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): March 14, 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 March 14, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing positive topline clinical data from its Phase 3 pivotal pharmacokinetic clinical study of Anaphylm™ (epinephrine) Sublingual Film and findings from the FDA Type C meeting. Anaphylm is the Company's orally administered epinephrine prodrug product candidate under development for the treatment of severe life-threatening allergic reactions, including anaphylaxis. A copy of the Company's press release is attached as Exhibit 99.1 to this Current Report and incorporated in this Item 7.01 by reference.

Additionally, the Company is furnishing this Current Report on Form 8-K in connection with the disclosure of information, in the form of an investor presentation, 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. A copy of the Company's investor presentation is attached hereto as Exhibits 99.2 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The investor presentation is available on the Company's website located at www.aquestive.com, although the Company reserves the right to discontinue that availability at any time.

The information in this Item 7.01 (including Exhibits 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 March 14, 2024, the Company released positive topline clinical data from its Phase 3 pivotal pharmacokinetic ("PK") clinical study of Anaphylm™ (epinephrine) Sublingual Film and findings from the FDA Type C meeting. Anaphylm is the Company's first and only orally administered epinephrine prodrug product candidate under development for the treatment of severe life-threatening allergic reactions, including anaphylaxis.

Topline Data from Pivotal Phase 3 Study in Adult Subjects

The two-part, Phase 3, single-center, open-label, randomized study was designed to compare the PK and pharmacodynamics ("PD") of single and repeat doses of Anaphylm versus single and repeat doses of the epinephrine intra-muscular ("IM") injection and epinephrine autoinjectors (EpiPen® and Auvi-Q®) in healthy adult subjects. The primary endpoint was to compare the PK of epinephrine following the single administration of Anaphylm to the single administration of Adrenalin (epinephrine IM injection) and autoinjectors in healthy adult subjects. The secondary endpoints included evaluating PK sustainability following repeat administration and the safety and tolerability following single and repeat administrations versus epinephrine IM injection and epinephrine autoinjectors.

The single dose part of the Phase 3 study was designed as a four-period, four-treatment, four-sequence, comparative PK study with 64 enrolled adult subjects. Key findings from the single dosing part of the study included that Anaphylm:

a. Achieved a geometric mean Cmax of 470 pg/mL bracketed by epinephrine autoinjectors AUVI-Q at 521 pg/mL and EpiPen at 469 pg/mL,
b. Generated partial AUCs between (bracketed) autoinjectors and Adrenalin manual IM injection from 5 to 60 minutes
c. Maintained a median Tmax of 12 minutes compared to 20 minutes for EpiPen, 30 minutes for AUVI-Q, and 50 minutes for Adrenalin,
d. Produced a meaningful change from baseline pharmacodynamic measures of blood pressure and heart rate at the first tracked time point of 2 minutes,
e. Reached 100 pg/mL threshold as rapidly as EpiPen and faster than Adrenalin,
f. Exhibited consistent PD results, and
g. Was consistently well tolerated with no SAEs.

The repeat dosing part of the Phase 3 study was designed as a three-period, three-treatment, six sequence, comparative PK study with 36 enrolled adult subjects. The key findings from the repeat dosing part of the Study included that Anaphylm:

a. Maintained epinephrine plasma concentrations equal to or greater than existing injection products at all but 1 timepoint out to 2 hours,
b. Demonstrated a median Tmax of 10 minutes after administration of the second dose,

c. Reached or exceeded 100 pg/mL threshold 5 minutes after second dosing,
d. Exhibited consistent pharmacodynamics, and
e. Was consistently well tolerated with no SAEs.

FDA Type C Meeting

The Company also successfully completed a Type C meeting with the FDA that addressed open items from the November 2022 End-of-Phase 2 meeting including addressing (1) the impact of any product hold time, (2) the potential for emesis (vomiting), and (3) the impact of potential mouth conditions such as angioedema (swelling).

In response to these questions, the FDA indicated that the Company has "adequately addressed" the FDA's previous concerns by removing product hold time from the administration instructions and provided additional information on how to characterize emesis in the Company's NDA submission.

Regarding mouth conditions, the FDA recommended administering Anaphylm after oral exposure to a known allergen and assessing PK performance thereunder. The Company will execute this study in the second quarter of 2024. This study will replace the Company's previously planned angioedema study.

The FDA noted that substantial progress had been made in the Anaphylm clinical development program and did not outline any new clinical development requirements. As expected, the FDA reiterated that, as with other epinephrine programs under development, concentrations of epinephrine above known EpiPen levels must be justified from a safety perspective, and PK sustainability remains a focus. Furthermore, the FDA recommended that Aquestive begin its pediatric study after completion of the remaining adult studies. The Company is aligned with this recommendation from the FDA. The FDA reserved judgement on the sufficiency of the Anaphylm clinical development program until completion of ongoing and planned studies, the results of which are expected to be presented at the pre-NDA meeting.

Table 1 below provides an updated view on the expected commencement dates of the specific clinical studies, unless otherwise specified therein.

Table 1: Anaphylm Clinical Study Timeline

Anticipated Timing	Pivotal PK Studies	Supportive PK Studies	FDA Meetings / Actions
Completed	Phase 3 PK Study Repeat Dose PK Study		Type C Meeting
Q1 2024		Temperature PK Study	
Q2 2024		Self-administration PK Study Allergen PK Study	
Q3 2024	Pediatric PK Study		
H2 2024			Pre-NDA Meeting

The next anticipated meeting with the FDA is the pre-NDA meeting targeted for the second half of 2024. Aquestive's goal is to file the NDA with the FDA before year end 2024.

Forward-Looking Statements

Certain statements in this Current Report on Form 8-K 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 expected clinical studies and clinical study dates, the timing of the pre-NDA meeting and Aquestive's goal of filing an NDA for Anaphylm before the end of 2024, the potential benefits Anaphylm could bring to patients, and other statements that are not historical facts.

