other trade restrictions; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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