

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): December 13, 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))

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 December 13, 2021, the Company issued a press release announcing its receipt of a written response from the U.S. Food and Drug Administration with respect to the Company's pre-investigational new drug (pre-IND) submission for the Company's drug candidate, AQST-109 (epinephrine prodrug sublingual film) and the commencement of its Pharmacokinetic and Safety Trial for AQST-109. 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 December 13, 2021 announcing receipt of FDA response regarding Pre-IND submission and commencement of PK and Safety Trial for AQST-109 (epinephrine prodrug sublingual 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: December 16, 2021

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr
Name: A. Ernest Toth, Jr.
Title: Chief Financial Officer
(Principal Financial Officer)



Source: Aquestive Therapeutics, Inc.

December 13, 2021 08:00 ET

Aquestive Therapeutics Receives Written Response to Pre-IND Submission for AQST-109 (epinephrine prodrug sublingual film) and Begins Recruitment for its Epinephrine Film Pharmacokinetic and Safety Trial (EPIPHAST)

- *FDA confirms 505(b)(2) pathway is acceptable for the development of AQST-109*
- *FDA indicates AQST-109 has the potential for Fast Track designation*
- *Health Canada provides clearance to commence the adaptive design crossover study*

WARREN, N.J., Dec. 13, 2021 (GLOBE NEWSWIRE) -- 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 reported that it has received a written response from FDA to its pre-investigational new drug (pre-IND) meeting submission confirming that the development of AQST-109 for the treatment of anaphylaxis under the 505(b)(2) pathway is acceptable.

The FDA's written response to Aquestive indicates that, pending review, Aquestive has performed sufficient clinical and nonclinical activity to support the opening of an Investigational New Drug (IND) application for AQST-109. In addition, the FDA provided comments on both Aquestive's toxicology plan and clinical development plan. The FDA confirmed its agreement that (i) the 505(b)2 pathway is appropriate for the development of AQST-109 and (ii) AQST-109 has the potential to meet the regulatory criteria for Fast Track designation. Aquestive plans to file its IND for AQST-109 early in the first quarter 2022.

In addition, Health Canada has provided clearance for Aquestive's crossover study, known as the EPIPHAST study, of AQST-109. Patient recruitment has begun and the Company expects the first dosing to occur before the end of the year. The EPIPHAST study is a randomized, open-label, three-part adaptive design, crossover study intended to compare the pharmacokinetics and pharmacodynamics of epinephrine following administration of AQST-109 and epinephrine administered as intramuscular injection in healthy adult subjects. This study will be used to determine the final product configuration that will be used to manufacture registration batches and conduct pivotal studies planned for the second half of 2022.

"We are pleased with the FDA's responses to our Pre-IND meeting request," said Keith Kendall, Chief Executive Officer of Aquestive. "We believe the FDA's responses confirm our development plan and we will move to file our IND and have AQST-109 designated Fast Track as soon as practical. At the same time, we are pleased to announce that enrollment has begun in our EPIPHAST study. These updates, along with our upcoming PDUFA target goal date of December 23, 2021 for Libervant™ (diazepam) Buccal Film, make this an exciting time for Aquestive."

About Anaphylaxis

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. 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 AQST-109

AQST-109 is a polymer matrix-based film that can be applied sublingually (under the tongue) for the rapid delivery of epinephrine. The product is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The packaging for AQST-109 is thinner and smaller than an average credit card, can be carried in a pocket, and is designed to withstand weather excursions such as exposure to rain and/or sunlight.

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

Certain statements in this press release include “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 and related timing of AQST-109 through the regulatory and development pipeline, the advancement of Libervant through FDA approval, and clinical 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 for AQST-109 and our other product candidates; risk of delays in FDA approval of AQST-109, Libervant and our other drug candidates or failure to receive FDA approval; ability to address the concerns identified in the FDA’s Complete Response Letter dated September 25, 2020 regarding the New Drug Application 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 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 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 liquidity and cash requirements and other cash needs, at the times and in the amounts needed; 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. 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.



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