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 24, 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 7.01 Regulation FD Disclosure.

On October 24, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing positive topline results from its oral allergy syndrome (OAS) challenge study for Anaphylm™ (epinephrine) Sublingual Film and posted on the Events and Presentations page within the Investor page on the Company's website located at www.aquestive.com information, in the form of an investor presentation, to be given at meetings with institutional investors, analysts and others. This information may be amended or updated at any time and from time to time through another Current Report on Form 8-K, a later company filing or other means. Anaphylm has the potential to be the first and only non-invasive, orally delivered epinephrine for the treatment of severe life-threatening allergic reactions, including anaphylaxis, if approved by the United States Food and Drug Administration (FDA). A copy of the Company's press release and investor presentation are attached as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report and incorporated in this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibit 99.1 and 99.2) 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 8.01 Other Events.

On October 24, 2024, the Company released positive topline results from its OAS challenge study for Anaphylm™ (epinephrine) Sublingual Film. Anaphylm has the potential to be the first and only non-invasive, orally delivered epinephrine for the treatment of severe life-threatening allergic reactions, including anaphylaxis, if approved by the FDA.

Item 9.01 Financial Statements and Exhibits

(d)Exhibits.

Exhibit Number	Description
99.1	Press Release, dated October 24, 2024.
99.2	Anaphylm™ (epinephrine) Sublingual Film Oral Allergy Syndrome Challenge Study Supplemental Materials, dated October 24, 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: **October 24, 2024**

Aquestive Therapeutics, Inc.

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

Aquestive Therapeutics Announces Positive Topline Results from Oral Allergy Syndrome (OAS) Challenge Study for Anaphylm™ (epinephrine) Sublingual Film

- *Completed OAS challenge study meets both primary and secondary endpoints*
- *Demonstrates rapid resolution of allergen-related symptoms beginning two minutes after administration*
- *Pharmacokinetic (PK) profile after allergen exposure comparable to non-allergen PK profile*
- *On track for a pre-NDA meeting on Anaphylm in Q4 2024*

WARREN, N.J., October 24, 2024 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced positive topline results from its Oral Allergy Syndrome (OAS) challenge study for Anaphylm™ (epinephrine) Sublingual Film. This marks the completion of the final supportive adult study in the Anaphylm development program prior to meeting with the U.S. Food and Drug Administration (FDA).

The OAS challenge study was designed as a two-part investigation to evaluate the PK and pharmacodynamics (PD) of Anaphylm in adults with allergen-induced oral physiological change. Part 1 of the study enrolled subjects with confirmed OAS into a three-period study with the following arms: (1) Anaphylm with allergen exposure (n=18 single dose; n=18 repeat dose); (2) Anaphylm without allergen exposure (n=15 single dose; n=13 repeat dose); and (3) Adrenalin intramuscular (IM) injection without allergen exposure (n=18 single dose; n=17repeat dose). Part 2 was an optional follow-on study to Part 1. Six subjects who received single dose in Part 1 received repeat dose; and six subjects who received repeat dose in Part 1 received single dose. Anaphylm was administered with allergen exposure, while IM was administered without allergen exposure. During allergen exposure arms in Parts 1 and 2, subjects were exposed to a fruit they were known to be allergic to, and the resulting symptoms were documented for location, severity, and duration. There were no reports of difficulty administering Anaphylm to subjects in the study.

Following allergen exposure, all subjects reported symptoms consistent with those experienced with their known allergies. Approximately twenty-five percent of subjects reported swelling of their tongues, lips, cheeks, and/or throat. Additional mucosal allergic symptoms included tingling, pain, and nasal congestion. Ninety-four percent of subjects were categorized as having moderate or severe symptoms according to the pre-defined oral severity score.

The median time for complete symptom resolution for subjects in the study following administration of Anaphylm was twelve minutes. This is faster than the median time to complete symptom resolution at screening, which was seventy-four minutes. After Anaphylm administration, symptoms began resolving as early as two minutes in some subjects and fifty percent of all symptoms across all subjects were resolved by five minutes. Importantly, all instances of symptomatic swelling were completely resolved by five minutes after administration of Anaphylm.

