Aquestive Therapeutics Announces FDA Issuance of Complete Response Letter for Anaphylm™

February 2, 2026 at 7:00 AM EST

- *Deficiencies limited to packaging and administration*
- *Company believes it can rapidly resolve deficiencies and expects to resubmit as early as Q3 2026*
- *Remains well-capitalized and anticipates ending 2026 with significant cash*
- *Reiterates plans to submit in Canada and EU by the end of 2026*
- *Company to host investor call on February 2, 2026, at 8:00am ET*

WARREN, N.J., Feb. 02, 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 announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) on January 30, 2026 for the New Drug Application (NDA) seeking approval of Anaphylm™ (dibutepinephrine) Sublingual Film for the treatment of Type I allergic reactions, including anaphylaxis, in patients weighing 30kg or more (approximately 66 pounds).

"While it is unfortunate to have received a CRL, we believe that, with the clarity we now have from the FDA, we have made significant progress toward approval. We are encouraged that the issues in the letter are limited to human factors and a supportive PK study, once human factors are addressed, and we noted several labeling comments that will inform the final label for Anaphylm, if approved by the FDA," said Daniel Barber, President and CEO of Aquestive. "We remain confident in the effectiveness and safety of Anaphylm and its potential as an easy-to-use, easy-to-carry, fast-acting epinephrine treatment. We look forward to working with the FDA to achieve approval for Anaphylm. Our commitment to bringing this innovative therapy to the allergy community remains steadfast."

In the CRL, which focuses on administration and labeling guidance, the FDA cited deficiencies in the Anaphylm human factors (HF) validation study. These included instances of difficulty opening the pouch and incorrect film placement which, if unaddressed, the FDA believes could cause significant safety issues in the setting of anaphylaxis. To resolve the FDA's concerns, the Company has modified the pouch opening, instructions for use, pouch and carton labeling, and plans to rapidly conduct a new HF validation study with these modifications. The Company also plans to further address potential tolerability issues in its resubmission. Comparability data submitted as part of the Anaphylm NDA, such as bracketing, repeat dose, and sustainability, were not questioned in the CRL. There were also no CMC issues noted in the CRL.

Due to the requirements related to HF, clinical pharmacology requested a single pharmacokinetics (PK) study to understand the impact of any modifications to packaging and labeling. The Agency indicated that the HF and PK studies can be conducted in parallel. No additional studies were requested in the CRL.

The Company plans to closely work with the Agency to achieve approval for Anaphylm as expeditiously as possible. As an initial step, the Company will request a Type A meeting with the FDA to discuss the most efficient path forward for resubmission. Based on its initial review of the CRL, the Company estimates resubmission in Q3 2026, assuming completion of the HF and PK studies and typical response times from the FDA. The Company plans to request rapid review by the FDA.

Allergist Jay Lieberman, M.D., Professor at the University of Tennessee Health Science Center and a practicing physician at LeBonheur Children's Hospital, said, "As a clinician and investigator for various allergy clinical trials, I am well versed in the nuances related to clinical development and regulatory approval. FDA's response is focused on patient experience issues and their potential impacts. I am confident in Aquestive's ability to address the issues described above and remain optimistic in having Anaphylm available for my patients in the future. Given the continued underuse of epinephrine in anaphylaxis, the availability of more treatment options remains a top priority for clinicians and the allergy community."

Aquestive also plans to continue advancing its global expansion strategy for Anaphylm, having initiated regulatory engagements in Canada, Europe, and the United Kingdom in 2025. 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 as well as its New Drug Submission (NDS) in Canada 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.

The Company believes that the original 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 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.

With 20 years since its founding, 6 FDA approvals, and more than 2.5 billion doses of oral film products shipped to patients worldwide, Aquestive continues to believe in Anaphylm's ease-of-use profile and potential to be the first and only non-invasive, orally delivered epinephrine for the treatment of severe life-threatening allergic reactions, including anaphylaxis, if approved by the FDA.

The Company believes that it has sufficient funding to complete the Anaphylm approval and pre-launch processes in the U.S., while progressing

Anaphylm in other key markets outside the U.S.

Conference Call and Webcast
The Company will host a conference call at 8:00 a.m. ET on Monday, February 2, 2026.

In order to participate, please register in advance here to obtain a local or toll-free phone number and your personal pin.

A live webcast of the call will be available on Aquestive's website here.

Further details regarding the FDA's comments are available in a supplemental presentation located in the Events and Presentation section of the Investor page on the Aquestive website.

About Anaphylm™ (dibutepinephrine) Sublingual Film
Anaphylm 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.

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 our clinical and other data will be adequate enough to address the concerns raised by the FDA in the Complete Response Letter dated January 30, 2026 (CRL) provided to the Company and for the FDA to finally approve Anaphylm or whether the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our resubmission, and challenges regarding 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; the advancement and related timing of our product candidate AQST-108 (epinephrine) Topical Gel through clinical development and FDA regulatory approval process, including design and timing of clinical studies including those necessary to support the targeted indication of alopecia areata for AQST-108; 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 for Anaphylm; risk of delays in advancement of the regulatory approval process through the FDA of our product candidate Anaphylm, or failure to receive FDA approval at all; 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 and other human factor data, including with respect to our submission of pharmacokinetic and pharmacodynamic (PK/PD) comparability data 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 concerns raised by the FDA in the Complete Response Letter dated January 30, 2026 issued to the Company for approval of Anaphylm; risks that the FDA may consider issues raised in the citizen petition submitted to the FDA regarding Anaphylm on October 1, 2025; 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 relating to the Company's 13.5% Senior Secured Notes 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.

Investor Contact:
Brian Korb
astr partners
brian.korb@astrpartners.com