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): August 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 August 10, 2020, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing that it had received U.S. Food and Drug Administration (FDA) Fast Track designation for the Company's drug candidate AQST-108, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of allergic reactions (Type 1), including anaphylaxis, using Aquestive's proprietary PharmFilm® technologies. A copy of the Company's press release is attached hereto as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 August 10, 2020, announcing the Company's receipt of FDA Fast Track designation for the Company's drug candidate AQST-108, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of allergic reactions (Type 1), including 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: August 10, 2020

Aquestive Therapeutics, Inc.

By: /s/ John T. Maxwell

Name: John T. Maxwell
Title: Chief Financial Officer

Exhibit 99.1

Aquestive Therapeutics Receives FDA Fast Track Designation for AQST-108 (Sublingual Film Formulation Delivering Systemic Epinephrine) for Treatment of Allergic Reactions Including Anaphylaxis

- Finalizing preparations for pharmacokinetic (PK) clinical trials of AQST-108
- First planned PK clinical trial expected to begin during the third quarter of 2020

Warren, NJ, August 10, 2020 – 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 granted Fast Track designation for the Company's drug candidate AQST-108, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of allergic reactions (Type 1), including anaphylaxis, using Aquestive's proprietary PharmFilm® technologies.

Fast Track is an FDA process designed to facilitate the development and expedite the review of therapies to treat serious conditions and fill unmet medical needs. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, eligibility for FDA accelerated approval and priority review, if relevant criteria are met, in addition to a rolling submission of the marketing application.

Aquestive received confirmation from the FDA in July 2020 that the agency completed its safety review of its IND and concluded that the Company could proceed with the first planned PK clinical trials of AQST-108. As such, the Company expects to commence its first PK clinical trial utilizing a four-treatment crossover design to compare the pharmacokinetics and pharmacodynamics of AQST-108 to that of epinephrine administered as subcutaneous and intramuscular injections before the end of the third quarter of 2020.

"Fast Track designation confirms the unmet medical need for patients who are at risk for allergic reactions including anaphylaxis but reluctant and hesitant to use the standard of care, subcutaneous and intramuscular injections. We believe that AQST-108, a highly portable, easy-to-administer sublingual film formulation delivering systemic epinephrine, satisfies this unmet medical need for this large underserved patient population," said Keith J. Kendall, Chief Executive Officer of Aquestive. "Our first planned PK clinical trial will begin this quarter."

About AQST-108

AQST-108 is a "first of its kind" oral sublingual film formulation delivering systemic epinephrine for the treatment of allergic reactions (Type 1), including anaphylaxis, using Aquestive's proprietary PharmFilm® technologies. 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 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.

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

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 include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of AQST-108, Libervant™ and our other product candidates; ability to obtain FDA approval and advance AQST-108, 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 also 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 and plans; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of our drug candidate 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 inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks and uncertainties concerning any potential monetization of royalty and other revenue stream of KYNMOBI (apomorphine) and of sufficiency of net proceeds of any such monetization after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable; 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; risk associated with Indivior’s cessation of 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 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® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

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