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 10, 2020

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 7.01 Regulation FD Disclosure.

On February 10, 2020, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing the U.S. Food and Drug Administration (FDA) filing acceptance of the Company's New Drug Application (NDA) for Libervant ™ (diazepam) Buccal Film for the management of seizure clusters. A copy of such press release is attached as Exhibit 99.1 to this report and incorporated into this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated February 10, 2020, announcing that the U.S. Food and Drug Administration accepted the Company's New Drug Application filing for Libervant ™ (diazepam) Buccal Film.

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 10, 2020

Aquestive Therapeutics, Inc.

By: /s/ John T. Maxwell
Name: John T. Maxwell
Title: Chief Financial Officer

Exhibit 99.1

Aquestive Therapeutics Announces U.S. Food and Drug Administration Filing Acceptance of New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film

- **FDA Acceptance of Libervant ™ (diazepam) Buccal Film NDA for Management of Seizure Clusters**
- **Potential for First Oral Diazepam-Based Therapy for Population of 1.2 million Refractory Epilepsy Patients**
- **Assigned Prescription Drug User Fee Act (PDUFA) Goal Date of September 27, 2020**

Warren, NJ, February 10, 2020 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, announced today that, as anticipated, the U.S. Food and Drug Administration (FDA) accepted the Company's 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) goal date of September 27, 2020. If approved by the FDA, Libervant will be the first oral diazepam-based therapy approved for management of seizure clusters in the population of 1.2 million refractory epilepsy patients. Libervant was designated by the FDA as an orphan drug in November 2016.

"The FDA filing acceptance for Libervant is an important milestone in our mission to provide epilepsy patients with a broader array of treatment options, that represent major contributions to patient care," said Keith J. Kendall, Chief Executive Officer of Aquestive. "Aquestive is committed to helping people affected by seizure clusters through bringing important and innovative products to the market. Epilepsy patients have been underserved for some time with little choice beyond device-based products such as rectally administered gels and nasal sprays. We believe that our drug candidate Libervant will, if approved by the FDA, represent a major contribution to patient care, as compared to available treatment options, and further expand patient choice as the first orally administered dosage form available to manage seizure clusters in epilepsy patients."

"The FDA has recently indicated that, when evaluating clinical superiority for drugs demonstrating a 'major contribution to patient care,' it may consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration," continued Mr. Kendall. "We look forward to working with the FDA in the coming months in seeking to demonstrate why we believe that our product candidate Libervant, as an orally delivered product for this indication, has one or more of the attributes required by the FDA to be considered a major contribution to patient care relative to the currently approved products."

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. It is anticipated 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.

The NDA submission was supported by data from Aquestive's single dose crossover study that was recently featured as a late breaker session at the American Epilepsy Society (AES) 2019 Annual Meeting and expanded upon by key opinion leaders at its investor and analyst forum held on December 9, 2019. This study demonstrated that Libervant provided similar systemic diazepam exposures to the reference drug and exhibited significantly less variability. The study supports the use of Libervant as an easily-administered treatment for patients with epilepsy experiencing seizure emergencies. A replay of this forum is available at https://investors.aquestive.com/events-and-presentations.

In a recent decision, the FDA's Center for Drug Evaluation and Research granted marketing exclusivity for seven years to another drug approved for the labeled indication of 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 six years of age and older. Although we cannot be assured of the FDA's approval of Libervant or finding that Libervant represents a "major contribution to patient care" to overcome this market exclusivity, Aquestive remains committed to helping people affected by seizure clusters by looking to bring important innovative products to the market that will improve the lives of patients. See below for a further explanation of the FDA's criteria for determining "major contribution to patient care" in "Additional Information Regarding Orphan Drug Exclusivity."

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. Aquestive is advancing a late-stage proprietary product pipeline to treat CNS conditions and 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. 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 may include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of Libervant and our other product candidates; ability to obtain FDA approval and advance Libervant and our other product candidates to the market; statements about our growth and future financial and operating results and financial position, regulatory approval and pathways, clinical trial timing and plans, 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, business strategies, market opportunities, and other statements that are not historical facts.

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 and plans; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as the orphan drug product for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks our product in the U.S. for seven years for the same indication; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of FDA regulations of our drug candidate Libervant relative to the FDA-approved Valtoco® (diazepam nasal spray) and Diastat® (diazepam rectal gel) including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved product and there can be no assurance that we will be successful; 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 legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; 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; 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 associated with Indivior's announcement of its intention to cease production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risk 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 action 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 governmental 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 risks and uncertainties affecting the Company including those described in the "Risk Factors" section and

in other sections included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019, in our quarterly reports on Form 10-Q, and in the Form 8-K filed on January 13, 2020. Given these 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.

Additional Information Regarding Orphan Drug Exclusivity

The FDA's response to the Company's Citizen's Petition dated November 1, 2019 includes the following in discussing orphan drug exclusivity, including pertinent factors that may be considered by the FDA in making a determination of "major contribution to patient care" for "clinical superiority" as: convenient treatment location; duration of treatment; patient comfort; reduced treatment burden; advances in ease and comfort of drug administration; longer periods between doses; and potential for self-administration:

Section 527 of the [Federal Food, Drug, and Cosmetic Act] defines "clinically superior" to mean "the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care." The orphan-drug regulations elaborate on the definition of "clinically superior" as follows:

Clinically superior means that a drug is shown to provide a significant therapeutic advantage over and above that provided by an approved drug (that is otherwise the same drug) in one or more of the following ways:

Greater effectiveness than an approved drug (as assessed by effect on a clinically meaningful endpoint in adequate and well controlled clinical trials). Generally, this would represent the same kind of evidence needed to support a comparative effectiveness claim for two different drugs; in most cases, direct comparative clinical trials would be necessary; or

Greater safety in a substantial portion of the target populations, for example, by the elimination of an ingredient or contaminant that is associated with relatively frequent adverse effects. In some cases, direct comparative clinical trials will be necessary; or

In unusual cases, where neither greater safety nor greater effectiveness has been shown, a demonstration that the drug otherwise makes a major contribution to patient care.

Because of the diverse ways in which drugs may qualify as clinically superior under these criteria, FDA evaluates clinical superiority on a case by case basis. Specifically, with respect to the major contribution to patient care prong of the clinical superiority definition, the FDA has further stated:

> There is no way to quantify such superiority in a general way. The amount and kind of superiority needed would vary depending on many factors, including the nature and severity of the disease or condition, the quality of the evidence presented, and diverse other factors;
> and
> The following factors, when applicable to severe or life-threatening diseases, may in appropriate cases be taken into consideration when determining whether a drug makes a major contribution to patient care: convenient treatment location; duration of treatment; patient comfort; reduced treatment burden; advances in ease and comfort of drug administration; longer periods between doses; and potential for self-administration.

Media Inquiries:
Mark Corbae
mark.corbae@icrinc.com
858.213.7956

Investor Inquiries:
Stephanie Carrington
stephanie.carrington@icrinc.com
646-277-1282