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): October 25, 2024

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 8.01 Other Events.

On October 25, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing a subsequent analysis of the data from the pivotal study of its product candidate Anaphylm™ (epinephrine) Sublingual Film demonstrating comparable PK and PD data regardless of variable placement or intraoral movement will be presented at the American College of Allergy Asthma and Immunology (ACAAI) annual meeting, which is being held from October 24-28 in Boston, Massachusetts. The press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

On October 25, 2024, the Company presented an abstract and poster titled "Sublingual Epinephrine Film's Mucoadhesive Properties Ensures Consistent Oral Placement and Drug Release" at the ACAAI annual meeting. A copy of the abstract is filed as Exhibit 99.2 and a copy of the poster is filed as Exhibit 99.3 hereto and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated October 25, 2024.
99.2	Sublingual Epinephrine Film's Mucoadhesive Properties Ensures Consistent Oral Placement and Drug Release Abstract
99.3	Sublingual Epinephrine Film's Mucoadhesive Properties Ensures Consistent Oral Placement and Drug Release Poster

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: **October 25, 2024**

Aquestive Therapeutics, Inc.

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

Aquestive Therapeutics to Present Subsequent Analysis of Pivotal Study for Anaphylm™ (epinephrine) Sublingual Film Demonstrating Comparable PK and PD Data to Epinephrine Injection Regardless of Variable Placement or Intraoral Movement at American College of Allergy Asthma and Immunology (ACAAI) 2024 Annual Meeting

- Initial placement or subsequent movement of Anaphylm showed no impact on epinephrine pharmacokinetics (PK) or pharmacodynamics (PD), with all results comparable to epinephrine injection
- Data demonstrates Anaphylm offers a consistent and permissive method of drug delivery in anaphylaxis management

WARREN, N.J., October 25, 2024 -- Aquestive Therapeutics, Inc. (NASDAQ:AQST) ("Aquestive" or the "Company"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced that a subsequent analysis of the data from the pivotal study of its product candidate Anaphylm™ (epinephrine) Sublingual Film demonstrating comparable PK and PD data regardless of variable placement or intraoral movement will be presented at the American College of Allergy Asthma and Immunology (ACAAI) annual meeting, which is being held from October 24-28 in Boston, Massachusetts.

"The poster, detailing a subsequent analysis of the data from the pivotal study of Anaphylm, being presented at ACAAI this year marks an important milestone in our development of Anaphylm, as it demonstrates the robustness and reliability of our sublingual film technology," said Dan Barber, Aquestive's President and Chief Executive Officer. "These findings show that our innovative PharmFilm™ delivery system maintains consistent pharmacokinetics and pharmacodynamics regardless of minor variations in placement, providing further evidence of Anaphylm's potential to offer healthcare providers and patients a dependable alternative for the treatment of severe allergic reactions. Anaphylm has the potential to be the first and only FDA-approved no-needle, no-device, oral epinephrine product for treating severe allergic reactions, including anaphylaxis, if approved by the FDA."

The poster presentation will showcase a subsequent analysis of the previously disclosed pivotal study that successfully met primary and secondary endpoints, found at the link here. The subsequent analysis was conducted to evaluate the impact of intraoral film placement and movement on variability in PK and PD. Movement was noted in 12.5% of subjects (8 of 64). Results of the pivotal study demonstrated consistent drug delivery, with 87.5% of subjects showing no change in film location between 1.5 to 3 minutes after administration of Anaphylm. In cases where movement was noted, there were no significant differences between subjects with or without film movement in geometric mean maximum concentration, or Cmax (351.14 and 490.27 pg/mL, respectively), or median peak drug concentration, or Tmax (12 minutes for both groups). These findings support that the initial placement or subsequent movement of the sublingual film had no impact on epinephrine PK or PD, with all results comparable to epinephrine injection.

Presentation Details:

Abstract Title: Sublingual Epinephrine Film's Mucoadhesive Properties Ensures Consistent Oral Placement and Drug Release

Abstract ID: 8103
ePoster ID: R008
Presentation Time: Friday, October 25, 2024, 3:45 PM ET
Location: Monitor 16, Exhibit Hall A, Hynes Convention Center

The poster are available online for registered participants of the meeting at annualmeeting.acaai.org, and will also be available on the Events and Presentations page of the Investor Section of the Company's website following the presentation.

