Aquestive Therapeutics Provides Business Update and Outlines Key 2025 Objectives

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- *On track to submit Anaphylm™ (epinephrine) Sublingual Film NDA in Q1 2025*
- *Actively recruiting subjects in the Anaphylm pediatric clinical trial*
- *Successfully completed AQST-108 (epinephrine) Topical Gel pre-IND meeting and on track to begin Phase 2a clinical trial in alopecia areata in Q2 2025*
- *Unaudited cash and cash equivalents of approximately $70 million as of December 31, 2024*

WARREN, N.J., Jan. 13, 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 provided an update on recent business developments and outlined key objectives for 2025.

"In 2024, we significantly advanced the Company and delivered on our key milestones. Our achievements last year have positioned the Company for continued success in 2025," said Dan Barber, President and Chief Executive Officer of Aquestive. "We believe our long-term growth strategy remains compelling with the potential approval and launches of Anaphylm, Libervant (patients 6+), and AQST-108 in the U.S. and around the world. Our focus in 2025 is on 1) preparing for the potential approval and launch of Anaphylm for the treatment of severe allergies, including anaphylaxis, in the U.S. as early as the first quarter of 2026, 2) actively pursuing our ex-U.S. development strategy for Anaphylm, 3) successfully conducting our Phase 2a clinical trial in alopecia areata for AQST-108, 4) continuing to expand our sales of Libervant® (diazepam) Buccal Film for patients between two to five years of age, and (5) continuing to shift our current revenue base from legacy products to Libervant and other growth opportunities. This is truly an exciting time at Aquestive."

Anaphylm™ (epinephrine) Sublingual Film
In 2024, Aquestive made significant progress with Anaphylm, its innovative epinephrine delivery system. The Company concluded a successful pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA), which provided clear guidance on the regulatory pathway to NDA submission for Anaphylm. Additionally, Aquestive initiated a Phase 1 pediatric trial of Anaphylm in children aged 7 to 17 years and ≥30 kg, further demonstrating its commitment to expanding access to this treatment across age groups.

Aquestive is on track to submit the NDA for Anaphylm in the first quarter of 2025, with the goal of addressing critical unmet needs in severe allergy management. The anticipated NDA submission marks a pivotal step toward bringing this innovative treatment to market, underscoring Aquestive's commitment to providing to patients the first and only orally delivered epinephrine product for the treatment of severe allergic reactions, including anaphylaxis, if approved by the FDA.

AQST-108 (epinephrine) Topical Gel
Aquestive successfully completed a pre-Investigational New Drug meeting with the FDA in December 2024. The written response received from the FDA was supportive of continued development and Aquestive remains on track to begin its Phase 2a trial in patients with alopecia areata (AA) in the second quarter of 2025.

An estimated 6.7 million people in the United States have been affected by AA. Of those affected, 43% are considered severe. The existing therapies for alopecia areata are janus kinase (or JAK) inhibitors. These systemic treatments with known side effects come with a "black box" warning and are expensive for patients. Even with these limitations, the current estimated market opportunity for JAK inhibitors is over one billion U.S. dollars. In the first in human Phase 1 clinical trial, AQST-108 demonstrated no serious adverse events or topical adverse events. Since AQST-108 is topical and there is evidence that it acts at the application site, it may not have systemic side effects. As a result of these conditions, AQST-108, if approved by the FDA as a treatment for severe alopecia areata, has the potential to capture meaningful market share for the treatment of these patients.

Libervant® (diazepam) Buccal Film
Aquestive received FDA approval for Libervant in 2024, enabling access for the treatment of seizure clusters in pediatric patients with epilepsy between two to five years of age. This milestone ensures younger patients in this age group have access to this essential treatment. In December 2024, the Company received Orphan Drug Exclusivity for Libervant for patients between two to five years of age until April 2031.

Libervant is the first and only FDA approved orally administered rescue product for the treatment of seizure clusters in patients with epilepsy between two to five years of age.

About Anaphylm™(epinephrine) Sublingual Film
Anaphylm™ (epinephrine) 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 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 AQST-108 (epinephrine) Topical Gel
AQST-108 is a topically delivered adrenergic agonist prodrug gel product candidate. Aquestive completed a first in human study for AQST-108 that measured the amount of epinephrine that remained on the skin or was found in circulation over time after the application of the gel and without any serious or topical adverse events. AQST-108 is based on Aquestive's Adrenaverse™ platform that contains a library of over twenty epinephrine prodrug product candidates intended to control absorption and conversion rates across a variety of possible dosage forms and delivery sites.

About Libervant® (diazepam) Buccal Film
Libervant is a buccally, or inside of the cheek, administered film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy between two to five years of age. Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including rectal gel and nasal spray products. The FDA granted tentative approval of Libervant in August 2022 for the treatment of these epilepsy patients 12 years of age and older, with U.S. market access for Libervant for this age group of patients subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved drug scheduled to expire in January 2027. The Company plans to submit an NDA and launch Libervant for these epilepsy patients between 6 to 11 years of age, if approved by the FDA, upon the expiration of the existing orphan drug market exclusivity scheduled to expire in January 2027. The FDA approval for U.S. market access received in April 2024 for Libervant is for these epilepsy patients between two to five years of age.

Important Safety Information Important Safety Information

Do not give Libervant® to your child if your child is allergic to diazepam or any of the ingredients in Libervant or has an eye problem called acute narrow angle glaucoma.
What is the most important information I should know about Libervant?

- **Libervant is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.** Get emergency help right away if any of the following happens:
    - **shallow or slowed breathing,**
    - **breathing stops (which may lead to the heart stopping),**
    - **excessive sleepiness (sedation).**

Do not allow your child to drive a motor vehicle, operate heavy machinery, or ride a bicycle until you know how taking Libervant with opioids affects your child.

