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): October 9, 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 October 9, 2023, Aquestive Therapeutics, Inc. (the "Company") issued a press release providing a business update on its lead pipeline programs and base business results. The business update includes 1) the receipt of feedback from the U.S. Food and Drug Administration (FDA) on the Company's proposed pivotal study protocol for Anaphylm™ (epinephrine) Sublingual Film, including that the Company's proposed endpoints, sample size, and statistical analysis are reasonable and reminding the Company that pharmacokinetics (PK) sustainability post-dosing (30 – 60 minutes) is an important factor and recommending that the Company use repeat-dose data to support PK sustainability; 2) reaffirmation of expected fourth quarter 2023 Anaphylm pivotal Phase 3 study start and expected first quarter 2024 topline data readout; 3) outline of expected remaining activities for the Anaphylm program prior to submission of the New Drug Application (NDA) for Anaphylm to the FDA; 4) indication that the FDA review of Libervant™ (diazepam) Buccal Film NDA is on track with no current open questions from the FDA; and 5) anticipation of increasing 2023 revenue and decreasing non-GAAP adjusted EBITDA loss guidance in upcoming earnings release.

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, the advancement and related timing of our product candidate Anaphylm through clinical development and approval by the FDA, including the filing of pivotal PK clinical trials and other supporting clinical studies for Anaphylm; regarding the Company's ability to provide sufficient data in its NDA submission to address the FDA's recent comments on the Company's proposed pivotal PK study protocol and the FDA's other concerns following the End-of-Phase 2 meeting with the FDA; regarding the FDA's approval for U.S. market access and the related timing of the filing of the NDA for Libervant with the FDA; regarding the 2023 financial outlook of the Company and its financial and operating results and financial position; and other statements that are not historical facts. 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 Libervant; risk of the Company's failure to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm or that subsequent studies will not match results seen in prior studies; risk of the Company's failure to address the concerns of the FDA, including those identified in the End-of-Phase 2 meeting for Anaphylm, and the risk that the FDA may require additional clinical studies for Anaphylm and Libervant; risk of delays in or the failure to receive FDA approval of Anaphylm and Libervant, including for U.S. market access for Libervant; risk that a competing pediatric epilepsy product of Libervant will receive FDA approval prior to the Company's receipt of FDA approval of the Libervant NDA for these epilepsy patients aged between 2 and 5 years; risk relating to the unpredictability of the FDA's decisions regarding orphan drug exclusivity; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product should the FDA approve Libervant for U.S. market access for any age group of epilepsy patients; risk in obtaining market access for Libervant for other reasons, and there can be no assurance that the Company will be successful in obtaining any such approvals; 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 Libervant; 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.

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 October 9, 2023, providing Aquestive Therapeutics Business Update

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: October 9, 2023

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.

Title: Chief Financial Officer

(Principal Financial Officer)

Aquestive Therapeutics Provides Business Update

- *Receives positive feedback from FDA on pivotal study protocol for Anaphylm™ (epinephrine) Sublingual Film*
- *Reaffirms Q4 2023 Anaphylm pivotal phase 3 study start and Q1 2024 topline data readout*
- *Outlines expected remaining activities for Anaphylm program prior to NDA submission*
- *Indicates FDA review of Libervant™ (diazepam) Buccal Film on track with no open questions*
- *Anticipates increasing 2023 revenue and decreasing non-GAAP adjusted EBITDA loss guidance in upcoming earnings release*

WARREN, N.J., October 9, 2023 -- 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 a business update on its lead pipeline programs and base business results.

The Company recently received comments from the U.S. Food and Drug Administration (FDA) on its pivotal Phase 3 pharmacokinetic (PK) clinical study protocol for Anaphylm™ (epinephrine) Sublingual Film. Anaphylm is a polymer matrix-based epinephrine prodrug administered as a sublingual film that is applied under the tongue for the rapid delivery of epinephrine. Anaphylm comes in a highly portable package with the durability to withstand many of the norms of daily life.

