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 2, 2024

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or other jurisdiction of incorporation)	**(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 December 2, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing receipt of positive feedback from the U.S. food and Drug Administration prior to its New Drug Application (NDA) submission for Anaphylm™ (epinephrine) Sublingual Film and reaffirmed NDA submission guidance in the first quarter of 2025. A copy of the press release is filed as Exhibit 99.1 hereto 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 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 8.01 Other Events.

The Company is planning to present certain supplemental materials (the "Supplemental Materials") in meetings with institutional investors, analysts and others. A copy of the Supplemental Materials is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d)Exhibits.

Exhibit Number	Description
99.1	Aquestive Therapeutics, Inc. Press Release, dated December 2, 2024
99.2	Anaphylm™ (epinephrine) Sublingual Film Pre-NDA Meeting Supplemental Materials, dated December 2024

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 2, 2024**

Aquestive Therapeutics, Inc.

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

Aquestive Therapeutics Announces Positive FDA Feedback and Reaffirms NDA Submission Guidance for Anaphylm™ (epinephrine) Sublingual Film

- *Reaffirms New Drug Application (NDA) first quarter 2025 submission guidance*
- *Confirms no additional adult clinical trials are necessary prior to NDA submission*
- *Commenced pediatric trial in the U.S. and Canada*

WARREN, N.J., December 2, 2024 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies ("Aquestive," the "Company" or "we"), today announced receipt of positive feedback from the U.S. Food and Drug Administration (FDA) prior to its planned NDA submission for Anaphylm™ (epinephrine) Sublingual Film. Anaphylm has the potential to be the first and only orally delivered epinephrine product for the treatment of severe allergic reactions, including anaphylaxis, if approved by the FDA.

"We believe FDA alignment on the completeness of our adult development program for Anaphylm is a major milestone for the Company and the allergy community," said Daniel Barber, President and Chief Executive Officer of Aquestive. "We have commenced our single-dose pediatric trial in December 2024, and we believe we have a clear path to an NDA submission in the first quarter of 2025. Currently, the estimated 33 million Americans with food allergies only have the option of carrying epinephrine medical devices. Our engagement with the allergy community continues to inform us that bringing the first and only orally delivered epinephrine product for anaphylaxis to market can potentially be transformative for patients. This patient community deserves continued innovation that creates easy-to-carry, easy-to-administer alternatives to today's approved medical devices."

In a written response, the FDA agreed with the Company's planned NDA content and format for the submission, planned safety evaluation, and planned pediatric trial, which has commenced at both U.S. and Canadian sites. The FDA also provided further guidance on additional data views to be included in the planned NDA submission and continued to emphasize their focus on pharmacokinetic sustainability for a single dose. In addition, the FDA requested minor modifications to the Company's pediatric trial protocol. We have incorporated these FDA requested changes in the final pediatric trial protocol and do not expect these changes to have any significant impact on the planned timing of the pediatric trial. Finally, the FDA noted that due to the new route of administration and the data supporting this route of administration, an advisory committee meeting may be necessary. Further details regarding the FDA's comments are available on the Events and Presentation section of the Investor page on the Aquestive website.

About Anaphylm™ (epinephrine) Sublingual Film
Anaphylm™ (epinephrine) Sublingual Film is a polymer matrix-based epinephrine prodrug product candidate. Anaphylm 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 Anaphylm 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. The Anaphylm trade name for AQST-109 has been conditionally approved by the FDA. Final

approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

About Aquestive Therapeutics
Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products marketed by the Company and its licensees in the U.S. and around the world, and is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product candidate for the treatment of severe allergic reactions, including anaphylaxis, and an earlier stage epinephrine prodrug topical gel for various possible dermatology conditions. For more information, visit Aquestive.com and follow us on LinkedIn.