Both primary and secondary endpoints of the OAS challenge study were successfully met with no significant differences found between Anaphylm PK results in subjects with and without allergen exposure. Anaphylm PK results in subjects with allergen exposure remained similar to previous profiles from the Company’s pivotal study in healthy subjects. The time to maximum plasma

concentration, or Tmax, remained at twelve minutes in subjects with and without allergen exposure following a single dose of Anaphylm. The maximum plasma concentration, or Cmax, was comparable between Anaphylm administered with and without allergen exposure. In addition, Anaphylm was safe and well-tolerated with all adverse events categorized as mild or moderate and resolving without medical intervention.

“Symptom relief is the most real-world scenario whereby subjects know their rescue product is working,” said Jay Lieberman, M.D., Professor at the University of Tennessee Health Science Center, physician at LeBonheur Children’s Hospital, and Chair of the Annual Meeting Program for the American College of Allergy, Asthma, and Immunology (ACAAI). “I am reassured by the speed of symptom relief seen in the OAS Study and by the continued and consistent rapid absorption profile of Anaphylm. These data provide strong evidence that Anaphylm could provide a reliable alternative to the approved epinephrine medical devices currently available to patients.”

"We are extremely pleased with the positive results from our OAS challenge study, which further validate Anaphylm's potential as a game-changing treatment option for severe allergic reactions, including anaphylaxis, if approved by the FDA" said Daniel Barber, President and Chief Executive Officer of Aquestive. "These results demonstrate that Anaphylm maintains its consistent PK and PD profile even when administered during oral allergic conditions, such as swelling. In addition, Anaphylm demonstrated its ability to resolve symptoms following the introduction of an oral allergen. This is a critical finding as we advance towards our NDA submission, as it confirms Anaphylm's potential effectiveness in real-world allergic scenarios."

Aquestive has requested a pre-NDA meeting with the FDA and expects to meet with the FDA in the fourth quarter of 2024. The Company remains on track to commence a pediatric study in subjects weighing 30 kgs and above in the fourth quarter 2024 and to submit a New Drug Application (NDA) to the FDA in the first quarter 2025. If approved by the FDA, Aquestive is poised to initiate a full product launch of Anaphylm in the first quarter of 2026.

A presentation containing additional information about this topline data is available on the Events and Presentations page within the Investor page of 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 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," "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, including the timing of submission of supporting and pediatric clinical studies, holding a pre-NDA meeting with the FDA and filing the NDA for Anaphylm with the FDA, and the following 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 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 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.

Investor Inquiries
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646-277-1282


Aquestive
Anaphylm™ (epinephrine) Sublingual Film
Oral Allergy Syndrome Challenge Study
Supplemental Materials
October 24, 2024
Advancing medicines.
Solving problems.
Improving lives.

Disclaimer

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PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. 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, AQST-109. All other registered trademarks referenced herein are the property of their respective owners.

Aquestive®

Key messages: Oral Allergy Syndrome (OAS) challenge study

1. Subjects experienced rapid symptom relief
   - 94% of subjects were categorized as having moderate or severe reactions after exposure to an allergen
   - Administration of Anaphylm™ (epinephrine) Sublingual Film resulted in rapid symptom relief in as little as two minutes
   - The median time to complete symptom resolution after Anaphylm was administered is 12 minutes (includes single and repeat dose administrations)

2. Comparable pharmacokinetic (PK) profiles were observed
   - Exposure to an allergen had little to no impact on the PK profile of Anaphylm when compared to no exposure to an allergen
   - A consistent PK profile was observed for both single and repeat doses of Anaphylm

