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 27, 2023

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 July 27, 2023, Aquestive Therapeutics, Inc. (the “Company”) issued a press release announcing topline pharmacokinetic (PK) data for Anaphylm™ (epinephrine) Sublingual Film from its latest clinical crossover pilot trial, Study AQ109103 ("the 103 study"). This crossover clinical trial in healthy human subjects was designed with the finalized dosing instructions expected for use in the Company’s upcoming pivotal PK clinical trial.

The 103 study demonstrated that Anaphylm, using the finalized dosing administration instructions, delivers epinephrine systemically as effectively as either commercially available autoinjectors or the manual intramuscular (IM) injection. Administration of Anaphylm 12mg resulted in a geometric mean maximum epinephrine concentration (Cmax) of 457 pg/mL and a median time to maximum concentration (Tmax) of 15 minutes after administration. The partial Area Under the Curve measurement, or pAUC, was bracketed between previously generated manual 0.3mg IM injection and epinephrine 0.3mg autoinjector data at all timepoints between 10 and 60 minutes, post-dosing. Importantly, Anaphylm 12mg met the standards of bracketing in the 103 study for all the critical parameters that the Company anticipates measuring in the pivotal PK study including Cmax and pAUC during the critical early time periods, while remaining similar to autoinjectors for Tmax. The product was safe and well-tolerated with no serious adverse events.

The 103 study also included crossover arms of Anaphylm 12mg with alternate dosing instructions as well as Anaphylm 14mg with the finalized dosing instructions. In both cases, the product was considered safe and well-tolerated.

The Company anticipates submitting its pivotal PK clinical study protocol to the United States Food and Drug Administration (FDA) in early August 2023 and commencement of its definitive pivotal PK clinical trial in the fourth quarter of 2023.

The product profile, data from the Company's trials, and related statements regarding Anaphylm have not been approved by the FDA. The Company has received conditional acceptance of the use of the trade name Anaphylm, which is subject to final FDA approval of the product candidate.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and incorporated into this Item 8.01 by reference.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this Current Report on Form 8-K 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; the potential benefits Anaphylm 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 Anaphylm; 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 Anaphylm; risk of the Company’s failure to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company’s failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for FDA approval of Analphylm; risk of delays in or the failure to receive FDA approval of Anaphylm and there can be no assurance that we will be successful in obtaining FDA approval of Anaphylm; 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, including to fund future clinical development activities for Anaphylm; risk of the rate and degree of market acceptance of our product candidate Anaphylm; risk of the success of any competing products; uncertainties related to general economic, political, 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 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.

In addition, topline and interim data from clinical trials may not be indicative of final results, and the results of early clinical trials may not be indicative of the results of later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the FDA or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available. 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 Current Report on Form 8-K, whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely upon this information as current or accurate after its publication date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	
99.1	Aquestive Therapeutics, Inc. Press Release dated July 27, 2023.

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 27, 2023

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.

Title: Chief Financial Officer

(Principal Financial Officer)

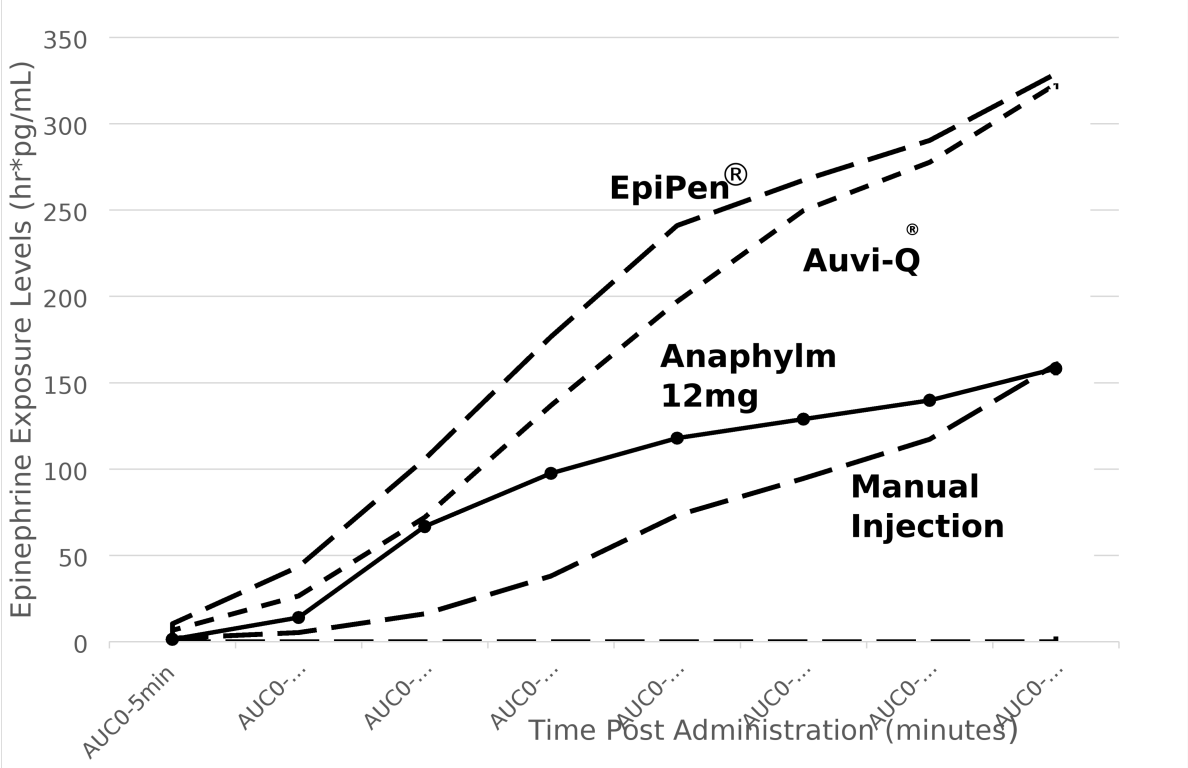
Aquestive Therapeutics Announces Positive Topline Pharmacokinetic Data for Anaphylm™ (epinephrine) Sublingual Film