About Anaphylm™
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 dermatology conditions including Alopecia areata. 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,” “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 FDA, the potential benefits Anaphylm could bring to patients, 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 PK and PD 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 concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; 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 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 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 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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Sublingual Epinephrine Film's Mucoadhesive Properties Ensures Consistent Oral Placement and Drug Release

Carl Kraus MD[1], David Golden MD[2], Matt Greenhawt MD[3], Jay Lieberman MD[4], David Bernstein MD[5], John Oppenheimer MD[6], Steve Wargacki PhD[1]

[1]Aquestive Therapeutics, Inc. [2]Medstar Franklin Square Hospital, Baltimore, MD, [3]Children's Hospital Colorado, University of Colorado, Aurora, CO, [4]University of Tennessee Health Science Center, Memphis, TN, [5]Cincinnati Children's Hospital Medical Center, University of Cincinnati, Cincinnati, OH, [6]UMDNJ Rutgers University School of Medicine

Introduction: Epinephrine is the first-line treatment for severe allergic reactions, including anaphylaxis. Prompt and reliable action are critical for patient outcomes. Recent advancements have led to the development of DESF, a sublingual film containing a novel epinephrine prodrug.

Methods: AQ109301, a randomized, cross-over trial in healthy adults evaluated the pharmacokinetics (PK) and pharmacodynamics (PD) of epinephrine delivered via sublingual film (DESF) compared to epinephrine autoinjectors (EAI) and manual IM injection (IM). Intraoral film placement and movement were evaluated to assess any impact on variability in PK and PD.

Results: DESF delivery resulted in epinephrine PK comparable to EAIs or IM injection. DESF PK and PD remained consistent independent of small variations in film location. Analysis of residual film location between 1.5 to 3 minutes post-administration revealed minimal displacement, with 87.5% of subjects having no change in film location between timepoints. When movement was noted, there were no significant differences between subjects with or without film movement for geometric mean Cmax (351.2 and 489.4 pg/mL, respectively; $p = 0.52$) or median Tmax (12 and 12 minutes, respectively, $p = 0.99$). Similarly, there were no significant differences in median change in systolic blood pressure between subjects with or without film movement (27.33 and 23.00 mmHg, respectively; $p = 0.46$).

Conclusion: The initial placement or subsequent movement of the sublingual film had no impact on epinephrine pharmacokinetics or pharmacodynamics, with all results comparable to injection. These findings suggest that sublingual epinephrine film offers a consistent, robust and permissive method of drug delivery in anaphylaxis management.

SUBLINGUAL EPINEPHRINE FILM'S MUCOADHESIVE PROPERTIES ENSURE CONSISTENT ORAL PLACEMENT AND DRUG RELEASE

Carl Kraus MD[1], David Golden MD[2], Matt Greenhawt MD[3], Jay Lieberman MD[4], David Bernstein MD[5], John Oppenheimer MD[6], Steve Wargacki PhD[1]

[1]Aquestive Therapeutics, [2]Medstar Franklin Square Hospital, Baltimore, MD, [3]Children's Hospital Colorado, University of Colorado, Aurora, CO, [4]University of Tennessee Health Science Center, Memphis, TN, [5]Cincinnati Children's Hospital Medical Center, University of Cincinnati, Cincinnati, OH, [6]UMDNJ Rutgers University School of M

INTRODUCTION

- Epinephrine administered intramuscularly into the anterolateral thigh via manual injection or auto-injector (e.g., EpiPen®, Auvi-Q®) is currently the first-line treatment for anaphylaxis.[1]
- The two injection methods have distinct pharmacokinetic (PK) profiles,[2] but both clinically stabilize a patient with anaphylaxis in the outpatient or hospital setting.
- AQST-109 (also referred to as DESF) is a novel prodrug of epinephrine delivered via sublingual film and is being developed for the emergency treatment of type 1 allergic reactions, including anaphylaxis.
- AQST-109 could be conveniently carried by patients (e.g., in a wallet, pocket, small purse, or on the back of a mobile phone).
- The potential impact of placement or movement of AQST-109 was not previously assessed.

OBJECTIVES

- The study objectives were to compare the PK of epinephrine following single administration of AQST-109 to that following single administration of epinephrine intramuscular (IM) injection in healthy adult subjects.
- To evaluate the safety and tolerability of epinephrine following single administration of AQST-109 to that following single administration of epinephrine IM injection in healthy adult subjects.
- Subsequent analysis was conducted to evaluate the impact of intraoral film placement and movement on variability in PK and pharmacodynamics (PD).