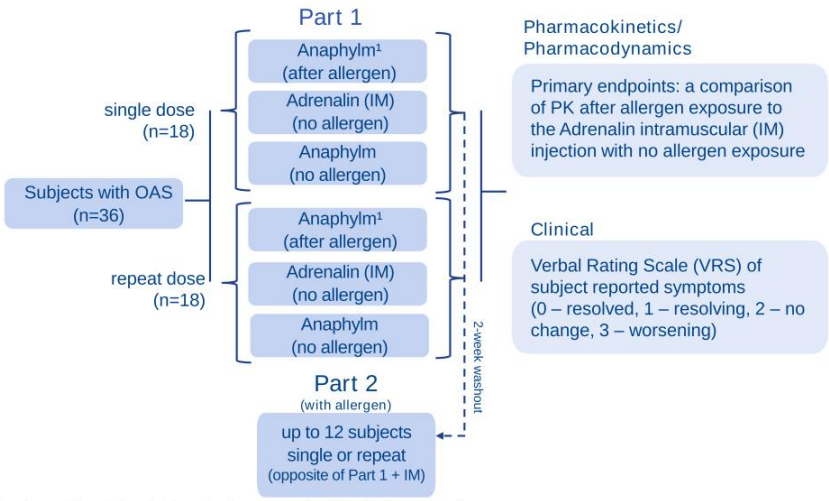
3. Consistent pharmacodynamic (PD) profiles were observed
   - Change from baseline for blood pressure and heart rate remained consistent with previous studies

4. All adverse events were either mild or moderate and resolved without medical intervention

OAS challenge study design

Study Design

Two-part investigation to evaluate the pharmacokinetics (PK) and pharmacodynamics (PD) of Anaphylm in adults with allergen-induced oral physiological change



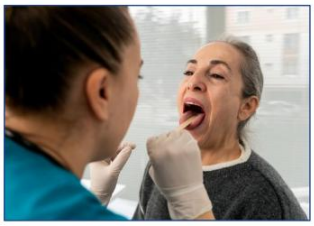
1.Volunteers with OAS were challenged by exposure to the allergen known to trigger their reaction (e.g., apple, cherry, mango, melon, kiwi, celery, banana or carrot).

Aquestive

OAS challenge study induced subject reactions

Step #1:
OAS subject's oral cavity exposed to allergen

Step #2:
Assessment of symptom severity[1]



First subject visit

Screening
Clinician tracks subject's symptoms until resolution

Second subject visit

Dosing
1. Subjects received either single dose or repeat dose of Anaphylm
2. **Clinician tracks subject's** symptoms from time of dosing until resolution

1. Steps #1 and #2 repeated until symptom score is moderate/severe; Only occurred in one subject.

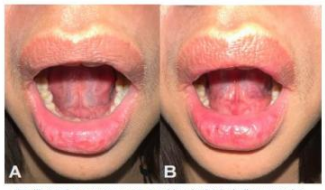
Aquestive

Subjects were exposed to an allergen prior to dosing

Allergen	# Exposures
Pineapple	14
Red Apple	7
Kiwi	7
Cherry	3
Banana	2
Avocado	2
Fig	2
Grapefruit	2
Lychee	2
Tangerine	2
All other	4
Total	47[1]

Subject profile	Post allergen challenge	Mucosal changes
17% severe 77% moderate 6% mild	100% had oral symptoms 36% also had systemic symptoms 100% successful administration of film	100% reported symptoms of allergic response in mucosa 81% reported ≥ 2 symptoms of allergic response in mucosa 25% reported swelling

Select Symptoms of Interest	% of dosing's with specified symptom
Lip swelling	31.9%
Throat swelling	10.6%
Tongue swelling	6.4%
Cheek swelling	4.3%
Nasal congestion	2.1%
Sublingual swelling	2.1%



