**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): December 22, 2022**

# 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 December 22, 2022, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing the completion of its End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for AQST-109 (epinephrine sublingual film) for the treatment of severe allergic reactions including anaphylaxis. A copy of the Company's press release is attached hereto as Exhibit 99.1 and incorporated into this Item 8.01 by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Aquestive Therapeutics Press Release dated December 22, 2022. |

**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: December 22, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

**Aquestive Therapeutics Announces Completion of FDA End-of-Phase 2 Meeting For AQST-109 (epinephrine sublingual film)**

- *FDA continues to indicate that the Company can conduct a comparability study rather than efficacy studies*
- *FDA provides clear guidance on approvability expectations for pharmacokinetic (PK) performance and patient administration attributes*
- *Company continues to anticipate a potential product launch in 2025 with an NDA submission in first half of 2024*

WARREN, N.J., December 22, 2022 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) (the "Company" or "Aquestive"), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today announced the completion of its End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration ("FDA") for AQST-109 (epinephrine sublingual film) for the treatment of severe allergic reactions including anaphylaxis.

The final EOP2 FDA meeting minutes provided clarity to the Company as to the FDA's expectations regarding key program areas related to pharmacokinetics, administration and use that should be addressed given the life-threatening condition that may be treated with AQST-109, if approved.

The FDA provided clear guidance on its expectation that AQST-109 PK performance be reasonably bracketed between approved injectable epinephrine products with similarity to epinephrine PK via auto-injectors, since autoinjectors are the most commonly used device for self-treatment. From a reference listed product perspective, the FDA urged the Company to utilize multiple approved injectable products to create a bracketing of high and low epinephrine plasma concentrations as well as mean maximum concentration (Cmax) and partial area under the curve (AUC) within 30 minutes to 60 minutes after dosing (as determined by the Company) with an emphasis on the early timepoints. Based on existing data, Aquestive believes it can achieve this 'bracketing' standard in an adequately powered, well-controlled pivotal PK study.

The FDA also provided comments on potential issues the Company will need to address in regard to a sublingually delivered product including (1) the impact of any product hold time, (2) the potential for emesis (vomiting), and (3) the impact of potential mouth conditions such as angioedema (swelling). At this time, the Company believes it can provide sufficient data related to administration and use conditions without overall delay to the New Drug Application ("NDA") submission timeline.

In addition, the FDA acknowledged that pharmacodynamic parameters (PD) (vital signs) following AQST-109 are generally higher than following administration of injectable products, and that the higher PD responses provided some supportive evidence to the PK-driven development program. The FDA further noted that use of these data as supportive evidence of acceptable PK should be accompanied by further characterization to explain similarities or any differences in mechanism of action.

"This positive interaction with the FDA marks a major step forward for our AQST-109 program," said Daniel Barber, Chief Executive Officer of Aquestive. "We continue to educate the FDA on our technology while also gaining important insights into the review division's expectations for a complete and thorough submission. We remain excited to bring AQST-109 to market, if approved by the FDA. We believe the appropriate data can be generated to create a robust review package and we plan on doing this as rapidly as possible."

"After participating with Aquestive in its recent FDA interaction, I remain excited by the potential benefits that AQST-109 could provide to patients," remarked David B.K. Golden, MD, Associate Professor,

Department of Allergy and Clinical Immunology at Johns Hopkins. “Combining portability with an orally delivered route of administration that delivers fast absorption creates the potential for increasing the number of patients who have their rescue medication with them when needed. I look forward to continuing to work with Aquestive as it progresses this important program.”

**About Anaphylaxis**
Anaphylaxis is a serious systemic hypersensitivity reaction with rapid onset and potentially fatal. As many as 49 million people in the United States are at chronic risk for anaphylaxis. Lifetime prevalence is at least 5%, or more than 16 million people in the United States. Direct costs of anaphylaxis have been estimated at $1.2 billion per year, with direct expenditures of $294 million for epinephrine, and indirect costs of $609 million. The frequency of hospital admissions for anaphylaxis has increased 500–700% in the last 10–15 years. 52% of patients, who previously experienced anaphylaxis, had never received an epinephrine autoinjector prescription, and 60% did not have an autoinjector currently available. The most common causes of anaphylaxis are foods (such as peanuts), venom from insect stings, and medications. Epinephrine injection is the current standard of treatment intended to reverse the severe manifestation of anaphylaxis, which may include skin rash, throat swelling, respiratory problems, gastrointestinal distress, and loss of consciousness.

**About AQST-109**
AQST-109 is a polymer matrix-based epinephrine prodrug administered as a sublingual film that is applied under the tongue for the rapid delivery of epinephrine. The product candidate 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 AQST-109 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.

**About Aquestive Therapeutics**
Aquestive Therapeutics, Inc. (NASDAQ: AQST) 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 our licensees in the U.S. and around the world. 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 pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis.

**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 not needing efficacy studies in the comparability submission for AQST-109 FDA approval, the timing of the AQST-109 product launch and NDA submission, the Company’s ability to provide sufficient data to address the FDA’s concerns, the potential benefits AQST-109 could bring to patients, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on the Company’s business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of AQST-109; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

These forward-looking statements are based on the Company's 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 the Company's development work, including any delays or changes to the timing, cost and success of its product development activities and clinical trials for AQST-109; risk of the Company's failure to generate sufficient data in its PK/PD comparability submission for FDA approval of AQST-109; risk of the Company's failure to address the concerns identified in the FDA E0P2 meeting for AQST-109; risk of delays in or the failure to receive FDA approval of AQST-109; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed with the 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 Inquiries:**
ICR Westwicke
Stephanie Carrington
**stephanie.carrington@westwicke.com**
646-277-1282