METHODS

STUDY DESIGN

- An open-label, single-center, randomized, four-period, four-treatment, four-sequence, comparative PK study.
- During the studies, subjects received:
  - AQST-109 12 mg
  - Epinephrine 0.3 mg via IM injection
  - Epinephrine 0.3 mg via EpiPen
  - Epinephrine 0.3 mg via Auvi-Q

METHODS (cont'd)

KEY INCLUSION CRITERIA

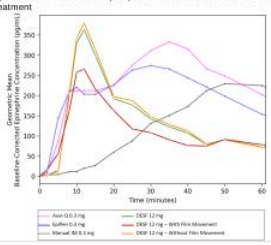
- Healthy adult males and females aged 18 to 55 years.
- Body mass index (BMI) between 18 and 30 kg/m^2.
- Weight ≥45 kg for females and ≥50 kg for males.

RESULTS

PK DATA

- Movement was noted in 12.5% of subjects (8 of 64) .
- DESF delivery resulted in epinephrine PK comparable to Epinephrine Auto-Injectors (EAIs) or IM injection, and remained consistent independent of variations in film location, defined by change in location upon mouth checks (Figure 1).
- When movement was noted, there were no significant differences between subjects with or without film movement.
- Geometric mean (GM) C_{max}
  - 351.14 pg/mL with film movement and 490.27 pg/mL without film movement; p = 0.49
- Median T_{max}
  - 12 minutes with film movement and 12 minutes without film movement; p = 0.96

Figure 1: Geometric Mean Epinephrine Concentration over Time By Treatment



RESULTS (cont'd)

Table 1: Epinephrine PK Parameters With and Without Film Movement

Parameter[a]	With Film Movement (N=8)	Without Film Movement (N=56)
T_{max}, min	12	12
C_{max}, pg/mL	351.14 (93.57%)	490.27 (84.4%)
$AUC_{0\text{-}10}$, h·pg/mL	16.92	17.72
$AUC_{0\text{-}20}$, h·pg/mL	57.14	73.83
$AUC_{0\text{-}30}$, h·pg/mL	79.31	108.99
$AUC_{0\text{-}45}$, h·pg/mL	102.31	144.79

[a]Geometric mean values except for median T_{max}. C_{max} also reports coefficient of variation (%).

PD DATA

- DESF PD remained consistent independent of small variations in film location, as shown in Figures 2 and 3. {PR not shown}.
- There were no significant differences in median change in systolic blood pressure (SBP), diastolic blood pressure (DBP), or pulse rate (PR) between subjects with or without film movement (Table 2).
- Additionally, there were no significant differences in median max SBP, DBP or PR between the two subgroups (Table 2).

Table 2: Epinephrine PD Parameters With and Without Film Movement

Parameter[b]	With Film Movement	Without Film Movement
SBP		
Change, mmHg	7.75	6.50
Max, mmHg	143.50	132.50
DBP		
Change, mmHg	3.25	1.50
Max, mmHg	88.50	80.00
Pulse		
Change, beats/min	2.00	3.25
Max, beats/min	87.50	84.00

[b]all values are median

RESULTS (cont'd)

Figure 2: Median Change from Baseline in Systolic Blood Pressure

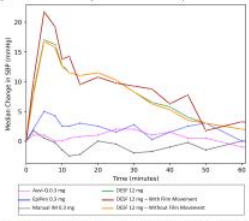
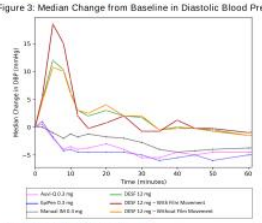


Figure 3: Median Change from Baseline in Diastolic Blood Pressure



SAFETY AND TOLERABILITY

- Most adverse events were consistent with known physiologic effects of epinephrine and were similar across treatments.
- There were no severe treatment-emergent adverse events (TEAEs) reported.
- All reported TEAEs were mild, transient, or resolved with minimal intervention.

CONCLUSIONS

- Analysis of residual film lo
  1.5 to 3 minutes post-admi
  revealed minimal displace
  - 87.5% of subjects ha
  film location betwee
- The initial placement or su
  movement of the sublingu
  impact on epinephrine PK
  results comparable to inje
- Similar to all prior studies
  109 was safe and well tole
  therapeutic dose.
- These results suggest AQS
  consistent, robust and per
  of drug delivery in anaphy
  management

REFERENCES

1. Shaker MS, Wallace DV, Golden DBK, Immunol. 2020;145(4):1082-1123.
2. Worm M, Nguyen D, Rackley R, et al. C 2020;10:21.

ACKNOWLEDGMENTS

This study was sponsored by Aquestive

DISCLOSURES

Drs. Golden, Greenhawt, Lieberman, Bern members of the advisory board and cons Therapeutics, Inc. Drs. Kraus and Wargac Aquestive Therapeutics.