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): April 26, 2024

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 April 29, 2024, Aquestive Therapeutics, Inc. ("Aquestive" or the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) approved the Company's drug candidate 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 between 2 to 5 years of age. The Company also announced in the same press release that the Company's Anaphylm™ (epinephrine) Sublingual Film clinical development program remains on track to complete the remaining clinical studies required for the submission of the New Drug Application (NDA) for Anaphylm, which submission is planned for the end of 2024.

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 Company's ability to expand its distribution capabilities and related timing of any distribution expansion and access to patients for Libervant™ (diazepam) Buccal Film, regarding the advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including expected clinical studies and clinical study dates, the timing of the pre-NDA meeting and Aquestive's goal of filing an NDA for Anaphylm before the end of 2024, and the potential benefits Libervant and Anaphylm could bring to patients, 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 distribution work for Libervant, including any delays or changes to the timing, cost and success of its distribution activities and expansion of market access to patients for Libervant; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product for these pediatric epilepsy patients; risk 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 ability to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's pivotal PK study protocol and other concerns identified in the FDA Type C meeting minutes 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; 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 Libervant, Anaphylm and our other products and product candidates; 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 commercialization activities relating to Libervant and clinical development activities relating to Anaphylm; risk that our manufacturing capabilities will be insufficient to support demand for Libervant; risk of eroding market share for Suboxone® and risk as 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 (including the wars in Israel and Ukraine and other acts of war and terrorism), 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 10-K for the year ended December 31, 2023, 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 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.

Item 9.01 Financial Statements and Exhibits

(d)Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company issued on April 29, 2024

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: **April 29, 2024**

Aquestive Therapeutics, Inc.

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

Aquestive Therapeutics Receives U.S. FDA Approval and Market Access for Libervant™ (diazepam) Buccal Film in Pediatric Patients Ages 2 to 5 and Provides Update on Anaphylm™ (epinephrine) Sublingual Film

- *Libervant is the first and only FDA approved orally administered rescue product for the treatment of seizure clusters in patients ages 2 to 5*
- *Announces immediate availability of Libervant 5mg, 7.5mg, 10mg, 12.5mg, and 15mg for patients between 2 to 5 years of age*
- *Company track record now includes 4 FDA approvals since 2018*
- *Anaphylm program on track; NDA submission expected by the end of 2024*
- *Hosts conference call for investors on April 29 at 8:00 a.m. ET*

WARREN, N.J., April 29, 2024– Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive" or the "Company"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced the U.S. Food and Drug Administration (FDA) has approved 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 between 2 to 5 years of age.

"We are thrilled to have received FDA approval for Libervant™ in patients between the ages of two and five," said Daniel Barber, Chief Executive Officer of Aquestive. "Patients have been waiting years for Libervant, the first and only FDA approved orally-administered rescue product for the treatment of seizure clusters. Our first priority is to provide and maintain availability of Libervant to the intended patient population. I am pleased to announce that we are currently able to accept and fill non-Medicaid prescriptions. We expect to expand our distribution capabilities over the coming weeks and months. I am also pleased with our continued track record of success with the FDA. We respect the FDA's mission to protect public health and we will always seek to partner with the FDA wherever possible."

"Libervant provides a new way to deliver diazepam for the treatment of acute repetitive seizure emergencies in children aged two to five," said Michael Rogawski, M.D., Ph.D, distinguished professor of neurology and pharmacology, University of California, Davis, "The film is placed onto the buccal mucosa inside the cheek where it adheres firmly and dissolves quickly, delivering a consistent dose of diazepam. Studies show that the film is easy to administer and performs reliably in children as young as 2 years of age. Libervant is packaged in a compact foil pouch that is convenient to carry so that the treatment can be available wherever these children may be."

In 2023, over 55,000 prescriptions were filled for patients between the ages of 2 and 5. This was an increase of 10.8% over the previous year and an average increase of 9.3% over the last three years for this patient population. Over 90% of filled prescriptions in 2023 for this patient population were for diazepam rectal gel. Prescription writing for this indication is highly concentrated among pediatric epileptologists and pediatric neurologists.

The Company's Anaphylm™ (epinephrine) Sublingual Film clinical development program remains on track. The Company is currently in the clinic completing the remaining studies required for the submission of the New Drug Application (NDA) for Anaphylm, which is planned for the end of 2024. The Company will provide a more detailed update on Anaphylm at its upcoming first quarter 2024 earnings call on May 8, 2024.

Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Monday, April 29, 2024.

In order to participate, please register in advance **here** to obtain a local or toll-free phone number and your personal pin.

A live webcast of the call will be available on Aquestive's website: **FDA Approval for Libervant Investor Call.** 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, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age. 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 granted tentative approval in August 2022 for Libervant for 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 FDA approval for U.S. market access received in April 2024 for Libervant is for these epilepsy patients between two and five years of age.