These forward-looking statements are based on the Company's 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 its product development activities and clinical trials for Anaphylm and our other product candidates, including the uncertain impact of the COVID-19 global pandemic; risk of the Company's ability to generate sufficient data in its 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 pivotal PK study protocol 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; risk of delays in or the failure to receive FDA approval of Anaphylm; risk of the success of any competing products; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks, and regulatory limitations); risk of the rate and degree of market acceptance of our product candidates and our licensed products in the U.S. and abroad; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's 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 activities for Anaphylm and our other product candidates; 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; 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 risks and uncertainties affecting the Company 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 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.

Item 9.01 Financial Statements and Exhibits

(d)Exhibits.

Exhibit Number	Description
99.1	Press Release, dated March 14, 2024.
99.2	Aquestive Therapeutics, Inc. Supplemental Presentation, dated March 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: **March 14, 2024**

Aquestive Therapeutics, Inc.

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

Aquestive Therapeutics Announces Pivotal Study for Anaphylm™ (epinephrine) Sublingual Film Successfully Meets Primary and Secondary Endpoints and Provides Clinical Development Update Following FDA Meeting

Your publication date and time will appear here. | Source: Aquestive Therapeutics, Inc.

- *Anaphylm meets all predefined primary and secondary pharmacokinetic endpoints*
- *Anaphylm time to maximum concentration (Tmax) is consistently faster than autoinjectors*
- *Anaphylm exposure levels (AUC) are comparable to autoinjectors for 30 minutes after dosing*
- *Anaphylm is well-tolerated with no serious adverse events*
- *Company receives positive Type C meeting feedback from the U.S. Food and Drug Administration (FDA) regarding the clinical development of Anaphylm*
- *Company reaffirms goal of filing NDA before the end of 2024*

WARREN, N.J., March 14, 2024 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today released positive topline clinical data from its Phase 3 pivotal pharmacokinetic (PK) clinical study of Anaphylm™ (epinephrine) Sublingual Film and findings from the FDA Type C meeting. Anaphylm is the Company's first and only orally administered epinephrine prodrug product candidate under development for the treatment of severe life-threatening allergic reactions, including

anaphylaxis.

“We are extremely pleased with the pivotal study results as well as our recent FDA interaction,” said Daniel Barber, President and Chief Executive Officer of Aquestive. “When it comes to treating severe allergic reactions including anaphylaxis, we often hear from clinicians that rapid absorption of epinephrine at the first sign of symptoms is critical. Our pivotal study indicates that Anaphylm is comparable to the leading autoinjectors immediately following administration and our time to maximum concentration, or Tmax, is faster than the leading autoinjectors. We believe this performance is unprecedented among the alternate delivery options under development and are excited at the potential of Anaphylm as the only oral medicine for treatment of severe allergies.”

“In addition, our recent discussions with the FDA remained consistent with our previous interactions,” continued Mr. Barber. “We believe we have a clear understanding of the remaining clinical development steps necessary for a pre-NDA meeting with the FDA in the second half of the year. Our goal continues to be to file our NDA before the end of 2024 following completion of a positive pre-NDA meeting.”

David Golden, M.D., a renowned expert on anaphylaxis and an allergy-immunology consultant at Sinai Hospital of Baltimore and Franklin Square Hospital in Baltimore, stated, “The data from the Anaphylm pivotal study build on the compelling data generated from the prior Anaphylm pilot studies. These latest study results show that the sublingual administration of epinephrine provides rapid and sustained levels of epinephrine similar to approved treatments. Anaphylm is a promising needle-free alternative to the current standard of care, allowing patients to easily carry and administer this life-saving medication.”

Topline Data from Pivotal Phase 3 Study in Adults

The two-part, Phase 3, single-center, open-label, randomized study was designed to compare the PK and pharmacodynamics (PD) of single and repeat doses of Anaphylm versus single and repeat doses of the epinephrine intra-muscular (IM) injection and epinephrine autoinjectors (EpiPen® and Auvi-Q®) in healthy adult subjects. The primary endpoint was to compare the PK of epinephrine following the single administration of Anaphylm to the single administration

of Adrenalin (epinephrine IM injection) and autoinjectors in healthy adult subjects. The secondary endpoints included evaluating PK sustainability following repeat administration and the safety and tolerability following single and repeat administrations versus epinephrine IM injection and epinephrine autoinjectors.

The single dose part of the Phase 3 study was designed as a four-period, four-treatment, four-sequence, comparative PK study with 64 enrolled adult subjects. As outlined in the presentation posted to the Company's website and filed with the SEC today, key findings from the single dosing part of the study included that Anaphylm:

- Achieved a geometric mean Cmax of 470 pg/mL bracketed by epinephrine autoinjectors AUVI-Q at 521 pg/mL and EpiPen at 469 pg/mL,
- Generated partial AUCs between (bracketed) autoinjectors and Adrenalin manual IM injection from 5 to 60 minutes
- Maintained a median Tmax of 12 minutes compared to 20 minutes for EpiPen, 30 minutes for AUVI-Q, and 50 minutes for Adrenalin,
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Company has “adequately addressed” the FDA’s previous concerns by removing product hold time from the administration instructions and provided additional information on how to characterize emesis in the Company’s NDA submission.

Regarding mouth conditions, the FDA recommended administering Anaphylm after oral exposure to a known allergen and assessing PK performance thereunder. The Company will execute this study in the second quarter of 2024. This study will replace the Company’s previously planned angioedema study.

The FDA noted that substantial progress had been made in the Anaphylm clinical development program and did not outline any new clinical development requirements. As expected, the FDA reiterated that, as with other epinephrine programs under development, concentrations of epinephrine above known EpiPen levels must be justified from a safety perspective, and PK sustainability remains a focus. Furthermore, the FDA recommended that Aquestive begin its pediatric study after completion of the remaining adult studies. The Company is aligned with this recommendation from the FDA. The FDA reserved judgement on the sufficiency of the Anaphylm clinical development program until completion of ongoing and planned studies, the results of which are expected to be presented at the pre-NDA meeting.