- **Risk of abuse, misuse, and addiction.** Libervant is used in children 2 to 5 years of age. The unapproved use of Libervant has a risk for abuse, misuse, and addiction, which can lead to overdose and serious side effects including coma and death.
- **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including diazepam (the active ingredient in Libervant).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
    - **Your child can develop an addiction even if your child takes Libervant as prescribed by your child's healthcare provider.**
    - **Give Libervant exactly as your child's healthcare provider prescribed.**
    - Do not share Libervant with other people.
    - Keep Libervant in a safe place and away from children.
- **Physical dependence and withdrawal reactions. Libervant is intended for use if needed in order to treat higher than usual seizure activity. Benzodiazepines, including** Libervant, can cause physical dependence and withdrawal reactions, especially if used daily. Libervant is not intended for daily use.
    - **Do not suddenly stop giving Libervant to your child without talking to your child's healthcare provider.** Stopping Libervant suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures that will not stop (status epilepticus), sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, homicidal thoughts, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child gets any of these symptoms.**
    - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning, or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
    - Physical dependence is not the same as drug addiction. Your child's healthcare provider can tell you more about the differences between physical dependence and drug addiction.
- Do not give your child more Libervant than prescribed or give Libervant more often than prescribed.

Libervant can make your child sleepy or dizzy and can slow your child's thinking and motor skills.

- Do not allow your child to drive a motor vehicle, operate machinery, or ride a bicycle until you know how Libervant affects your child.
- Do not give other drugs that may make your child sleepy or dizzy while taking Libervant without first talking to your child's healthcare provider. When taken with drugs that cause sleepiness or dizziness, Libervant may make your child's sleepiness or dizziness much worse.

Like other antiepileptic medicines, Libervant may cause suicidal thoughts or actions in a small number of people, about 1 in 500.

- Call a healthcare provider right away if your child has any of these symptoms, especially if they are new, worse, or worry you:
  - thoughts about suicide or dying
  - new or worse depression
  - feeling agitated or restless
  - trouble sleeping (insomnia)
  - acting aggressive, being angry or violent
  - other unusual changes in behavior or mood
  - attempts to commit suicide
  - new or worse anxiety or irritability
  - an extreme increase in activity and talking (mania)
  - new or worse panic attacks
  - acting on dangerous impulses
- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your child's healthcare provider as scheduled.
- **Call your child's healthcare provider between visits as needed, especially if you are worried about symptoms.** Suicidal thoughts or actions can be caused by things other than medicines. If your child has suicidal thoughts or actions, your child's healthcare provider may check for other causes.

What are the possible side effects of Libervant?

- The most common side effects of Libervant are sleepiness and headache.
- These are not all the possible side effects of Libervant.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For more information about Libervant, talk to your doctor, and see Product Information: **Medication Guide and Instructions For Use**.

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 five commercialized products marketed by the Company and 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 for various dermatology conditions. 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™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of submission of a pediatric clinical trial, filing the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; 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; plans to submit the Investigational New Drug (IND) Application for AQST-108 and initiation of a Phase 2a clinical trial for AQST-108 for the treatment of patients with alopecia areata; the potential indications and potential benefits our products and product candidates could bring to patients, including for Anaphylm and AQST-108; plans to expand the development program for Anaphylm and AQST-108 outside the U.S.; the commercial opportunity for AQST-108 and its ability to capture market share for treatment of alopecia areata, if approved by the FDA; the expansion of the launch of Libervant for patients between two to five years of age; the approval for U.S. market access of Libervant for this patient population aged twelve years and older and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for these epilepsy patients six years of age and older; our ability to support the manufacture and supply of our product and product candidates and other growth opportunities; our cash and cash position at the end of fiscal year 2024; 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 (including for pediatric patients); risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective INDs and NDAs, including for Anaphylm

and AQST-108, or the failure to receive FDA approval at all of any of these product candidates; 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 comparability submission for FDA approval of Anaphylm (including for pediatric patients); risk of the Company's ability to address the FDA's comments on the Company's clinical trials (including for pediatric patients) and other concerns identified in the FDA Type C meeting minutes and other comments of the FDA for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk that we may not overcome the seven year orphan drug market exclusivity granted by the FDA for the approved nasal spray product of another company in the U.S. in order for Libervant to be granted U.S. market access for patients aged twelve years and older until the expiration of the orphan drug market exclusivity period of the nasal spray product scheduled to expire in January 2027, or for other reasons; risk of loss of U.S. market approval of Libervant for patients between two to five years of age resulting from a legal challenge relating to U.S. orphan drug market exclusivity by the owner of the approved nasal spray product with respect to the FDA's approval for U.S. market access of Libervant for this pediatric patient population, or for other reasons; risk of the success of any competing products; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations), including with respect to market expansion of Libervant for epilepsy patients between two to five years of age; risk of the rate and degree of market acceptance of our products and product candidates including for Anaphylm in the U.S. and abroad for severe allergic reactions, including anaphylaxis, and for AQST-108 in the U.S. for alopecia areata, if these product candidates are approved by applicable regulatory authorities; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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 fund activities relating to future clinical development and commercial activities for our product candidates, including Anaphylm and AQST-108, should these product candidates be approved by the FDA; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk that our manufacturing capabilities will be sufficient to support demand for Libervant for patients between two to five years of age and our other products and product candidates and for demand for our licensed products in the U.S. and abroad; 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 for our licensed products in the U.S. and abroad; risk of the success of any competing products including generics; risk of the size and growth of our product markets; risk of 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; 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 products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive 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 rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; 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; 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 Form 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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