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): July 25, 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 7.01 Regulation FD Disclosure.

On July 25, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing positive topline pharmacokinetic (PK) data from the self-administration study of Anaphylm™ (epinephrine) Sublingual Film. Anaphylm has the 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 United States Food and Drug Administration (FDA). A copy of the Company's press release is attached as Exhibit 99.1 to this Current Report and incorporated in this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

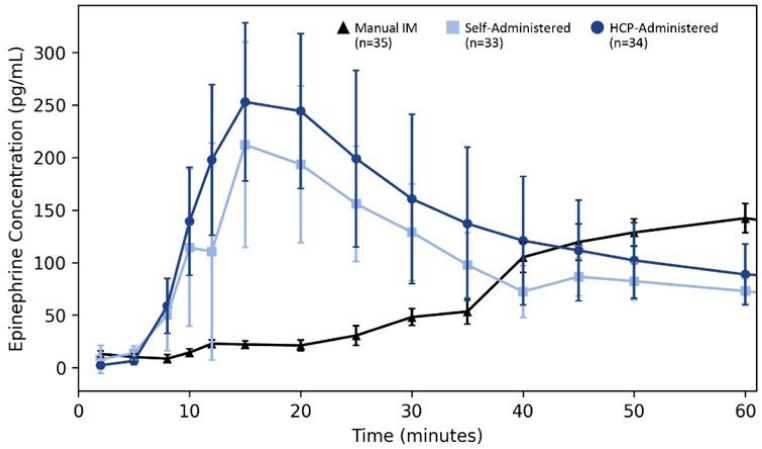
Item 8.01 Other Events.

On July 25, 2024, the Company released positive topline PK data from the self-administration study of Anaphylm™ (epinephrine) Sublingual Film. Anaphylm has the 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.

Topline PK Data from Self-Administration Study

The single-dose, three-period, randomized crossover study design compared the PK and pharmacodynamics (PD) of Anaphylm self-administered, Anaphylm HCP administered, and Adrenalin manual intramuscular (IM) injection HCP administered. The primary PK parameters were the maximum amount of epinephrine measured in plasma (Cmax) and exposure, or the area under the curve (AUC), at various times after dosing in 36 healthy adult subjects. Graph 1 below provides a comparison of epinephrine concentration across the first 60 minutes post-administration. There was no statistical difference between the Anaphylm self-administered and HCP-administered arms of the study. The median time to maximum concentration (Tmax) was 15 minutes for both the Anaphylm self-administered and HCP-administered arms, while the median Tmax for the Adrenalin IM HCP administered arm was 50 minutes post administration.

Graph 1: Baseline-Corrected Epinephrine Concentration Across Time*:



(*Lines on the graph above represent the geometric means of baseline-corrected epinephrine concentration across study timepoints. Baseline-corrected values were calculated by subtracting from the mean of three pre-dose concentrations measured at 60-, 30- and 15-minutes prior to treatment administration.)

The Company's remaining supportive study, the oral allergy syndrome (OAS) challenge study, is underway, and the study is expected to be completed late in the third quarter or early fourth quarter of 2024. The Company is maintaining its guidance on a full product launch of Anaphylm at the end of 2025 or in the first quarter of 2026. This is based on filing an NDA late in the fourth quarter of 2024 or early in the first quarter of 2025. The table below indicates the remaining clinical studies anticipated before the submission of the NDA.

Anticipated Timing**	Pivotal PK Studies	Supportive PK Studies	FDA Meetings / Actions
Completed	Phase 3 PK Study (including repeat dose)	Temperature/pH PK Study	Type C Meeting
		Self-administration PK Study	
Currently Underway		Oral Allergy Syndrome (OAS) Challenge Study	
Remaining	Pediatric Study (30kg and above)		Pre-NDA Meeting FDA filing

(**Timeline does not include chemistry, manufacturing, and controls (CMC), preclinical and human factors activities.)

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 timing of expected supporting and pediatric clinical studies, request for a pre-NDA meeting in the third quarter 2024 and Aquestive's goals of filing an NDA for Anaphylm before the end of 2024 or early in 2025 and launching Anaphlym before the end of 2025 or in the first quarter of 2026, as well as the potential benefits Anaphylm could bring to patients.

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 any delays or changes to the timing, cost and success of its product development activities and clinical trials for Anaphylm; 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 pivotal PK study protocol 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 delays in or the failure to receive FDA approval of Anaphylm; risk of the success of any competing products; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks, and regulatory limitations); risk of the rate and degree of market acceptance of Anaphylm; risk of sufficient capital and cash resources, including sufficient 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, including to fund clinical development activities relating to Anaphylm; 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 of the size and growth of our product markets; risks 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 the Company's products; risk of unexpected patent developments; uncertainties related to general economic, political (including the wars in Israel and Ukraine and other acts of war and terrorism), business, industry, regulatory, financial 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 the Company's 10-K for the year ended December 31, 2023, 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 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 July 25, 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: **July 25, 2024**

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Aquestive Therapeutics Reports Positive Topline Data for Anaphylm™ (epinephrine) Sublingual Film from Self-Administration Study

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

- *Meets primary study endpoints with pharmacokinetics (PK) comparable whether Anaphylm is administered by subjects or by healthcare providers (HCPs)*
- *Final supportive study, the Oral Allergy Syndrome (OAS) challenge study, currently enrolling*
- *Continues to anticipate requesting a pre-New Drug Application (NDA) meeting before the end of the third quarter*

WARREN, N.J., July 25, 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 released positive topline PK data from the self-administration study of Anaphylm™ (epinephrine) Sublingual Film. Anaphylm has the 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 United States Food and Drug Administration (FDA).