Important Safety Information

Do not give Libervant™ to your child if your child is allergic to diazepam or any of the ingredients in Libervant or has an eye problem called acute narrow angle glaucoma.

What is the most important information I should know about Libervant?

- **Libervant is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.** Get emergency help right away if any of the following happens:
  - **shallow or slowed breathing,**
  - **breathing stops (which may lead to the heart stopping),**
  - **excessive sleepiness (sedation).**

  Do not allow your child to drive a motor vehicle, operate heavy machinery, or ride a bicycle until you know how taking Libervant with opioids affects your child.
- **Risk of abuse, misuse, and addiction.** Libervant is used in children 2 to 5 years of age. The unapproved use of Libervant has a risk for abuse, misuse, and addiction, which can lead to overdose and serious side effects including coma and death.
  - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including diazepam (the active ingredient in Libervant).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
    - **Your child can develop an addiction even if your child takes Libervant as prescribed by your child's healthcare provider.**
    - **Give Libervant exactly as your child's healthcare provider prescribed.**
    - Do not share Libervant with other people.
    - Keep Libervant in a safe place and away from children.
- **Physical dependence and withdrawal reactions. Libervant is intended for use if needed in order to treat higher than usual seizure activity. Benzodiazepines, including** Libervant, can cause physical dependence and withdrawal reactions, especially if used daily. Libervant is not intended for daily use.

- **Do not suddenly stop giving Libervant to your child without talking to your child's healthcare provider.** Stopping Libervant suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures that will not stop (status epilepticus), sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, homicidal thoughts, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child gets any of these symptoms.**
- **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning, or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
- Physical dependence is not the same as drug addiction. Your child's healthcare provider can tell you more about the differences between physical dependence and drug addiction.

- Do not give your child more Libervant than prescribed or give Libervant more often than prescribed.

Libervant can make your child sleepy or dizzy and can slow your child's thinking and motor skills.

- Do not allow your child to drive a motor vehicle, operate machinery, or ride a bicycle until you know how Libervant affects your child.
- Do not give other drugs that may make your child sleepy or dizzy while taking Libervant without first talking to your child's healthcare provider. When taken with drugs that cause sleepiness or dizziness, Libervant may make your child's sleepiness or dizziness much worse.

Like other antiepileptic medicines, Libervant may cause suicidal thoughts or actions in a small number of people, about 1 in 500.

- **Call a healthcare provider right away if your child has any of these symptoms, especially if they are new, worse, or worry you:**
  - thoughts about suicide or dying
  - new or worse depression
  - feeling agitated or restless
  - trouble sleeping (insomnia)
  - acting aggressive, being angry or violent
  - other unusual changes in behavior or mood
  - attempts to commit suicide
  - new or worse anxiety or irritability
  - an extreme increase in activity and talking (mania)
  - new or worse panic attacks
  - acting on dangerous impulses
- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your child's healthcare provider as scheduled.
- **Call your child's healthcare provider between visits as needed, especially if you are worried about symptoms.** Suicidal thoughts or actions can be caused by things other than medicines. If your child has suicidal thoughts or actions, your child's healthcare provider may check for other causes.

What are the possible side effects of Libervant?

- The most common side effects of Libervant are sleepiness and headache.
- These are not all the possible side effects of Libervant.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For more information about Libervant, talk to your doctor, and see Product Information: Medication Guide and Instructions For Use.

About Anaphylm
Anaphylm is a polymer matrix-based epinephrine prodrug candidate product in late-stage clinical development. 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 Therapeutics
Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. The Company is 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.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 Company's ability to expand its distribution capabilities and related timing of any distribution expansion and access to patients for Libervant, regarding the advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including expected clinical studies and clinical study dates, the timing of the pre-NDA meeting and Aquestive's goal of filing an NDA for Anaphylm before the end of 2024, and the potential benefits Libervant and Anaphylm could bring to pediatric patients aged 2 to 5.

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 distribution work for Libervant, including any delays or changes to the timing, cost and success of its distribution activities and expansion of market access to patients for Libervant; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product for these pediatric epilepsy patients; risk 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 ability to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's pivotal PK study protocol and other concerns identified in the FDA Type C meeting minutes 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; 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 Libervant, Anaphylm and our other products and product candidates; 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 commercialization activities relating to Libervant and clinical development activities relating to Anaphylm; risk that our manufacturing capabilities will be insufficient to support demand for Libervant; risk of eroding market share for Suboxone® and risk as 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 (including the wars in Israel and Ukraine and other acts of war and terrorism), 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 10-K for the year ended December 31, 2023, 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 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