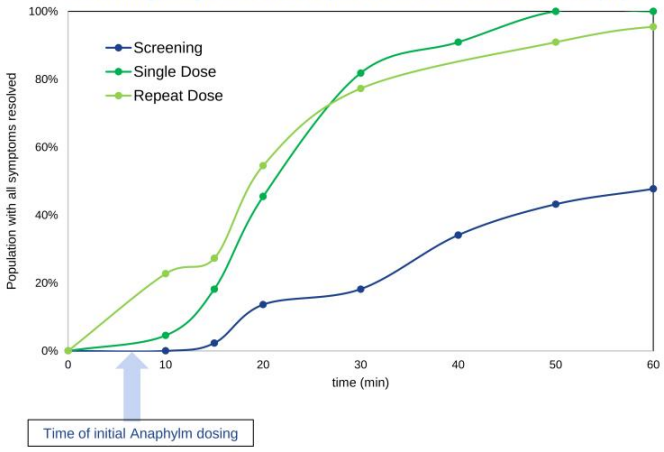
For illustrative purposes, not a subject in OAS challenge study[2]

1. Thirty-five subjects participated in Part 1, 12 patients returned for participation in optional Part 2, totaling forty-seven exposures. 2. Irin Vichara-anont JAAAAI Volume 153, (2) 2024.

Aquestive

Complete symptom resolution occurs rapidly after Anaphylm administration[1]

Time from allergen exposure to complete symptom resolution following screening, single dose, and repeat dose administration of Anaphylm

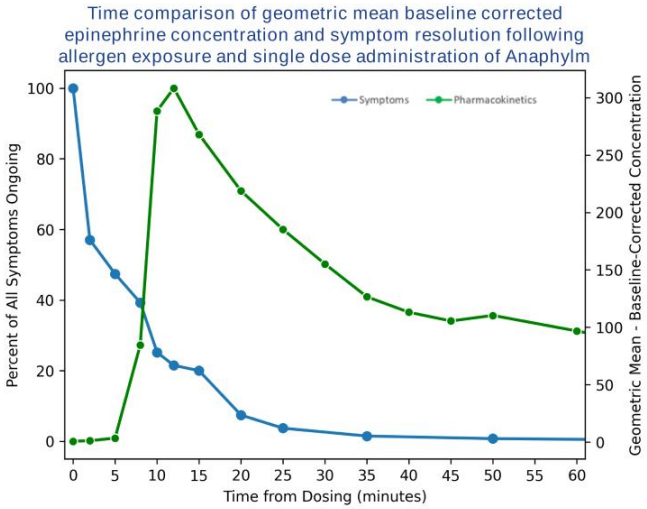


- Median time to complete symptom resolution was 12 minutes after Anaphylm administration
- Median time to resolution was 74 minutes without Anaphylm administrations

1. Aquestive Therapeutics data on file.

Aquestive

Symptom relief correlates to Anaphylm PK levels[1,2]



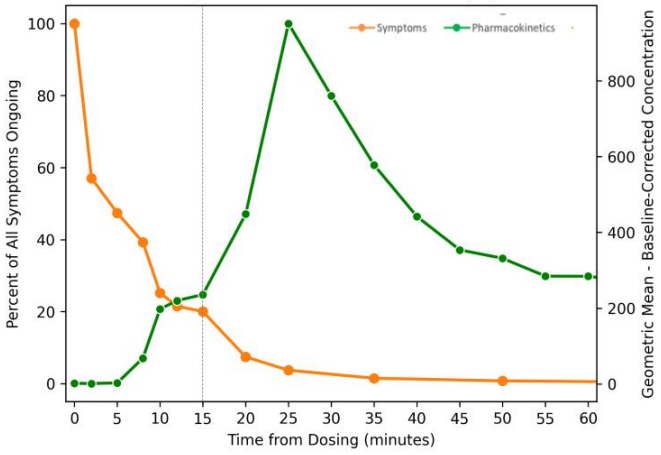
- Symptom resolution was observed as early as 2 minutes in some subjects
- Median symptom resolution was 5 minutes

1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population.