Table 1 provides an updated view on the expected clinical study dates.

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The next anticipated meeting with the FDA is the pre-NDA meeting targeted for the second half of 2024. Aquestive’s goal is to file the

NDA with the FDA before year end 2024.

A presentation containing additional information about this topline data and the Company's recent FDA Type C meeting is available on the Events and Presentations page within the Investor page of the Aquestive website.

About Anaphylaxis

Anaphylaxis is a serious systemic hypersensitivity reaction with that is rapid in onset and potentially fatal. As many as 49 million people in the United States are at chronic risk for anaphylaxis. Lifetime prevalence is at least 5%, or more than 16 million people in the United States. Direct costs of anaphylaxis have been estimated at $1.2 billion per year, with direct expenditures of $294 million for epinephrine, and indirect costs of $609 million. The frequency of hospital admissions for anaphylaxis has increased 500–700% in the last 10–15 years. Of patients who previously experienced anaphylaxis, 52% had never received an epinephrine auto-injector prescription, and 60% did not have an auto-injector currently available. The most common causes of anaphylaxis are foods (such as peanuts), venom from insect stings, and medications. Epinephrine injection is the current standard of treatment intended to reverse the severe manifestation of anaphylaxis, which may include skin rash, throat swelling, respiratory difficulty, gastrointestinal distress, and loss of consciousness.

About Anaphylm™

Anaphylm is a polymer matrix-based epinephrine prodrug candidate product. 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 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 tradename for AQST-109, "Anaphylm" has been conditionally approved by the United States Food and Drug Administration (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 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 pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit Aquestive.com and follow us on LinkedIn.

Forward-Looking Statements

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 expected clinical studies and clinical study dates, the timing of the pre-NDA meeting and Aquestive's goal of filing an NDA for Anaphylm before the end of 2024, the potential benefits Anaphylm could bring to patients, and other statements that are not historical facts.

These forward-looking statements are based on the Company's 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 its product development activities and clinical trials for Anaphylm and our other product candidates, including the uncertain impact of the COVID-19 global pandemic; risk of the Company's ability to generate

sufficient data in its 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 pivotal PK study protocol 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; risk of delays in or the failure to receive FDA approval of Anaphylm; risk of the success of any competing products; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks, and regulatory limitations); risk of the rate and degree of market acceptance of our product candidates and our licensed products in the U.S. and abroad; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's 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 activities for Anaphylm and our other product candidates; 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; 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 risks and uncertainties affecting the Company 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 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.

Investor Inquiries:

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646-277-1282


Aquestive
Pivotal Study and FDA Meeting Supplemental Slides
March 2024
Advancing medicines.
Solving problems.
Improving lives.
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Disclaimer

This presentation and the accompanying oral commentary have 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 for the emergency treatment of severe allergic reactions, including anaphylaxis, through clinical development and approval by the U.S. Food and Drug Administration (FDA), including the expected clinical studies and clinical study dates, the timing of the pre-NDA meeting with the FDA and Aquestive's goal of filing an NDA for Anaphylm before the end of 2024, the receipt and release of topline data from the Company's Anaphylm clinical studies and addressing the FDA's comments on the Company's pivotal pharmacokinetic (PK) study and other concerns identified in the FDA minutes from the Company's Type C meeting with the FDA for Anaphylm, the potential benefits Anaphylm could bring to patients, and other statements that are not historical facts.

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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; risk of the Company's ability to generate sufficient data in the clinical trials for Anaphylm and addressing the FDA's comments on the Company's pivotal pharmacokinetic (PK) study and other concerns identified by the FDA in its minutes for the Type C meeting with the Company for Anaphylm; risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in regulatory advancement through the FDA of Anaphylm or failure to receive FDA approval at all; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of the success of any competing products; risk of the rate and degree of market acceptance of our product candidates, including Anaphylm; risk of sufficient capital and cash resources, including insufficient 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 the Company's 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 activities for Anaphylm; risk of failure to satisfy all financial and other debt covenants and of any default under our existing debt financing; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; risk of achieving growth in our base business; risk of our ability to enter into other commercial transactions with third parties that will support growth of our business and execution of key initiatives; risk of development of a sales and marketing capability for future commercialization of our product candidates; risk related to product liability and other claims against Indivior Inc. for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risk of eroding market share for Suboxone and its market position as a sunsetting product; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; risk of the success of any competing products including generic products; 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 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 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 cyberattacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of the uncertainties of global business and macroeconomic conditions including adverse developments affecting the financial services industry, instability of the global banking system, and as a result of inflation and rising interest rates; risks and uncertainties related to general economic, geopolitical conflicts (including the wars in Ukraine and Israel and other acts of war and terrorism), business, industry, regulatory and market conditions and other unusual items; risks related to the impact of the COVID-19 global pandemic 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; and other risks and uncertainties affecting Aquestive, including those described in the "Risk Factors" section and in other sections included in the Company's recent 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 (SEC). Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as 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. We assume no obligation to update forward-looking statements 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.

PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. The trade name for AQST-109 "Anaphylm" 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.

Anaphylm Pivotal Study Results

Advancing medicines.
Solving problems.
Improving lives.

