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): August 30, 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 August 31, 2022, the Company issued a press release announcing its receipt of a written notification from the U.S. Food and Drug Administration (FDA) providing tentative approval by the FDA for the Company's New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film, with U.S. market access for Libervant subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved drug. 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 August 31, 2022 announcing the Company's receipt of a written notification from the FDA providing tentative approval by the FDA for the Company's NDA for Libervant™ (diazepam) Buccal Film, with U.S. market access for Libervant subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved drug.

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: August 31, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Aquestive Therapeutics Receives FDA Tentative Approval for Libervant™ (diazepam) Buccal Film

- Libervant provided tentative approval from the FDA for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity
- Libervant U.S. Market Access currently subject to the expiration of Valtoco® orphan drug market exclusivity
- Company hosts conference call at 8:30 am ET on August 31, 2022

WARREN, N.J., Aug. 31, 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, announced today that the U.S. Food & Drug Administration (FDA) has granted tentative approval for Libervant™ (diazepam) Buccal Film 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 12 years of age and older.

"Tentative approval" means the FDA has concluded that Libervant has met all required quality, safety, and efficacy standards for approval but, due to an existing FDA regulatory grant of orphan drug market exclusivity for Valtoco®, a diazepam nasal spray product, Libervant is not yet eligible for marketing in the United States. As a result of the FDA determination, the Agency cannot give final approval for Libervant until the expiration or inapplicability of the orphan drug market exclusivity, including, for example, by court order, a selective waiver of the orphan drug exclusivity, or a reversal of the FDA's decision and determination that Libervant is "clinically superior" to Valtoco.

"The FDA's decision provides welcome clarity to our business," said Daniel Barber, Chief Executive Officer of Aquestive. "The tentative approval of Libervant is a significant achievement that brings us one step closer to bringing this important medicine to patients who are unable or choose not to use the current standards of care. Libervant has the potential to offer these patients a treatment option that is simple, portable, and precise. A significant unmet need exists for additional alternate delivery options given the ongoing shortage of diazepam rectal gel, which continues to represent a substantial portion of the current diazepam rescue market. This FDA action further validates our ability to gain FDA approval of our pipeline programs. We look forward to continuing the rapid progression of AQST-109 (epinephrine sublingual film) for the treatment of severe allergic reactions, including anaphylaxis, towards a filing with the FDA."

"We continue to examine the FDA's determination on Libervant market access and plan to request a meeting with the Agency as soon as possible. We disagree with the FDA's determination on the various points presented by the Agency and believe that, particularly in the case of our submitted studies on the effect of food on the absorption of diazepam formulations, Libervant has the distinct advantage of being able to be readily administered when needed without regard to food, providing an important benefit to patients. This is important to patients as rapid and extensive drug absorption is critical in a rescue situation. We will continue to vigorously engage with the FDA on the need for these data to be carefully considered."

During the review process, the Company submitted to the FDA the results of a 2021 Aquestive sponsored randomized, open-label, two-sequence, two-period, two-treatment crossover study to evaluate the effect of food on the pharmacokinetics of Valtoco in healthy adult subjects. The results of this study indicated that, when Valtoco is administered after a high fat meal, the maximum drug concentration (Cmax) was reduced by 48% compared to Valtoco administered to subjects in a fasted state. The study also showed that the time to maximum drug concentration (Tmax) of Valtoco doubled from 2 hours to 4 hours when administered after a high fat meal. Aquestive provided the data along with a cross-study comparison to a similar study performed with Libervant, to FDA during the review process.

The FDA's decision concluded that the information Aquestive submitted was not sufficient to overturn the Agency's previous conclusion regarding the lack of food effect for Valtoco. Specifically, the FDA stated that "[a] cross-study comparison is not considered [by the reviewer] to be a suitable approach for making a quantitative comparison of plasma concentrations between different products because of the lack of a common reference standard between the two studies." Aquestive will seek to gain alignment with the Agency on a reasonable path to appropriately characterize the food effect of Valtoco including potentially conducting a comparative study as indicated by the FDA.

Conference Call and Webcast

Aquestive will host a conference call on Wednesday, August 31, 2022 at 8:30 a.m. ET to discuss the FDA approval of Libervant. To participate in the conference call, please register here to obtain a local or toll-free phone number and your personal pin. There will also be a simultaneous, live webcast available on the Investors section of the Company's website at https://investors.aquestive.com/events-and-presentations. The webcast will be archived for 30 days.

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) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. 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. Approximately 1.0 million patients with epilepsy suffer from uncontrolled refractory seizures, approximately 85% of whom will not interact with the available treatments.

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 potential approval for U.S. market access of Libervant prior to the expiration of orphan drug market exclusivity of Valtoco®, statements regarding the Company's development activities and clinical trials for AQST-109, 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, risk that the FDA will not agree to grant U.S. market access for Libervant until the expiration of the orphan drug market exclusivity granted by the FDA to Valtoco®; 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 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
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