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): January 6, 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 January 6, 2023, Aquestive Therapeutics, Inc. (the "Company") issued a press release providing an update on recent business developments and outlining key 2023 objectives. 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 January 6, 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: January 23, 2023

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Exhibit 99.1

Aquestive Therapeutics Provides Business Update and Outlines Key 2023 Objectives

- *Anticipates commencing pivotal pharmacokinetic (PK) trial for AQST-109 (epinephrine sublingual film) in second half of 2023*
- *Anticipates receipt in the coming months of FDA response to request for Libervant™ (diazepam) Buccal Film accelerated market access*
- *Expects preliminary unaudited cash and cash equivalents of approximately $27 million as of December 31, 2022*

WARREN, N.J., January 6, 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 provided an update on recent business developments and outlined key 2023 objectives. In addition, Aquestive's Chief Executive Officer, Daniel Barber, and Chief Financial Officer, Ernie Toth, will host investor meetings from January 9 to 11, 2023 in San Francisco, concurrent with the 41st Annual J. P. Morgan Healthcare Conference.

"In 2023, we plan to focus our resources on the following key initiatives: (1) advancing AQST-109 into a pivotal PK study, (2) continuing to work with the FDA to potentially accelerate the market access for Libervant, (3) exploring new capabilities for our manufacturing business, (4) continuing to expand our base of strategic collaborations with other companies, and (5) strengthening our balance sheet," remarked Mr. Barber. "We are thankful for the collaborations that we have forged with a variety of global companies, including Indivior Inc., Zambon S.p.A., Otter Pharmaceuticals, LLC (a subsidiary of Assertio Holdings, Inc. ("Assertio"), Mitsubishi Tanabe Pharma America, Inc., Atnahs Pharma UK Limited (Pharmanovia), Haisco Pharmaceutical Group Co., Ltd., and Hypera S.A. It is worth highlighting that the majority of these collaborations were entered into over the last 24 months. We look forward to securing possible additional collaborations in 2023 as we continue to prioritize our alliance strategies to bringing innovative and, in some cases, life-saving medications to patients."

"This is a pivotal year for Aquestive as we seek to build upon our momentum from the second half of 2022. We have an experienced team that has not only driven multiple FDA approvals, but has also excelled at collaborating with leading life sciences companies. We will be focused on realizing our potential as we progress through the year," concluded Mr. Barber.

AQST-109 (epinephrine sublingual film)
In late December 2022, Aquestive received the final minutes from the End-of-Phase 2 (EOP2) meeting with the United States Food and Drug Administration (FDA) for AQST-109 (epinephrine sublingual film) for the treatment of severe allergic reactions including anaphylaxis, which provided clarity as to the FDA's expectations regarding key program areas. Aquestive is conducting additional analysis regarding the bracketing of PK performance of approved epinephrine products and plans to finalize its protocol for the pivotal PK trial in the first half of 2023. Aquestive anticipates conducting the pivotal PK study in the second half of 2023, and continues to plan for a potential launch in 2025, if approved by the FDA.

Libervant
The Company continues to actively pursue U.S. market access for Libervant™ (diazepam) Buccal Film. Libervant was tentatively approved by the FDA in August 2022, subject to an Orphan Drug Exclusivity block until January 2027 based on a competing product.

The Company provided the FDA with additional clinical data in September 2022 and has been informed that the FDA is reviewing this data. Furthermore, in October 2022, the Company provided the FDA with a draft protocol for a head-to-head comparative PK study of Libervant versus the competing product. This was followed by a publication of a crossover food effect PK study of diazepam nasal spray in the peer-reviewed scientific journal *Epilepsia* in late November 2022.

Commercial Collaborations and Manufacturing
The Company continues to anticipate strong order demand for the manufacture of Indivior's Suboxone® Sublingual Film in 2023. In addition, the Company is prepared to support the continued growth of Hypera's Ondif (ondansetron) Oral Film in Brazil, Zambon's upcoming launch of riluzole oral film in Europe, and the ongoing marketing efforts of Assertio with Sympazan® (clobazam) Oral Film.

Furthermore, the Company is currently exploring possible out-licensing opportunities for Libervant in several markets, including the U.S., China, and South America. The Company plans on exploring possible out-licensing opportunities for AQST-109 outside of the United States in 2023.

In 2022, the Company completed work to expand its manufacturing capabilities to include serialization and secondary packaging. This expansion allows the Company to support its existing and possible future business collaborations more broadly. With over 90,000 square feet of GMP facilities in Indiana, the Company will continue to explore possible additional manufacturing capabilities in 2023.

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 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. For more information, visit Aquestive.com and follow us on LinkedIn.

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 the advancement and related timing of our product candidate AQST-109 through clinical development and FDA approval, including the Company's ability to provide sufficient data in its NDA submission to address the FDA's concerns and the potential benefits AQST-109 could bring to patients, as well as the timing of a possible launch of AQST-109, if approved by the FDA; statements regarding the approval of Libervant by the FDA for U.S. market access and overcoming Orphan Drug Exclusivity of a competing product before January 2027; statements regarding the demand for the manufacture of Suboxone Sublingual Film; statements regarding the potential and related timing for expanding the Company's manufacturing capabilities and supporting the growth of demand for other existing and potential future licensed products in the U.S. and other countries; statements regarding potential outlicensing of AQST-109 outside of the U.S. and of Libervant in the U.S. and other countries; statements regarding entering into commercial transactions with other companies and the ability to provide innovative and life-saving medications to patients; statements regarding the Company's ability to strengthen its balance sheet and available cash and cash equivalents; 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 the Company's product development activities and clinical trials for AQST-109; risk of the Company's failure to generate sufficient data in its PK and pharmacodynamics (PD) comparability submission for FDA approval of AQST-109; risk of the Company's failure to address the concerns identified in the FDA EOP2 meeting for AQST-109; risk of delays in or the failure to receive FDA approval of AQST-109, including the risk that the FDA may require additional clinical studies for FDA approval of AQST-109; risks that the FDA will not approve Libervant for U.S. market access by overcoming the seven year Orphan Drug Exclusivity of a competing product, and there can be no assurance that the Company will be successful in obtaining such approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of our ability to out-license our proprietary products; 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; risk of failure to satisfy all financial and other debt covenants and of any default; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk that we are unable to refinance our current corporate debt on terms and conditions satisfactory to the Company, or not at all; 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 rate and degree of market acceptance of our licensed and product candidates; the success of any competing products, including generics; 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 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.

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