Phase 3 pivotal study meets all primary and secondary endpoints

Pivotal Study meets endpoints for single dose and repeat dose

- Single dose: maximum concentration (Cmax) and partial area under the curve (AUC) measures met as predefined
- Repeat dose: Safety and pharmacokinetic (PK) sustainability measures met as predefined

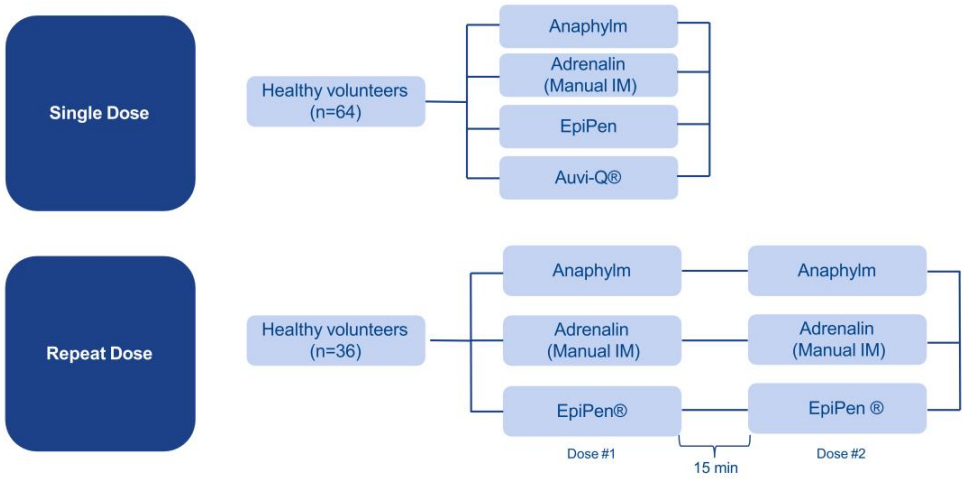
Positive FDA Type C meeting provides clarity on path to filing

- Alignment reached on open items from end-of-phase 2 meeting
- FDA remains consistent on approach to PK sustainability and comparability to existing autoinjectors

We continue to anticipate a pre-NDA meeting with FDA prior to filing

- Pre-NDA meeting to align on content and format of the NDA submission

AnaphylmTM pivotal study design



Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Key endpoints

Pharmacokinetic (PK)	• Maximum plasma concentration (Cmax) • Time to maximum plasma concentration (Tmax) • Partial area under the curve at 10, 20, 30, and 45 minutes • Subjects reaching 100pg/mL over time
Pharmacodynamic (PD)	• Change in systolic blood pressure (SBP) • Change in diastolic blood pressure (DPB) • Change in heart rate (Pulse)

Anaphylm Topline Pivotal Study Results: Single Dose (n=64)

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Anaphylm 12mg single dose study meets primary endpoints

Primary endpoints predefined as Anaphylm values bracketed between injectable products for (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.

Cmax Bracketing

	Amnt (pg/mL)
Auvi-Q	520.6
Anaphylm	470.2
EpiPen	469.2
Adrenalin	308.2

All figures are baseline corrected and geometric means

Partial AUCs Bracketing (hr*pg/mL)

	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$	$AUC_{0\text{-}45min}$
Adrenalin	3.3	11.3	29.7	74.6
Anaphylm	17.7	71.5	104.8	138.6
EpiPen	23.4	62.0	109.7	179.8
Auvi-Q	21.8	61.5	112.4	200.3

$pAUC_{0\text{-}20min}$ not statistically different ($p > 0.05$) (comparison to EpiPen))

All figures are baseline corrected and geometric means

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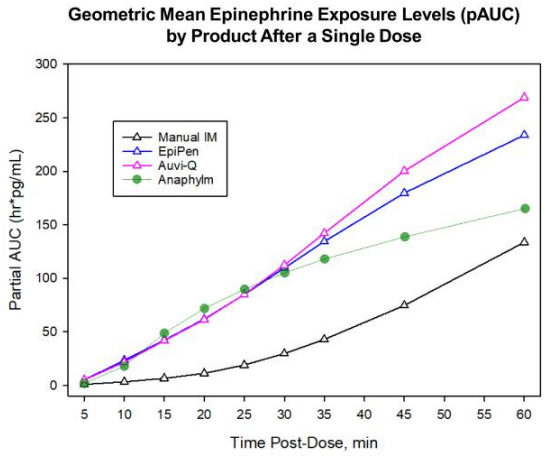
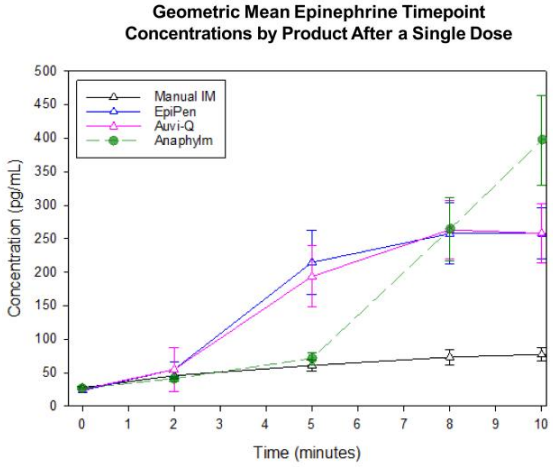
Anaphylm is biocomparable to injectors



- Anaphylm partial AUC values are comparable to autoinjectors for 30 minutes post dosing and remain bracketed past 60 minutes after dosing

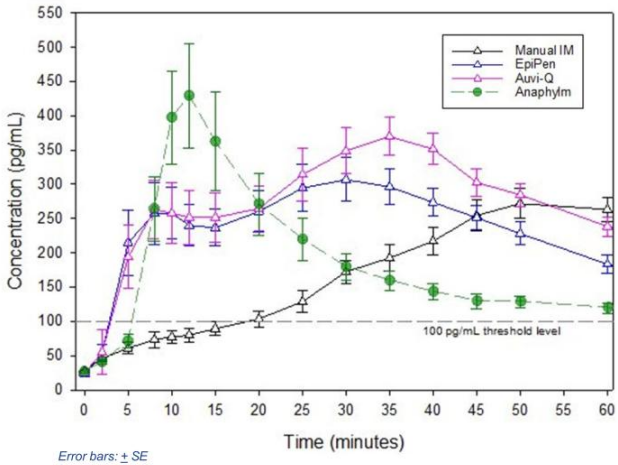
Anaphylm continues to show rapid uptake during the first 10 minutes after dosing



