UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 14, 2024

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

30 Technology Drive
Warren, NJ 07059
(908) 941-1900
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	AQST	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On August 14, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release commenting on the recent United States Food and Drug Administration (FDA) approval of a non-injection-based epinephrine device for the treatment of anaphylaxis and reiterates the expected timing for filing of the New Drug Application (NDA) for Anaphylm™ (epinephrine) Sublingual Film to the FDA in the first quarter of 2025. A copy of the Company's press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated in this Item 8.01 by reference.

Forward-Looking Statements

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 submission of supporting clinical studies and the NDA for Anaphylm and the following launch of Anaphylm, if approved 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; the potential benefits Anaphylm could bring to patients; 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 Anaphylm, or failure to receive FDA approval at all; risk of the Company's ability to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's future clinical trials and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; 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); risk of development of a sales and marketing capability for commercialization of our product Anaphylm; 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 future clinical development and commercial activities for Anaphylm, should Anaphylm be approved by the FDA; risk that our manufacturing capabilities will be sufficient to support demand for Anaphylm in the U.S. and around the world; 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; risk of the rate and degree of market acceptance in the U.S. and abroad of Anaphylm, should it be approved by the FDA; 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 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 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 cyberattacks; 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 2023 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.

Item 9.01 Financial Statements and Exhibits

(d)Exhibits.

Exhibit Number	Description
99.1	Press Release, dated August 14, 2024.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated:**August 14, 2024**

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.
Title: Chief Financial Officer

Aquestive Therapeutics Comments on Recent FDA Approval of Non-Injection-Based Epinephrine Product for the Treatment of Anaphylaxis and Reiterates Expected Timing for NDA Filing of Anaphylm™

Your publication date and time will appear here. | Source: Aquestive Therapeutics, Inc.

- *Applauds first FDA approval of non-injection-based epinephrine device*
- *Reiterates expected timing for filing of New Drug Application (NDA) for Anaphylm™ (epinephrine) Sublingual Film to the FDA in the first quarter of 2025*

WARREN, N.J., Aug. 14, 2024 (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 commented on the approval of a non-injection-based device for delivery of epinephrine for the treatment of severe allergic reactions, including anaphylaxis, by the United States Food and Drug Administration (FDA).

"Use of epinephrine for the treatment of severe allergic reactions, including anaphylaxis, has been in needle-based form since its original U.S. FDA approval in 1939," said Daniel Barber, President & Chief Executive Officer of Aquestive. "We are excited to see the FDA's recent approval of an alternative non-injection-based device form of epinephrine. Literature and patient surveys indicate that adherence and compliance will likely improve as products become less invasive, easier to carry, easier to use, and easier to fit into daily life. We look forward to seeing more products in the hands of patients, including our lead pipeline program, Anaphylm™ (epinephrine) Sublingual Film, if approved by the FDA. Anaphylm is in late-stage

development and has the potential to be the first and only oral epinephrine product for the treatment of severe allergic reactions, including anaphylaxis."

"As both a clinician and a food allergy patient, I recognize the critical role needle-free epinephrine delivery methods play in reducing injection hesitancy, which can delay life-saving treatment during anaphylaxis," said Sung Poblete, PhD, RN, CEO of FARE (Food Allergy Research & Education). "At FARE, we are dedicated to driving innovation in the food allergy space and are encouraged by FDA approval of the first alternate treatment for anaphylaxis. The community is eager for more options and improved access to care, and we look forward to seeing additional life-saving epinephrine delivery methods for food allergy patients."

"I am pleased to see the first non-needle form of epinephrine for the treatment of anaphylaxis get approved by the FDA," said John Oppenheimer, MD, Director of Clinical Research at Pulmonary and Allergy Associates as well as Clinical Professor of Medicine at UMDNJ-Rutgers, "I am also excited to see further innovation coming for patients with anaphylaxis. It is critical that patients receive epinephrine quickly and to do so they need to have the medication with them and be able to take it when needed without barriers which can include fear of needles."

Aquestive is currently conducting its remaining supportive study for Anaphylm, the oral allergy syndrome (OAS) challenge study, which is expected to be completed late in the third quarter or early fourth quarter of 2024. The Company is reiterating its guidance of initiating a full product launch of Anaphylm, if approved by the FDA, at the end of 2025 or in the first quarter of 2026. This is based on completing an NDA submission with the FDA in the first quarter of 2025.

About Anaphylm™

Anaphylm is a polymer matrix-based epinephrine prodrug candidate product administered as a sublingual film for the rapid delivery of epinephrine. The product 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 tradename "Anaphylm" 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

Aquestive is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. 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 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.

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