Aquestive

Symptom relief was also observed with repeat dosing of Anaphylm[1,2]

Time comparison of geometric mean baseline corrected epinephrine concentration and symptom resolution following allergen exposure and repeat dose administration of Anaphylm



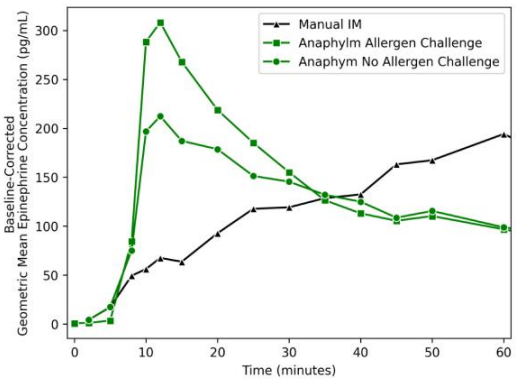
- Repeat dose at 15 minutes resulted in rapid resolution of remaining symptoms

1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population.

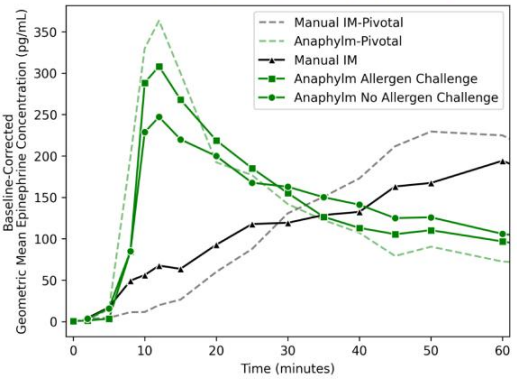
Aquestive

Anaphylm PK profile remains consistent with and without allergen exposure[1,2]

Geometric mean baseline-adjusted epinephrine concentration over time in OAS subjects after single dose administration



Geometric mean baseline-adjusted epinephrine concentration over time in OAS subjects after single dose administration compared to previously reported pivotal data



1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population.

Aquestive

Anaphylm single dose meets primary endpoints under oral allergen challenge[1,2]

- Primary endpoints predefined as Anaphylm values above manual injection for maximum concentration (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.
- No statistical impact of allergen challenge on key Anaphylm pharmacokinetics

Cmax and Tmax[3]

Administration	Cmax (pg/mL)	Median Tmax (min)
Manual IM (n=24)	261.2	50
Anaphylm with allergen (n=23)	403.5	12
Anaphylm without allergen (n=15)	372.8	12

Partial AUC's (hr*pg/mL)[3]

Administration	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$	$AUC_{0\text{-}45min}$
Manual IM (n=24)	6.0	18.9	39.0	76.0
Anaphylm with allergen (n=23)	14.4	63.2	97.0	132.1
Anaphylm without allergen (n=15)	11.0	50.3	82.6	124.1

1. Aquestive Therapeutics data on file. 2 Data represent per protocol patient population. 3. Geometric means, median for Tmax.

Aquestive

Anaphylm repeat dose meets primary endpoints under oral allergen challenge[1,2]

- Primary endpoints predefined as Anaphylm values above manual injection for (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.
- No statistical impact of allergen challenge on key Anaphylm pharmacokinetics

Cmax and Tmax[3]

Administration	Cmax (pg/mL)	Tmax (min) median
Manual IM (n=22)	538.8	57.5
Anaphylm with allergen (n=23)	1194.0	25
Anaphylm without allergen (n=13)	585.5	25

Partial AUC's (hr*pg/mL)[3]

