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 11, 2022

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 11, 2022, the Company issued a press release providing a business update in connection with the positive topline results from the final two arms of Part 3 of the EPIPHAST study for the Company's AQST-109 epinephrine oral film product candidate in clinical development. 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	Press Release dated July 11, 2022.

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 11, 2022

Aquestive Therapeutics, Inc.

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

Aquestive Therapeutics Reports Positive Results from Final Two Arms of EPIPHAST Trial Supporting Performance and Real-World Functionality of AQST-109 Epinephrine Oral Film

- Study results for the sublingual administration of AQST-109 epinephrine oral film after consuming a peanut butter sandwich demonstrates consistent Tmax of 12 minutes
- Study results for swallowing AQST-109 whole immediately with water showed an unexpectedly high level of gastrointestinal absorption
- EPIPHAST II, a crossover study, is now underway, comparing AQST-109 to epi 0.3mg IM injection (repeat dose) and AQST-109 to EpiPen® 0.3mg (single dose)

WARREN, N.J., July 11, 2022 (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 announced positive topline results from the final two arms of Part 3 of the EPIPHAST study for its AQST-109 epinephrine oral film.

The purpose of Part 3 was to continue to study the administration of the film under a variety of conditions to further characterize its pharmacokinetics, pharmacodynamics, and safety. The final two arms were designed to assess the impact of (1) administering the film sublingually two minutes after consuming a peanut butter sandwich and (2) swallowing the film whole immediately with water.

The data showed that administering the film sublingually two minutes after consuming a peanut butter sandwich had no statistical impact on the resulting pharmacokinetics when compared to previous data from the initial Part 3 dataset. The medium time to maximum concentration (Tmax) and partial area under the curve (AUC) results were comparable and the time to reach Tmax remained 12 minutes when sublingually administered after consumption of a peanut butter sandwich. The geometric mean maximum concentration, or Cmax of 286 pg/mL was also comparable to previous data from Part 3.

The data also showed that swallowing the film whole immediately with water unexpectedly resulted in significant absorption of epinephrine. This finding has the potential of further de-risking the development program by lowering the risks associated with patient non-compliance to the administration instructions in a real-world setting. The Cmax was 313 pg/mL and the Tmax, while slower than the sublingual administration was significantly faster than the epinephrine 0.3mg IM injection from Parts 1 and 2 of the EPIPHAST study.

"We are thrilled to conclude and share the data from Part 3 of the EPIPHAST study further demonstrating AQST-109's strong and differentiated pharmacokinetic performance under a variety of conditions which now includes dosing the sublingual film after eating a peanut butter sandwich and swallowing the film whole immediately with water," said Dan Barber, Chief Executive Officer of Aquestive. "It is very promising that AQST-109 continues to perform well in challenging and less than ideal circumstances, further validating performance and real-world functionality."

"Epinephrine is unquestionably the cornerstone of anaphylaxis management, yet studies have found that epinephrine is significantly underutilized during an anaphylactic emergency," said David Bernstein, M.D., Professor: Division of Immunology, Allergy and Rheumatology University of Cincinnati. "As an allergist who treats patients at risk for anaphylaxis, I have witnessed the underutilization of epinephrine to be based on a number of factors, including fear of needles or the patient simply not having an epinephrine auto-injector with them when they need it. I am pleased to see the accumulating, positive data on AQST-109. These latest results from the EPIPHAST trial continue to show that sublingual administration of epinephrine has the potential to deliver epinephrine in a safe and effective way and may also make it easier for patients to carry and more quickly administer the medicine during a life-threatening allergic event."

EPIPHAST was a randomized, open-label, three-part adaptive design, crossover study in healthy adult subjects comparing the pharmacokinetics and pharmacodynamics of epinephrine delivered via Aquestive's AQST-109 oral film compared to intramuscular injection of epinephrine. The study was being conducted pursuant to clearance from Health Canada.

Aquestive received a written response from the U.S. Food and Drug Administration (FDA) in December 2021 to its Pre-Investigational New Drug Application (IND) meeting submission confirming that the development of AQST-109 for the treatment of anaphylaxis under the 505(b)(2) approval pathway is acceptable. Aquestive opened the IND for AQST-109 after receiving FDA clearance in February 2022. AQST-109 met the regulatory criteria for Fast Track designation as announced in March 2022.

Aquestive is conducting its EPIHPHAST II study comparing AQST-109 to epi 0.3mg IM injection (repeat dose) and AQST-109 to EpiPen 0.3mg (single dose). This data, along with the data from the complete EPIPHAST study, will be the basis for the End-of-Phase 2 meeting with the FDA that the Company plans to request in the fourth quarter 2022.

About Anaphylaxis

Anaphylaxis is a serious systemic hypersensitivity reaction with rapid onset and potentially fatal. As many 49 million people in the United States are at chronic risk for acute anaphylactic episodes. Lifetime prevalence may be higher than 5%. Chronic allergic illness costs the US healthcare system more than $18 billion annually. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years. 52% of patients, who had previously experienced anaphylaxis, had never received an epinephrine autoinjector prescription, and 60% did not have an autoinjector currently available. The most common causes of reactions that can include anaphylaxis are medications, foods (such as peanuts), and venom from insect stings. Epinephrine injection is the current standard of treatment intended to reverse the potentially severe manifestation of anaphylaxis, which may include red 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 on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome. Our licensees market their products 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, or CNS, 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 AQST-109 through the regulatory and development pipeline and clinical and business strategies, market opportunities, 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 our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are based on our 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 our product development activities and clinical trials for AQST-109 and our other product candidates; risk of delays in FDA approval of AQST-109, Libervant™ (diazepam) Buccal Film and our other drug candidates or failure to receive FDA approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk in obtaining market access for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product 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; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings and associated costs, including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our 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 us or any person acting on our 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.

Investor Inquiries
ICR Westwicke
Stephanie Carrington
Stephanie.carrington@westwicke.com
646-277-1282