- Rapid uptake follows film dissolution and absorption profile

Anaphylm remains above 100 pg/mL at 60 minutes after dosing

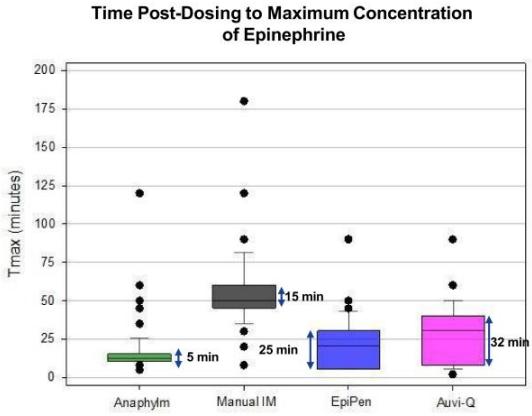
Geometric Mean Epinephrine Concentrations by Product After a Single Dose



Error bars: ± SE

- Anaphylm achieves rapid PK within first 10 minutes similar to autoinjectors
- Anaphylm exceeds Adrenalin beginning at 2 minutes
- PK is sustained greater than Adrenalin out to 35 minutes
- PK is sustained greater than 100 pg/mL for duration of observation period

Time to maximum concentration (Tmax) of Anaphylm significantly more consistent compared to autoinjectors



- Tmax is a surrogate for speed of absorption, a critical factor in treating anaphylaxis
- Tmax consistency is an important measure of clinical performance
- Anaphylm Tmax interquartile range (5 min) is significantly more consistent than EpiPen, Auvi Q, and Adrenalin
- Anaphylm median Tmax of 12 minutes is faster than EpiPen (20 mins), Auvi Q (30 mins), and Adrenalin (50 mins)

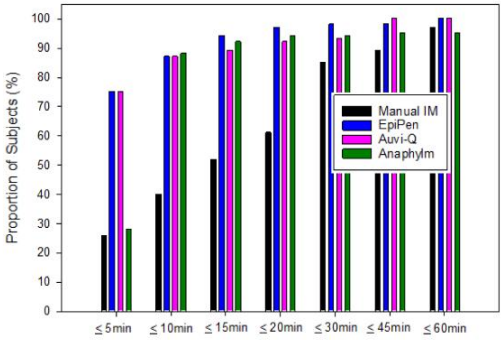
Anaphylm reaches 100 pg/mL threshold as rapidly as EpiPen and faster than Adrenalin

Common FDA-cited key threshold level is an important target to achieve hemodynamic stability and curb the progression of anaphylaxis.

Time (minutes)	Number and Proportion of Subjects >100 pg/mL			
	Adrenalin* (N=62)	EpiPen (N=63)	Auvi-Q (N=61)	Anaphylm (N=64)
5	16 (26%)	47 (75%)	46 (75%)	18 (28%)
10	**25 (40%)**	**55 (87%)**	**53 (87%)**	**56 (88%)**
15	32 (52%)	59 (94%)	54 (89%)	58 (92%)
20	37 (61%)	61 (97%)	56 (92%)	59 (94%)
30	53 (85%)	62 (98%)	57 (93%)	60 (94%)
45	55 (89%)	62 (98%)	61 (100%)	61 (95%)
60	60 (97%)	63 (100%)	61 (100%)	61 (95%)

* Subject 139 is missing the 15-, and 20-minute concentration. Therefore, the percent at these timepoints is based on N=61.
@ Subject 108 is missing the 15- and 20-minute concentration. Therefore, the percent at these timepoints is based on N=63.

Proportion of Subjects Achieving 100 pg/mL in Single Dose Pivotal Study



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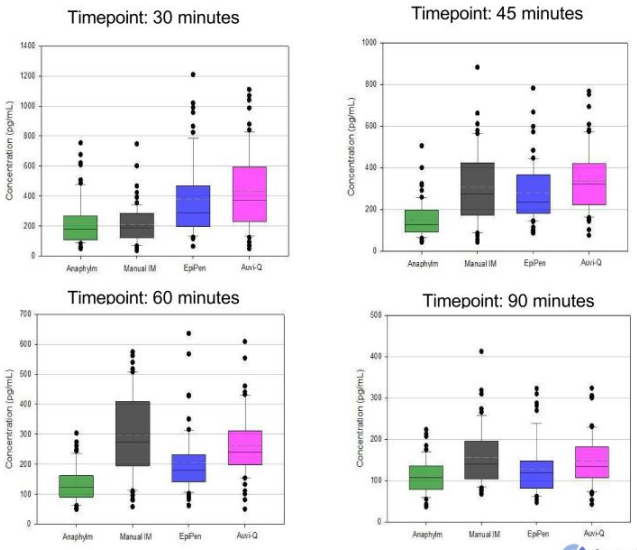
Anaphylm overlaps with comparators at later timepoints (PK Sustainability)

- Anaphylm remains above the 100 pg/mL threshold well past the critical time for treatment
- Overlapping exposures even after 30 minutes with comparators reinforces comparable sustainability beyond the critical time for treatment



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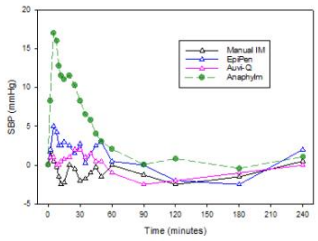
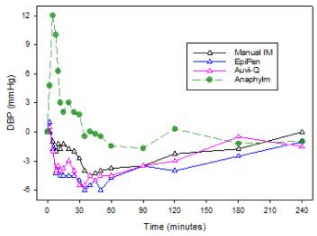
Pharmacodynamics consistent with previous results