- *Reports positive topline data from latest pilot pharmacokinetic (PK) study*
- *Plans to submit pivotal PK clinical study protocol to the FDA in early August*
- *Anticipates commencement of its definitive pivotal PK clinical trial in the fourth quarter of 2023*

WARREN, N.J., July XX 2023 -- 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 released topline data from its latest clinical crossover pilot trial, Study AQ109103 (the "103 study"), for Anaphylm™ (epinephrine) Sublingual Film. This crossover clinical trial in healthy human subjects was designed with the finalized dosing instructions expected for use in the Company's upcoming pivotal clinical trial.

The 103 study demonstrated that Anaphylm, using the finalized dosing administration instructions, delivers epinephrine systemically as effectively as either commercially available autoinjectors or the manual intramuscular (IM) injection. Administration of Anaphylm 12mg resulted in a geometric mean maximum epinephrine concentration (Cmax) of 457 pg/mL and a median time to maximum concentration (Tmax) of 15 minutes after administration. The partial Area Under the Curve measurement, or pAUC, was bracketed between previously generated manual 0.3mg IM injection and epinephrine 0.3mg autoinjector data at all timepoints between 10 and 60 minutes, post-dosing. Importantly, Anaphylm 12mg met the standards of bracketing in the 103 study for all the critical parameters that the Company anticipates measuring in the pivotal PK study including Cmax and pAUC during the critical early time periods, while remaining similar to autoinjectors for Tmax. The product was safe and well-tolerated with no serious adverse events. Chart 1 below highlights Anaphylm 12mg pAUC from the103 study when compared to autoinjector and manual IM injection pAUC from a previous study conducted by the Company.

Chart 1: **Anaphylm 12mg Exceeds Lower Bracket at All Expected Pivotal Targets**[1]



1. Bracketing end points subject to alignment with FDA. Cross-study comparison from AQ109102 and AQ109103.

The 103 study also included crossover arms of Anaphylm 12mg with alternate dosing instructions as well as Anaphylm 14mg with the finalized dosing instructions. In both cases, the product was considered safe and well-tolerated. Table 1 below provides a comparison of the two arms that utilized final dosing instructions from the 103 study to autoinjector and manual IM injection data from a previous study conducted by the Company.

Table 1**: Anaphylm 12mg Achieves Targeted Cmax and Tmax in Healthy Subjects**

	Cmax (pg/mL) Geometric Mean (CV%)	Tmax (median, min)
Anaphylm 12mg (n=22)*	457 (120)	15
Anaphylm 14mg (n=23)*	811 (105)	12
EpiPen® 0.3mg (n=27)**	628 (48)	10
Auvi-Q® 0.3mg (n=29)**	646 (49)	30
Epinephrine 0.3mg manual IM injection (n=27)**	344 (60)	50

**Study AQ109103; **Study*

"This is a major step forward for our Anaphylm development program. We are delighted that the latest results meet all of the PK bracketing parameters that we expect to evaluate in the upcoming pivotal PK trial. We are ready to finalize our trial protocol and initiate the study as we are hopeful that the FDA will agree with our assessment." said Daniel Barber, Chief Executive Officer of Aquestive. "Anaphylaxis is a serious condition that requires immediate treatment with epinephrine. We continue to believe that a convenient, oral product such as Anaphylm has the potential to be transformative for patients and caregivers. Anaphylm allows patients to have medication with them where they need it, when they need it and is convenient enough to carry in their wallets or pockets."

Dr. John Oppenheimer, M.D. Director of Clinical Research at Pulmonary and Allergy Associates and Clinical Professor of Medicine at UMDNJ-Rutgers, stated, "The data from the 103 study builds on the compelling data generated from prior Anaphylm pilot studies. These latest study results showed that the sublingual administration of epinephrine provides a promising alternative to the current standard of care allowing patients to carry and administer a needle-free alternative of this life-saving medication."

About Anaphylaxis
Anaphylaxis is a serious systemic hypersensitivity reaction with 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 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 difficulty, gastrointestinal distress, and loss of consciousness.

About Anaphylm
Anaphylm (AQST-109) is a polymer matrix-based epinephrine prodrug candidate product administered as a sublingual film that is applied under the tongue 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.

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 a developing pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit Aquestive.com and follow us on LinkedIn.

Forward-Looking Statements
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