"The self-administration data again demonstrates the versatility of Anaphylm, as a product that is easy to remember, easy to carry, and easy to use," said Daniel Barber, President & Chief Executive Officer of Aquestive. "Our groundbreaking Anaphylm formulation indicates that rapid and substantial epinephrine absorption is achieved under a variety of administration conditions. This built-in functionality addresses potential real-world emergency scenarios, where ideal administration may not

happen. In contrast to single-use medical devices, Anaphylm has unique administration properties that allow delivery of the needed levels of epinephrine to provide life-saving medication to patients."

The single-dose, three-period, randomized crossover study design compared the PK and pharmacodynamics (PD) of Anaphylm self-administered, Anaphylm HCP administered, and Adrenalin manual intramuscular (IM) injection HCP administered. The primary PK parameters were the maximum amount of epinephrine measured in plasma (Cmax) and exposure, or the area under the curve (AUC), at various times after dosing in 36 healthy adult subjects. Graph 1 below provides a comparison of epinephrine concentration across the first 60 minutes post-administration. There was no statistical difference between the Anaphylm self-administered and HCP-administered arms of the study. The median time to maximum concentration (Tmax) was 15 minutes for both the Anaphylm self-administered and HCP-administered arms, while the median Tmax for the Adrenalin IM HCP administered arm was 50 minutes post administration.

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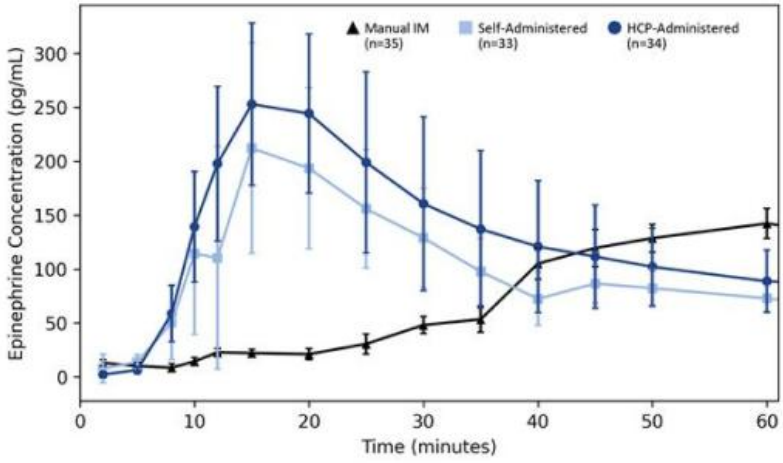

(*Lines on the graph above represent the geometric means of baseline-corrected epinephrine concentration across study timepoints. Baseline-corrected values were calculated by subtracting from the mean of three pre-dose concentrations measured at 60-, 30- and 15-minutes prior to treatment administration.)

"Experiencing and managing a severe allergic reaction can be unsettling and chaotic for patients and caregivers," said Matthew Greenhawt, MD, MBA, MSc, an anaphylaxis expert, and allergist at Children's Hospital Colorado and Aquestive Scientific Advisory Board member. "An orally administered product that can be rapidly and easily administered has the potential to be a game-changer for the allergy community. Anaphylm

encompasses many features important to patients and caregivers, including ease of carry, ease of administration, rapid delivery of epinephrine, and no needles."

The Company's remaining supportive study, the oral allergy syndrome (OAS) challenge study, is underway, and the study is expected to be completed late in the third quarter or early fourth quarter of 2024. The Company is maintaining its guidance on a full product launch of Anaphylm at the end of 2025 or in the first quarter of 2026. This is based on filing an NDA late in the fourth quarter of 2024 or early in the first quarter of 2025. The table below indicates the remaining clinical studies anticipated before the submission of the NDA.

Anticipated Timing**	Pivotal PK Studies	Supportive PK Studies	FDA Meetings / Actions
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About Anaphylaxis

Anaphylaxis is a serious systemic hypersensitivity reaction that is rapid in 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. Of patients who previously experienced anaphylaxis, 52% had never received an epinephrine auto-injector prescription, and 60% did not have an auto-injector 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 difficulty, gastrointestinal distress, and loss of consciousness.

About Anaphylm™

Anaphylm™ (epinephrine) Sublingual Film has the 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. Anaphylm is a polymer matrix-based epinephrine prodrug candidate product. 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 "Anaphylm" tradename 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

Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. The Company is 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 pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis.

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Investor Inquiries:

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646-277-1282

A photo accompanying this announcement is available at https://pr.globenewswire.com/FileDownloader/DownloadFile?source=pnr&fileGuid=e5822b41-eb91-499d-b64d-d6663fdf4083