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): February 25, 2021

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 February 25, 2021, Aquestive Therapeutics, Inc. (the "Company") issued a press release reaffirming its plans to resubmit its New Drug Application for its drug candidate Libervant™ around the end of the second quarter of 2021. 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 February 25, 2021.

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: February 25, 2021

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive Therapeutics Reaffirms Near-Term NDA Resubmission for Libervant™ (diazepam) Buccal Film Following FDA Feedback

- **Reaffirms plans to resubmit its New Drug Application (NDA) around the end of second quarter 2021**
- **Received additional feedback from FDA after completion of Type A meeting and submission of revised weight based dosing regimen**
- **Anticipates an FDA action date in 2021**

Warren, NJ, February 25, 2021 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, today announced that the Food and Drug Administration (FDA) has provided further guidance to Aquestive regarding the information to be included in the New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. The further guidance from the FDA addresses the revised weight-based dosing regimen, modeling and simulations data that Aquestive provided to the Agency in December 2020.

"We have a clear path to resubmitting our NDA for Libervant and expect to do so around the end of the second quarter of 2021. The Agency provided additional guidance and clarity regarding information and supporting analysis that should be included in our resubmission," said Keith Kendall, President and Chief Executive Officer of Aquestive. "We believe our focus on engaging in multiple communications with the FDA prior to resubmitting our application will ultimately result in a collaborative review process and we look forward to continuing our interactions with the FDA."

The FDA's written feedback provided direction on the FDA's expectations for the information and supporting analysis relating to the population pharmacokinetic model, which the Company will be working to provide in a form acceptable to the FDA. Aquestive is aligned with the FDA's expectations and will include the requested information in its upcoming resubmission of the NDA for Libervant. In addition, the FDA provided guidance on its expectations around the nature and format of safety data that should be included in the resubmission.

Aquestive received a Complete Response Letter (CRL) from the FDA on September 25, 2020 and subsequently completed a Type A meeting with the FDA in November of 2020. Based on the FDA's feedback at the Type A meeting, as well as this further guidance from the Agency, Aquestive continues to believe that no further clinical studies are necessary for the resubmission of the NDA for Libervant. Once resubmitted, Aquestive anticipates a six month review process.

About Libervant

Libervant™ is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for rapid treatment of acute uncontrolled seizures in selected, refractory patients with epilepsy on stable regimens of AEDs who require intermittent use of diazepam to control bouts of increased seizure activity. Aquestive is developing Libervant as an alternative to Diastat (diazepam rectal gel), the current standard of care rescue therapy for patients with refractory epilepsy which, as a rectal gel, is invasive, inconvenient, and difficult to administer. As a result, a large portion of the patient population does not receive adequate treatment or foregoes treatment altogether. The Company believes that Libervant will enable a larger share of these patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures.

About Aquestive Therapeutics
Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, Sympazan® (clobazam) oral film, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven capabilities for drug development and commercialization.

Forward-Looking Statements
Certain statements in this press release are "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 of Libervant through the FDA regulatory approval process for U.S. market access; that the FDA review process will be collaborative; that clinical trials will not be necessary to obtain approval from the FDA; 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. 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, the risk that the resubmission of the NDA for Libervant to the FDA will not be satisfactory; that unforeseen factors will delay the resubmission of the NDA for Libervant; the possibility that clinical trials will in fact be necessary to advance Libervant for FDA approval for U.S. market access; risks of delays in or failure to obtain FDA approval of Libervant; risks of the Company's ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the NDA for Libervant or subsequent communications with the FDA; 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 will obtain other market exclusivity with respect to our products; risks associated with the Company's development work, including any delays or changes to the timing; 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; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risks 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 Exchange Commission (SEC). 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.

PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

Investor inquiries:
Westwicke, an ICR Company
Stephanie Carrington
stephanie.carington@westwicke.com
646-277-1282