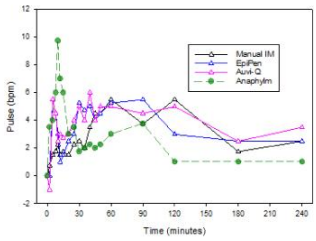
Median Change in Systolic Blood Pressure over Time



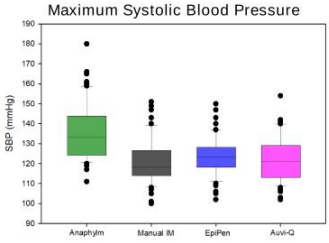
Median Change in Diastolic Blood Pressure over Time



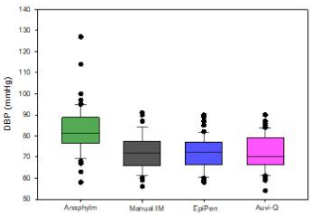
Median Change in Pulse over Time



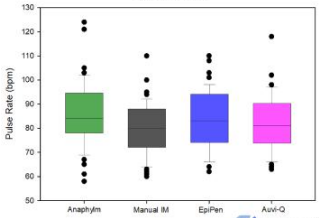
Maximum Systolic Blood Pressure



Maximum Diastolic Blood Pressure



Pulse Rate



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Tolerability summary

	Severity	12 mg DESF[1] Incidence (%)	0.3 mg Man. IM[2] Incidence (%)	0.3 mg EpiPen[3] Incidence (%)	0.3 mg Auvi-Q[4] Incidence (%)	0.5 mg Man. IM[5] Incidence (%)
Cardiac Disorders		**1.6%**	**1.6%**	**9.5%**	**1.6%**	**18.8%**
Palpitations (subjective, patient-reported)	Mild	1.6%	1.6%	6.3%	1.6%	12.5%
Tachycardia (objective, clinician-measured)	Mild	0%	0%	3.2%	0%	6.3%
GI						
Emesis*	Mild	1.6%	0%	0%	0%	0%

- All TEAE categorized as mild (Grade 1).
- No SAEs; No severe AEs
- TEAEs were transient and resolved without major intervention
- Primary cardiovascular TEAE associated with mild palpitations
- No intervention required
- No AEs of AV block or tachycardia for DESF group
- No severe cardiac events observed

1. AQ109301, T1, N=64; 2. AQ109301, R1, N=62; 3. AQ109301, R2, N=63; 4. AQ109301, R5, N=61; 5. DESF-AX-101, R1, N=16
**emetic event must be observed and have pH<4*

Anaphylm TopLine Pivotal Study Results: Repeat Dose (n=36)

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Anaphylm 12mg repeat dose study meets primary endpoints

Primary endpoints predefined as Anaphylm values greater than or equal to (1) geometric mean concentration at 45 minutes and 60 minutes and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, and $AUC_{0\text{-}30min}$.

Geometric Mean Concentrations (pg/mL)

	45 minutes	60 minutes	Cmax	CV%
Anaphylm	380	275	2028	91%
EpiPen	497	347	899	47%
Adrenalin	365	432	539	56%

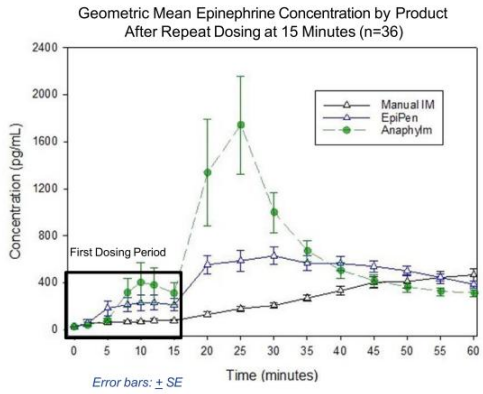
**Model based estimates from ANOVA for Conc45min and Conc60min Difference between Anaphylm and EpiPen concentrations at 60 minutes not statistically different (p>0.05)*

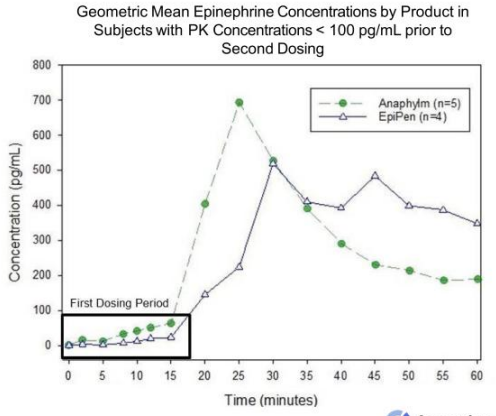
Partial AUCs Bracketing (hr*pg/mL)

	$AUC_{0\text{-}10min}$	$AUC_{0\text{-}20min}$	$AUC_{0\text{-}30min}$
Adrenalin	4.1	13.8	39.0
Anaphylm	20.3	120.8	378.5
EpiPen	21.0	69.8	172.3

Repeat dose study indicates subjects at risk for needing a second dose rapidly exceed threshold value of 100 pg/mL with Anaphylm

*100% of subjects were > 100 pg/mL within **5 minutes** of receiving a second dose of Anaphylm compared to 30 minutes for EpiPen. Overall study data demonstrates repeat dosing is well-tolerated for all evaluated subjects.*





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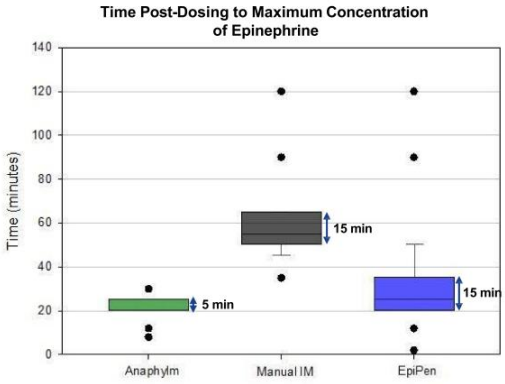
Time to maximum concentration (Tmax) of Anaphylm remained significantly more consistent compared to autoinjectors