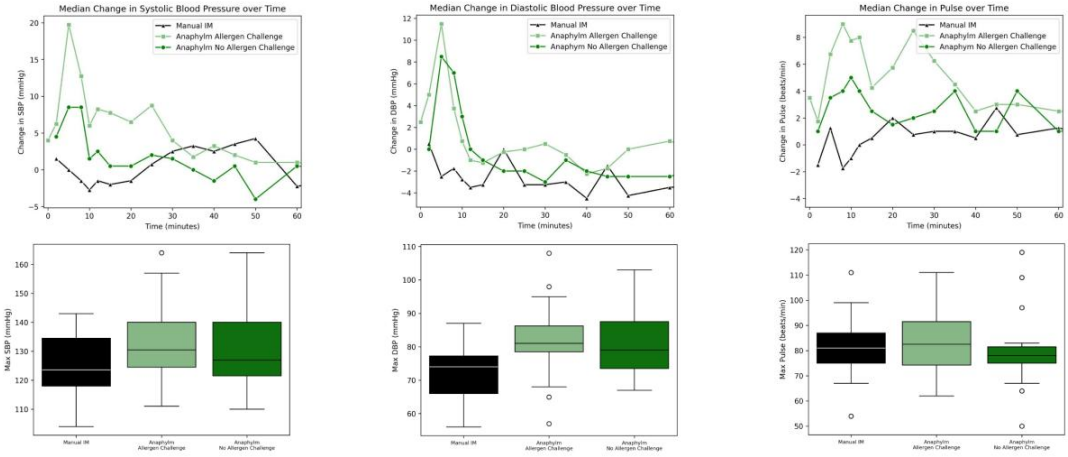
Administration	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$	$AUC_{0\text{-}45min}$
Manual IM (n=22)	5.1	15.5	39.2	99.4
Anaphylm with allergen (n=23)	10.1	62.6	216.8	360.5
Anaphylm without allergen (n=13)	9.2	35.0	106.5	180.4

1. Aquestive Therapeutics data on file. 2 Data represent per protocol patient population. 3. Geometric means, median for Tmax.

Aquestive

Single dose pharmacodynamics[1,2]

Anaphylm elicits the desired pharmacodynamic response in key metrics of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Pulse (HR), consistent with and without allergen exposure

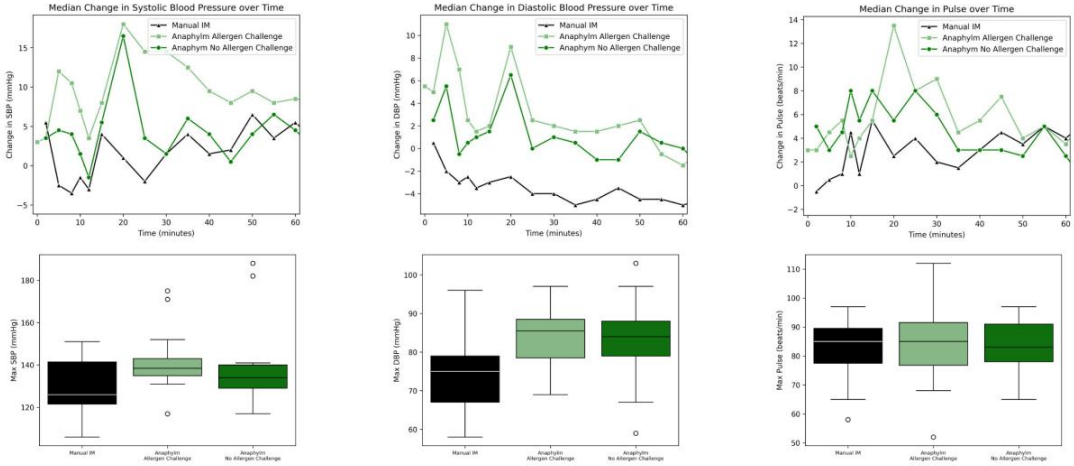


1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population..

Aquestive

Repeat dose pharmacodynamics[1,2]

Anaphylm elicits the desired pharmacodynamic response in key metrics of SBP, DBP and HR, consistent with and without allergen exposure



1. Aquestive Therapeutics data on file. 2. Data represent per protocol patient population..

OAS challenge study single dose safety summary[1]

- All treatment-emergent adverse events (TEAEs) were categorized as mild (Grade 1)
- No serious adverse events (SAEs) were observed
- TEAEs were transient and resolved without medical intervention
- Primary cardiovascular TEAE associated with mild palpitations were observed
- No emesis was reported in single dose administration

System Organ Class	Severity	12 mg Anaphylm with allergen challenge Incidence (%) n=24	0.3 mg Manual IM Incidence (%) n=23	12 mg Anaphylm without allergen challenge Incidence (%) n=16
Cardiac Disorders				
Palpitations (subjective, subject-reported)	Mild	2 (8.3%)	0	0
Gastrointestinal Disorders				
Nausea	Mild	1 (4.2%)	0	0