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," "may," 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 our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of submission of a pediatric clinical trial and NDA for Anaphylm with the FDA, and the anticipated launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; the potential indications and potential benefits our products and product candidates could bring to patients; and 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 our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm (including for pediatric patients); risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, including for Anaphylm, or the failure to receive FDA approval at all of any of these product candidates; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our pharmacokinetic and pharmacodynamic comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's clinical trials and other guidance including those identified in the FDA Type C meeting minutes and pre-NDA minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of the success of any competing products; risks and uncertainties inherent in commercializing a new product (including technology risks, financial

risks, market risks and implementation risks and regulatory limitations); risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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, including to fund commercialization activities relating to fund future clinical development and commercial activities for our product candidates, including Anaphylm, should these product candidates be approved by the FDA; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of default of our debt instruments; 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 in the U.S. of Anaphylm and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of 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 our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; risks related to the impact of any global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K as of and for the year ended December 31, 2023, subsequent Quarterly Reports on Form 10-Q, and subsequent Current Reports on Form 8-K filed with the U.S. Securities and 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 the Company or any person acting on its 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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Aquestive®

Anaphylm™ Pre-NDA Meeting Supplemental Material

December 2, 2024

Disclaimer

This presentation has been prepared by Aquestive Therapeutics, Inc. ("Aquestive", the "Company", "our" or "us") and contains 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 our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the U.S. Food and Drug Administration (FDA) 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 our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm (including for pediatric patients); risk of the Company's ability to generate sufficient clinical data for approval of our Anaphylm product candidate, including with respect to our PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's future clinical trials and other guidance identified in the FDA Type C meeting minutes and pre-New Drug Application (NDA) meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of the success of any competing products; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of Anaphylm; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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, including to fund future clinical development and commercial activities for Anaphylm; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of default of our debt instruments; 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 in the U.S. and abroad of Anaphylm, if approved by the FDA; risk of 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 our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office (PTO); risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 2023 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and 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 the Company or any person acting on its 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 presentation whether as a result of new information, future events or otherwise, except as may be required by applicable law.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

The Aquestive logo is a registered trademark of Aquestive Therapeutics, Inc. and has been conditionally approved by the FDA. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate, AQST-109. All other registered trademarks referenced herein are the property of their respective owners.

Anaphlym Briefing Book Highlights

- Aquestive highlighted the continued unmet need for a non-device based medical product for the treatment of severe allergic reactions, including anaphylaxis
- Aquestive provided an overview of all studies to date including pharmacokinetic (PK), pharmacodynamic (PD), and safety analysis
- Aquestive provided a section focused on our OASIS study results
- The Company provided a section focused on single-dose PK sustainability
- Aquestive provided a section focused on repeat-dose PK Cmax levels and safety