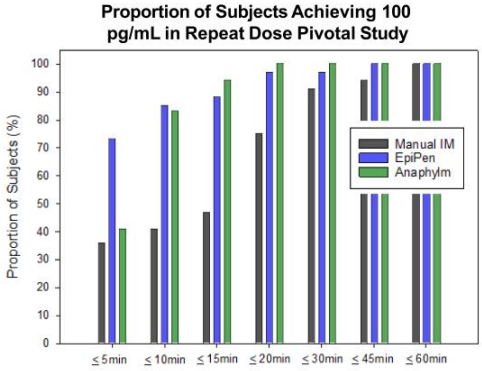


- Anaphylm median Tmax of 10 minutes after second dosing demonstrates rapid absorption, a critical factor for initial treatment failures
- Anaphylm Tmax interquartile range (5 min) is significantly more consistent than EpiPen and Adrenalin
- Anaphylm median Tmax is the same as EpiPen and is significantly faster than Adrenalin

All Anaphylm subjects reach or exceed 100 pg/mL five minutes after second dosing

Common FDA-cited key threshold level is an important target to achieve hemodynamic stability and curb the progression of anaphylaxis.

Time (minutes)	Number and Proportion of Subjects >100 pg/mL		
	Adrenalin (N=36)	EpiPen (N=35)	Anaphylm (N=36)
5	13 (36%)	25 (74%)	15 (42%)
10	15 (42%)	30 (86%)	30 (83%)
15	17 (47%)	31 (89%)	34 (94%)
20	27 (75%)	34 (97%)	**36 (100%)**
30	33 (92%)	34 (97%)	36 (100%)
45	34 (94%)	**35 (100%)**	36 (100%)
60	**36 (100%)**	35 (100%)	36 (100%)



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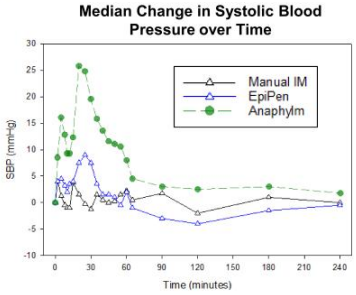
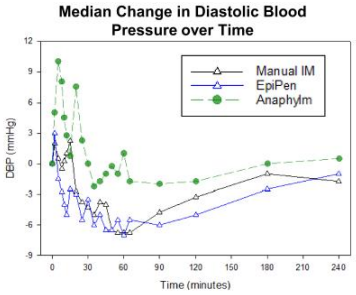
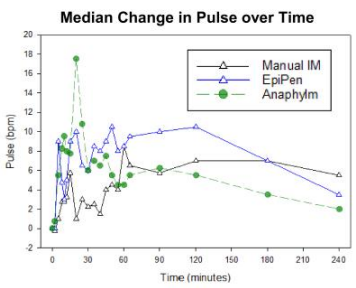
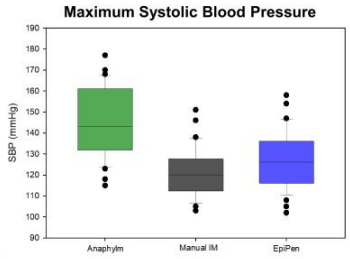
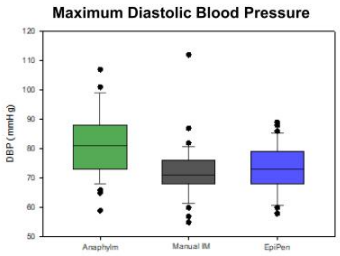
Pharmacodynamics remain consistent with past performance

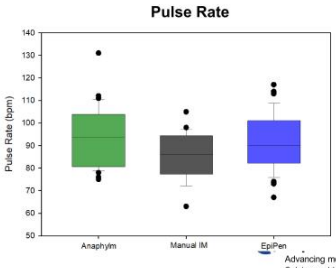












Tolerability summary

Preferred Term System Organ Class	Severity	12 mg DESF[1] Incidence (%)	0.3 mg Man. IM[2] Incidence (%)	0.3 mg EpiPen[3] Incidence (%)	0.5 mg Man. IM[4] Incidence (%)
Cardiac Disorders		**13.9%**	**5.6%**	**8.6%**	**18.8%**
Palpitations (subjective, patient-reported)	Mild	13.9%	2.8%	5.7%	12.5%
Tachycardia (objective, clinician-measured)	Mild	0%	2.8%	2.9%	6.3%
GI					
Emesis*	Mild	5.6%*	0%	0%	0%

- Most TEAE categorized as mild (Grade 1)
- No SAEs; No severe AEs; No severe cardiac events observed
- TEAEs were transient and resolved without major intervention
- Primary cardiovascular TEAE associated with mild palpitations
- No intervention required
- No AEs of AV blocks or tachycardia for DESF repeat dose group
- For majority of subjects, Anaphylm observed concentration levels < EpiPen observed levels at all timepoints

[1]AQ109301, T2, N=36; [2]AQ109301, R3, N=36; [3]AQ109301, R4, N=35; [4]DESF-AX-101, R1, N=16
*emetic event must be observed and have pH<4

