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): September 20, 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 September 20, 2023, Aquestive Therapeutics, Inc. (the "Company") issued a press release reaffirming the possible FDA regulatory approval pathway and related timeline for the Company's product candidate Anaphylm™ (epinephrine) Sublingual Film, including with respect to top-line data relating to the Company's recent clinical studies and expected commencement of its pivotal trial and filing of the New Drug Application for Anaphylm. 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 as Exhibit 99.1 to this Current Report on Form 8-K 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 Anaphylm; 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	Description
99.1	Press Release, dated September 20, 2023, announcing the Company's Reaffirmation of Timeline and Pathway for Anaphylm™ (epinephrine) Sublingual Film

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: September 20, 2023

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Source: *Aquestive Therapeutics, Inc.*

September 20, 2023 09:04 ET

Aquestive Therapeutics Reaffirms Timeline and Pathway for Anaphylm™ (epinephrine) Sublingual Film

WARREN, N.J., Sept. 20, 2023 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ:AQST), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today provided an update on the development timeline and pathway for its oral epinephrine product candidate, Anaphylm™.

As previously disclosed, Aquestive submitted its revised protocol for the proposed pivotal PK clinical trial to the Food and Drug Administration (FDA) in August 2023. The Company intends to commence the pivotal trial in the fourth quarter 2023, following alignment with the FDA. In addition, the Company's current development plan continues to include a standard repeat-dose study of Anaphylm and an already-approved comparator.

Earlier this year, the Company disclosed repeat-dose data of Anaphylm 12mg at 25 minutes post initial dosing from Study AQ109102 including a cross-study comparison to epinephrine manual injection 0.3mg with a repeat dose at 10 minutes post initial dosing. Further information on this comparison is available in the Company's corporate presentation located on the Investor page of the Company's website.

"Based on our previous interactions with the FDA and our review of publicly available disclosures, we continue to anticipate starting our pivotal trial in the fourth quarter 2023," stated Daniel Barber, Chief Executive Officer of Aquestive. "We are focused on completing the necessary work to reach our goal of filing our NDA in 2024."

Mr. Barber continued, "We are advancing the development of Anaphylm, the first and only non-invasive, orally delivered epinephrine product candidate to demonstrate clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of severe allergic reactions, including anaphylaxis. Our orally delivered product candidate comes in a highly portable package with the durability to withstand many of the norms of daily life and potentially combines the convenience with enhanced portability with positive clinical outcomes."

Aquestive has evaluated Anaphlym in six clinical studies across 200 healthy volunteers. In the most recent pilot PK study (AQ109103 or the "103" study) completed in July 2023, Anaphylm, using the proposed final dosing administration instructions, was shown to deliver epinephrine systemically as effectively as either commercially available autoinjectors or the manual intramuscular (IM) injection. The Anaphylm 12mg data met all of the critical parameters, including maximum concentration (Cmax) and partial area under the curve (pAUCs), during the critical early time periods by falling between the levels demonstrated for comparator products (bracketing) that the Company anticipates measuring in the pivotal PK clinical trial. The Anaphylm 12mg also generated time to maximum blood concentration (median Tmax) data similar to the autoinjectors. In the 103 study, Anaphylm was safe and well-tolerated with no serious adverse events.

About Anaphylm™
Anaphylm™ 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. The tradename for AQST-109 "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 pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit Aquestive.com and follow us on LinkedIn.

Forward-Looking Statement

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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 and our other product candidates; 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 Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm and our other product candidates, and there can be no assurance that we will be successful in obtaining FDA approval; 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 and our other product candidates; risk of the rate and degree of market acceptance of our product candidates including 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 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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