Anaphlym Pre-NDA Questions

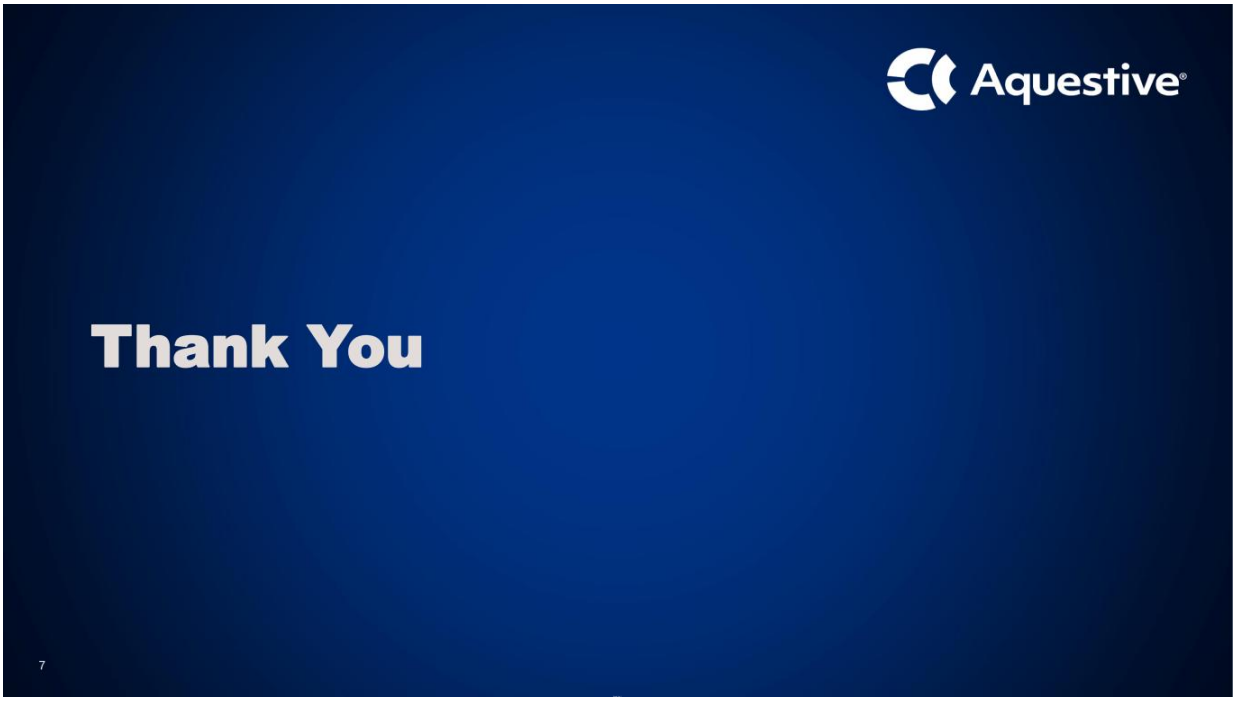
Aquestive Briefing Book Questions to FDA	FDA response
Does the Agency consider the Sponsor's planned safety evaluation reasonable for the Anaphylm NDA?	FDA agreed. The FDA recommended a few updates to the proposed data groupings. Aquestive views none of these updates as material.
Does the Agency agree that the text portion of the Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy can serve as Module 2.7.4, Summary of Clinical Safety and Module 2.7.3, Summary of Clinical Effectiveness, respectively, with the tables, figures, and datasets in Module 5.3.5?	FDA agreed.
Does the Agency agree with the Sponsor's proposed content and safety cut-off date for the 120-safety update?	FDA agreed.
Does the Agency agree with the Sponsor's plan to initiate the pediatric PK/PD Study AQ109302?	FDA agreed. Additional FDA statement: "We do not have safety concerns regarding initiation of pediatric studies."
Does the Agency agree with the Sponsor's approach in demonstrating single-dose sustainability in the planned Anaphylm NDA?	FDA noted that the Company's "justifications provide valuable evidence" and reiterated that "the adequacy of the data to support PK sustainability after a single dose will be a review issue." The Agency further recommended that we provide "a comparison of the epinephrine repeat-dose PK profile from DESF to the single dose PK profile from epinephrine injection products as additional justification in your future submission."
Does the Agency agree with the Sponsor's planned content and format of the Anaphylm NDA?	FDA agreed.

Additional FDA Comments

Additional Unsolicited FDA Comments	Aquestive viewpoint
FDA noted that the non-allergen exposure arm for Anaphylm in the OASIS allergen challenge study was lower than the allergen exposure arm. FDA also noted that all treatment arms in the self-administration study were at similar levels to the lower arm in the OASIS study. FDA stated that this will be a review issue and recommended Aquestive provide justification for these lower values in the NDA.	Justification will be provided in the NDA. Regarding self-administration, data levels were consistent across Anaphylm and injectable epinephrine.
FDA requested more analysis in the NDA from the pH and temperatures conditions studies and the potential role of water consumption.	The requested data analysis is available and will be included in the NDA.
FDA requested more information regarding the bioanalytical methods used across studies.	The requested data is available and will be included in the NDA.
The FDA indicated comments on Aquestive's human factors validation study plan and protocols are "forthcoming."	As expected, planned human factors validation work remains on schedule.
The FDA recommended that Aquestive provide a comparison of epinephrine PK profiles by clinical batch for Anaphylm as well as the injection products.	The requested data is available and will be included in the NDA.

Advisory Committee Guidance

FDA Comment	Aquestive viewpoint
FDA noted that due to the new route of administration and the data supporting this route of administration, an advisory committee meeting "may be necessary."	Aquestive welcomes the opportunity to present its data at an advisory committee meeting (anticipated to occur 2-3 months before a scheduled PDUFA action date).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Thank You
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