

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 19, 2021

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or
Organization)

001-38599
(Commission File Number)

82-3827296
(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))

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.

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

Item 8.01 Other Events.

On July 19, 2021, Aquestive Therapeutics, Inc. (the “Company”) issued a press release announcing the U.S. Food and Drug Administration has accepted for filing the resubmission of the New Drug Application for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated July 19, 2021, the U.S. Food and Drug Administration has accepted for filing the resubmission of the New Drug Application for Libervant™ (diazepam) Buccal Film for the management of seizure clusters.

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 19, 2021

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr.

Name: A. Ernest Toth, Jr.

Title: Chief Financial Officer
(Principal Financial Officer)

Aquestive Therapeutics Announces FDA Acceptance of New Drug Application (NDA) Resubmission for Libervant™ (diazepam) Buccal Film

- Prescription Drug User Fee Act (PDUFA) Target Goal Date set for December 23, 2021
- If approved by the FDA for U.S. market access, Libervant would be the first orally delivered diazepam product for the management of seizure clusters

WARREN, N.J., July 19, 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, announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the resubmission of the New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") target goal date of December 23, 2021.

"We are pleased with the FDA's decision to accept for review the Libervant NDA. We believe this underscores the unmet need in the underserved population of refractory epilepsy patients for a non-invasive and innovative product for the management of seizure clusters," stated Keith Kendall, Chief Executive Officer of Aquestive. "We are preparing for the commercial launch of Libervant, if approved for U.S. market access, in the first half of 2022 and remain committed to fill this unmet need and improve the quality of life for patients suffering from this disease with this first of its kind treatment option."

Aquestive received a Complete Response Letter (CRL) from the FDA in September 2020, completed a Type A meeting with the FDA in November 2020 and received further guidance from the FDA in February 2021. Based upon the Agency's guidance, the submission included additional statistical modeling and supporting analyses of the existing clinical data. The Company continues to believe that no additional clinical studies will be required for FDA approval of Libervant for U.S. market access.

About Libervant

The Company believes that Libervant, if approved by the FDA for U.S. market access, will enable a larger share of patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. 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.

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 Statement

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, 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, including our belief that the resubmitted NDA addresses all of the issues raised in the CRL, through the regulatory and development pipeline 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; risk of delays in FDA approval of Libervant or failure to receive approval or U.S. market access; ability to address the concerns identified in the FDA’s CRL 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 Libervant 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 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; our and our competitors’ orphan drug approval and resulting drug exclusivity for our products or products of our competitors; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; 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, 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 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
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