In its comments, the FDA indicated that the Company's proposed endpoints, sample size, and statistical analysis are reasonable. As anticipated, the FDA also reminded the Company that PK sustainability post-dosing (30 – 60 minutes) is an important factor and recommended using repeat-dose data to support PK sustainability. The Company has incorporated the FDA's feedback into its upcoming studies and remains on track to start the pivotal Phase 3 study in Q4 2023. Table 1 below provides a list of anticipated clinical and regulatory activities to be completed prior to the planned New Drug Application (NDA) submission for Anaphylm in the second half of 2024.[1]

Anticipated Timing	Pivotal PK Studies	Supportive PK Studies	FDA Meetings / Actions
Q4 2023 – Q1 2024	Phase 3 PK Study	Temperature/pH PK Study	Type C Meeting[2]
	Repeat Dose PK Study		
Q2 2024 – Q3 2024	Pediatric PK Study	Self-administration PK Study	
		Sublingual Angioedema PK Study	
Pre-Submission			Pre-NDA Meeting

[1]Timeline does not include chemistry, manufacturing and controls (CMC), preclinical and human factors activities.
[2]Determination of whether a sublingual angioedema study is needed will occur in the Type C Meeting.

As previously announced, the Company's NDA for approval of Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients between two and five years of age was recently accepted for review by the FDA. Diastat® (diazepam) Rectal Gel is the only approved treatment currently available to this patient population for this indication. Based on the latest information available to the Company, the review for this NDA remains on track and there are currently no outstanding information requests from the FDA. The NDA for Libervant has a PDUFA assignment date of April 28, 2024.

In addition, the Company's base business continues to generate strong results. Based on preliminary Q3 results and binding supply purchase orders, the Company anticipates increasing current full year guidance on revenue and decreasing full-year guidance on non-GAAP-adjusted EBITDA loss. Updated guidance will be provided during the Company's third quarter earnings call in early November.

"We are pleased with the progress we have made in multiple areas of our business," stated Daniel Barber, Chief Executive Officer of Aquestive. "Our base business remains on track to have double-digit growth in 2023, we are on track to bring Libervant to pediatric patients under the age of 6, if approved by the FDA for U.S. market access, and we remain on track to launch Anaphylm in 2025, if approved by the FDA. We believe these advancements are important steps forward for the Company and for the patients who may benefit from our products."

About Anaphylm™
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 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 Libervant™
Libervant is a buccally, or inside of the cheek, administered film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern. Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products. The FDA has granted tentative approval for Libervant for the treatment of these epilepsy patients 12 years of age and older, with U.S. market access for Libervant for this age group of patients subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved drug scheduled to expire in January 2027. The NDA submitted for Libervant for epilepsy patients between two and five years of age is subject to FDA approval, including for U.S. market access, and has been given a PDUFA assignment date of April 28, 2024.

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
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 the filing of pivotal PK clinical trials and other supporting clinical studies for Anaphylm; regarding the Company's ability to provide sufficient data in its NDA submission to address the FDA's recent comments on the Company's proposed pivotal PK study protocol and the FDA's other concerns following the End-of-Phase 2 meeting with the FDA; regarding the Company's ability to commercialize Anaphylm in 2025; regarding the FDA's approval and related timing of the filing of the NDA for Libervant with the FDA for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy between two and five years of age; regarding the approval for U.S. market access of Libervant for these epilepsy patients aged 12 years and older, and overcoming the orphan drug market exclusivity of a

competing FDA approved nasal spray product extending to January 2027 for this age group of the patient population; regarding the potential benefits Anaphylm and Libervant could bring to patients; regarding the 2023 financial outlook of the Company and its growth and future financial and operating results and financial position; 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, Libervant 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 FDA's comments on the Company's pivotal PK study protocol and other concerns identified in the FDA End-of-Phase 2 meeting 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; risks that the FDA will not approve Libervant for U.S. market access by overcoming the seven year orphan drug market exclusivity of an FDA approved nasal spray product in effect until January 2027; risk of delays in or the failure to receive FDA approval of the NDA for Libervant for these epilepsy patients between two and five years of age, including the risk that the FDA may require additional clinical studies for approval of Libervant for this age group, and there can be no assurance that the Company will be successful in obtaining any of the foregoing FDA approvals for Anaphylm and Libervant, including for U.S. market access for Libervant; risk that a competing pediatric epilepsy product of Libervant will receive FDA approval prior to the Company's receipt of FDA approval of the Libervant NDA for these epilepsy patients aged between 2 and 5 years; risk relating to the unpredictability of the FDA's decisions regarding orphan drug exclusivity; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product should the FDA approve Libervant for U.S. market access for any age group of epilepsy patients; risk in obtaining market access for Libervant for other reasons; risks associated with the Company's development work, including any delays or changes to the timing, cost and success of the Company's product development activities; 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 our product candidates, including Anaphylm and Libervant; 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, Libervant and our other product candidates; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; risk of the success of any competing products; risk of eroding market share for Suboxone® and risk of 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, 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 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.

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