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 6, 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 6, 2020, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing that the FDA confirmed a 505(b)(2) pathway for the Company's candidate product, AQST-108 (Sublingual Film Formulation Delivering Systemic Epinephrine) that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies. 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 6, 2020, announcing that the FDA confirmed a 505(b)(2) pathway for the Company's candidate product, AQST-108 (Sublingual Film Formulation Delivering Systemic Epinephrine) for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies.

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 6, 2020

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive Therapeutics Announces FDA Confirmed 505(b)(2) Pathway for AQST-108 (Sublingual Film Formulation Delivering Systemic Epinephrine) for Anaphylaxis Treatment

- Pre-IND Meeting on AQST-108 Completed
- FDA Confirmed AQST-108 To Be Reviewed Under 505(b)(2)
- No Additional Clinical Studies Would Be Required Prior to Opening Proposed IND
- Pivotal Pharmacokinetic (PK) Clinical Trials Planned To Be Initiated Before Year End 2020

Warren, NJ, February 6, 2020 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products that meet patients' unmet needs and solve therapeutic problems, announced today that it had a constructive face-to-face pre-Investigational New Drug (IND) Application meeting with the U.S. Food and Drug Administration (FDA) for its drug candidate, AQST-108, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies.

A pre-IND meeting provides an opportunity for an open communication between a drug sponsor and the FDA to discuss the sponsor's IND development plan and to obtain the agency's guidance for clinical studies for the sponsor's new drug candidate. The FDA has confirmed that the clinical development for AQST-108 will be reviewed under the 505(b)(2) pathway as proposed by Aquestive and that no additional studies would be necessary prior to opening the proposed IND Application. The FDA indicated that there appears to be an unmet medical need among patients who resist the standard of care use of intramuscular injection in the treatment of anaphylaxis and that AQST-108 may potentially address some of those unmet needs. Aquestive plans to move forward with opening an IND and initiating its pivotal pharmacokinetic (PK) clinical trials before the end of 2020.

"We are very pleased with the outcome of the pre-IND meeting with the FDA. We look forward to preparing the IND filing and commencing our pivotal PK study before year end," said Keith J. Kendall, Chief Executive Officer of Aquestive. "Anaphylaxis is a serious condition that impacts a large patient population for which there is a significant unmet need. The only options currently available to patients require an injection and AQST-108 can potentially bring meaningful innovation and positive change for patients. We are focused on providing the first highly portable, easy-to-administer and anxiety-free sublingual film medication to treat this serious condition."

About AQST-108
AQST-108 is a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies.

The data from the previously completed Phase 1 dose escalation study demonstrated that AQST-108 achieved similar ranges of mean values of maximum concentration (Cmax) and time to reach maximum concentration (Tmax) to that reported for injectables EpiPen® and Auvi-Q®, provided a greater total exposure (AUC0-t; area under the curve) than that reported for EpiPen and Auvi-Q, had less interpatient variability when compared to degree of variation (CV%) data reported for EpiPen and Auvi-Q, and was well tolerated, with no study participants discontinuing participation due to an adverse event.

Anaphylaxis is a potentially life-threatening systemic allergic reaction, with an estimated incidence of 50 to 112 episodes per 100,000 people per year. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years.[1] The most common causes of reactions that can include anaphylaxis are medications, foods (such as peanuts), and venom from insect stings. Epinephrine injection is the current standard of treatment intended to reverse the potentially severe manifestation of anaphylaxis, which may include red rash, throat swelling, respiratory problems, gastrointestinal distress and loss of consciousness.

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 the Company’s product candidates; ability to obtain FDA approval and advance our 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.

[1] Epidemiology of anaphylaxis. Tejedor Alonso MA, Moro Moro M, Mugica Garcia MC, Clin Exp Allergy. 45(6):1027-39, Jun 2015

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 our drug candidate Libervant® (diazepam) Buccal Film 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 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.

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