1. Aquestive Therapeutics data on file.

Aquestive

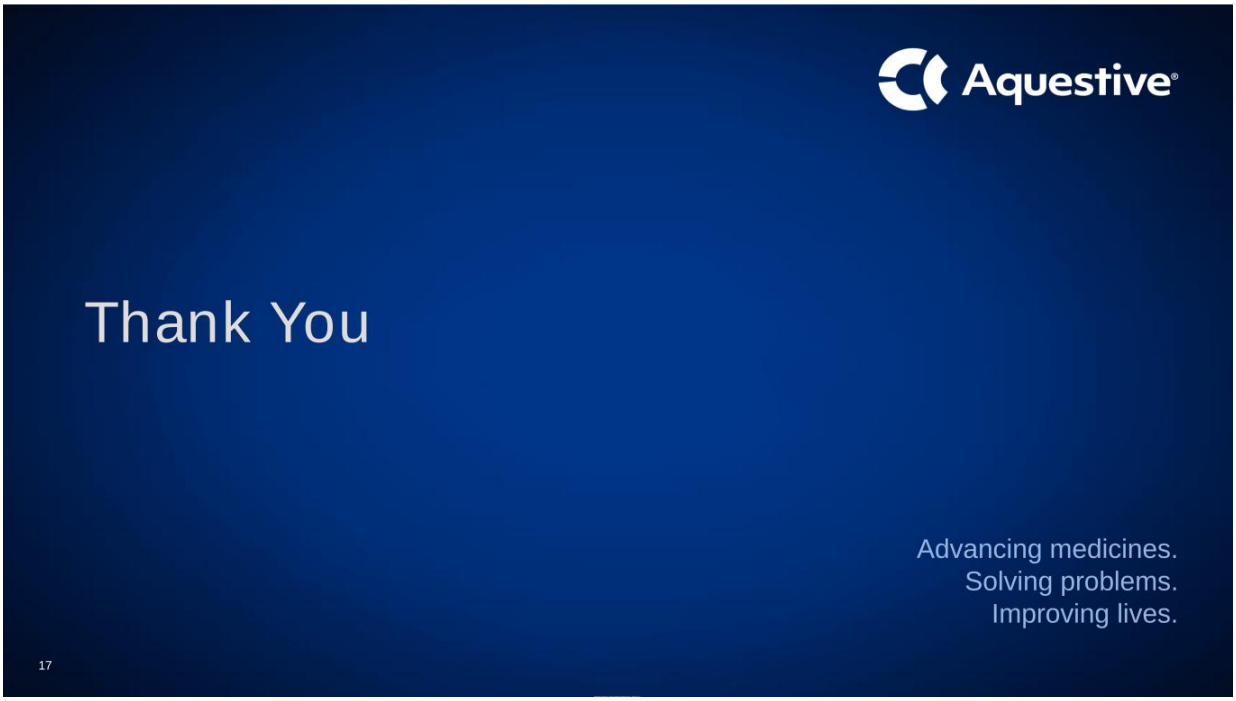
OAS challenge study repeat dose safety summary[1]

- Most TEAE (96.2%) were categorized as mild (Grade 1)
- No SAEs were observed
- TEAEs were transient and resolved without medical intervention
- Primary cardiovascular TEAE associated with mild palpitations were observed

System Organ Class	Severity	12 mg x 2 Anaphylm with allergen challenge Incidence (%) n=24	0.3 mg x 2 Manual IM Incidence (%) n=23	12 mg x 2 Anaphylm without allergen challenge Incidence (%) n=16
Cardiac Disorders				
Palpitations (subjective, subject-reported)	Mild	4 (16.7%)	0	0
Gastrointestinal Disorders				
Vomiting	Mild	1 (4.2%)	0	1 (6.3%)
Nausea	Mild	2 (8.3%)	0	0

1. Aquestive Therapeutics data on file.

Aquestive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Thank You
Advancing medicines.
Solving problems.
Improving lives.
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