# Aquestive Therapeutics Announces Regulatory Development for Anaphylm™ (dibutepinephrine) Sublingual Film and Provides Business Update

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- ***Announces receipt of FDA letter stating it has identified deficiencies that preclude labeling discussions for Anaphylm at this time***
- ***Receives confirmation from FDA that Agency's review of Anaphylm NDA application is ongoing and no final FDA decision has been made***
- ***Progresses global regulatory expansion activities in Canada, Europe, and the United Kingdom for Anaphylm***
- ***Unaudited cash and cash equivalents of approximately $120 million as of December 31, 2025***

WARREN, N.J., Jan. 09, 2026 (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 provided an update on the regulatory approval of Anaphylm™ and its business.

"As part of its ongoing review of the Company's NDA for Anaphylm, the FDA notified us that it had identified deficiencies in the NDA that preclude discussion of labeling and post-marketing commitments at this time," said Dan Barber, President and Chief Executive Officer of Aquestive. "Although the notification did not specify the deficiencies, Aquestive is working to understand and resolve the concerns. The FDA stated that the notification does not reflect a final decision on the pending application and the FDA's review remains ongoing."

"While we await further information from the FDA, we remain confident about Anaphylm and its potential to be the first and only FDA-approved sublingual film," continued Mr. Barber. "Designed to be easy-to-use, fast-acting, and highly portable, we continue to believe Anaphylm represents a major step forward for people living with severe allergies. We are advancing our global expansion of Anaphylm with plans to submit for regulatory approval in Canada, Europe, and the United Kingdom in 2026. We believe our long-term growth strategy remains compelling with the potential approval and subsequent launch of Anaphylm in the U.S. and around the world. With the recent equity raise and our current cash position, we also believe that we have the necessary capital to execute on our current growth strategy."

**Anaphylm™ (dibutepinephrine) Sublingual Film**
The Company is in contact with the U.S. Food and Drug Administration (FDA) to gather further information about the deficiencies presently identified by the FDA in the New Drug Application (NDA) for Anaphylm, with the goal of addressing those deficiencies prior to the scheduled PDUFA action date of January 31, 2026, once disclosed to the Company. The FDA has indicated that the review remains ongoing and further clarified that a Discipline Review Letter will not be issued, while information requests are possible during the remaining review period. However, further delays in communicating the specific deficiencies may lead to a delay in the potential approval of Anaphylm. The Anaphylm NDA submission is supported by a comprehensive clinical development program consisting of eleven independent clinical studies with approximately 967 total administrations across 411 subjects, including 840 single-dose and 127 repeat-dose exposures of Anaphylm. As part of the clinical development program, Aquestive conducted a first-of-its-kind oral allergy syndrome (OAS) study, which demonstrated Anaphylm's performance in a real-world, allergen-induced setting. The program demonstrated that Anaphylm delivers a pharmacokinetic (PK) profile comparable to the leading epinephrine auto-injectors. These studies showed that Anaphylm was generally well tolerated and had a safety profile similar to that of epinephrine.

Aquestive continues to advance its global expansion strategy for Anaphylm, initiating regulatory engagements in Canada, Europe, and the United Kingdom in 2025. Aquestive expects to submit its New Drug Submission (NDS) to Health Canada in the first half of 2026. In addition, the Company received positive feedback from the European Medicines Agency (EMA) that no further clinical trials are needed prior to regulatory approval submission. Aquestive expects to submit its marketing authorization application in Europe in the second half of 2026. The Company also expects to receive feedback from the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom in the first quarter of 2026. These markets represent important opportunities to expand access to the Company's non-invasive epinephrine therapy globally.

As previously planned, the Company intends to hire its U.S. sales force following approval, if granted by the FDA, and continues to advance other pre-commercial activities for Anaphylm. In both the U.S. and globally, Aquestive's goal of addressing critical unmet needs in severe allergy management by bringing this innovative treatment to market underscores the Company's commitment to providing patients the first and only orally delivered epinephrine product for the treatment of severe allergic reactions, including anaphylaxis, if approved by the respective regulatory authorities in these jurisdictions.

**Cash Guidance**
Aquestive ended 2025 with approximately $120 million in cash and cash equivalents. The Company continues to believe this

funding is sufficient to complete the Anaphylm approval and launch processes in the U.S., if approved by the FDA, while progressing Anaphylm in other key markets outside the U.S.

**About Anaphylm™**

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 primary packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a pocket, and is designed to withstand weather excursions such as exposure to rain and/or sunlight. 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 Anaphylm.

**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 licensed 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 early-stage epinephrine prodrug topical gel product candidate for various possible dermatological 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, including whether the clinical data submitted to the FDA will be adequate enough for the FDA to approve Anaphylm, and the following commercial launch of Anaphylm, if approved by the FDA; the advancement and related timing of potential international regulatory filings and marketing authorization of Anaphylm outside of the U.S.; that Anaphylm will be the first and only oral administration of epinephrine and accepted as an alternative to existing standards of care, if Anaphylm is approved by the FDA; the potential benefits Anaphylm could bring to patients, if approved by the FDA; our future financial and operating results and financial position, including with respect to our 2025 financial outlook, estimated cash runway and sufficiency to support the Company’s long-term growth strategy for the potential regulatory approval and subsequent launch of Anaphylm in the U.S. and around the world, if approved by the respective regulatory authorities in such jurisdictions; 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; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including for Anaphylm, or failure to receive FDA approval at all for Anaphylm or any of our other product candidates; risk of FDA inspections of manufacturing and clinical study sites for any of our product candidates, including Anaphylm; risk of government shutdowns or actions to reduce government workforces on the ability of the FDA to act on the approval of our product candidates, including Anaphylm; 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 and identified deficiencies in 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, if approved by the FDA; 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; 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 to support our growth strategy, and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Senior Secured Notes in 2026, and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, should these product candidates be approved by the FDA; 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% Senior Secured Notes; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates in the U.S. and abroad, including Anaphylm, 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 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, 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 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 government tariffs and other trade restrictions; and other uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on 10-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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