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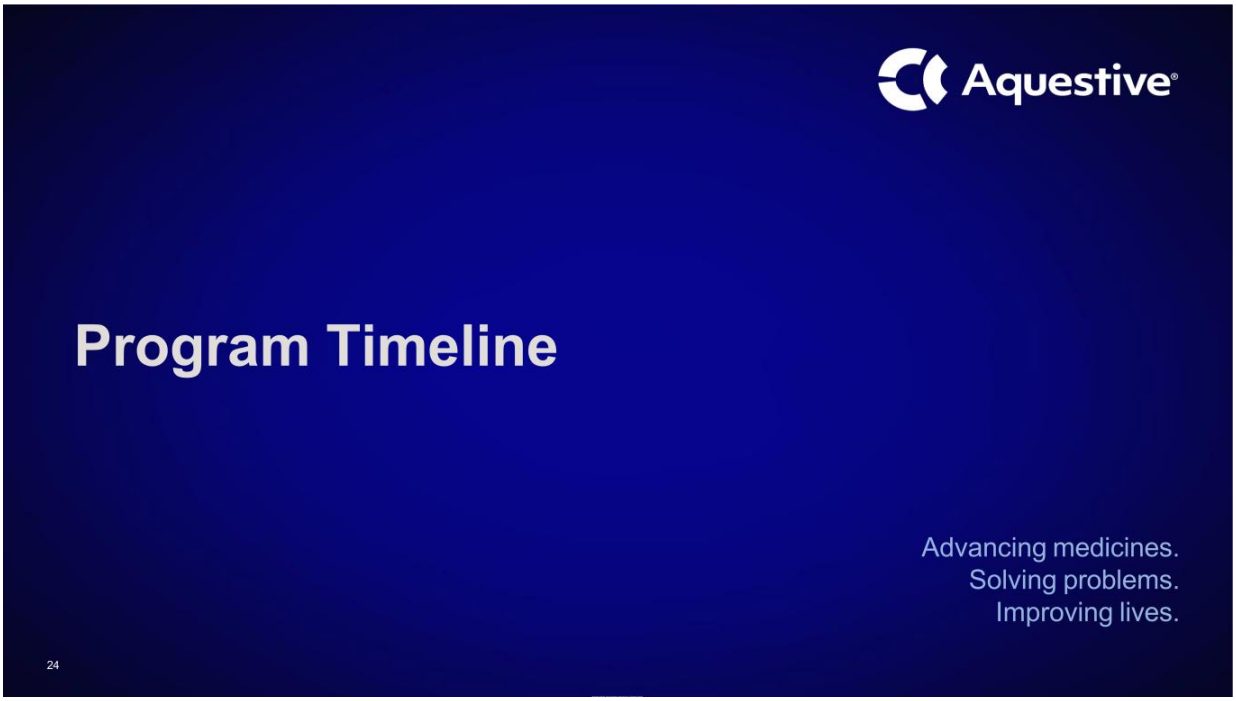
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Program Timeline
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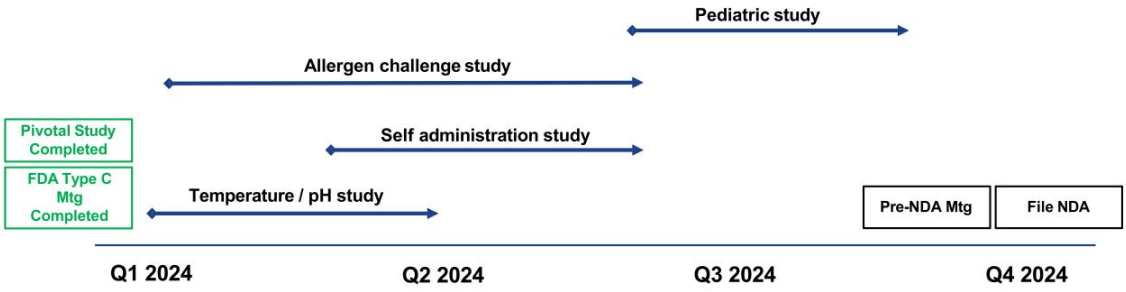
Anaphylm clinical trials to date

Study	Description	Study Status	N	Data Publicly Disclosed
210010	First-in-Human (FIH), Single Ascending Dose (SAD) study to evaluate safety and tolerability, as well as pharmacokinetic (PK) performance and pharmacodynamic (PD) effect, of DESF (Anaphylm)	Complete	44	Y
EPIPHAST Part 1	• Evaluate multiple formulations and strengths of DESF (Anaphylm) • Benchmark against epinephrine 0.5mg manual intramuscular (IM) injection	Complete	35	Y
Part 2	• Confirm benchmarking vs. epinephrine 0.3mg manual IM injection • Evaluate intrasubject variability and adequacy of washout period	Complete	24	Y
Part 3	• Characterize conditions of use and effect of use errors (different saliva hold times and directly swallowing film) • Film performance after ingestion of sticky substance (peanut butter)	Complete	24	Y
EPIPHAST II	Characterize: • repeat dose performance of DESF (Anaphylm) • performance against EpiPen	Complete	24	Y
AQ109102	Evaluate: • differences in PK and PD results based on changes to administration instructions • additional repeat dose data on DESF (Anaphylm) • performance of various approved auto-injectors	Complete	30	Y
AQ109103	Further characterization of PK performance and PD effect of DESF (Anaphylm) to inform pivotal study design	Complete	24	Y
AQ109106	Evaluate differences in PK and PD results based on changes to administration instructions	Complete	35	Y
AQ109301	Pivotal pharmacokinetic study	Complete	Part A=64 Part B=36	N

Agency interactions on Anaphylm program to date

Interaction	Key Takeaways
Pre-IND Meeting *(December 1, 2021)*	• 505(b)(2) NDA regulatory approval pathway acceptable (no efficacy trials required) • Bracket PK to 0.3mg IM and safety to 0.5mg IM • Evaluate potential for extrinsic factors to impact DESF (ANAPHYLM) absorption
Stability Excursion Protocol Review *(July 29, 2022)*	• Design and planned analysis of the proposed excursions are reasonable and can be expected to provide data to support product and patient labeling
End Of Phase 2 (EOP2) Meeting-CMC Meeting Feedback *(October 4, 2022)*	• Proposed Chemistry Manufacturing and Controls (CMC) package for both active pharmaceutical ingredients (API) and DESF (Anaphylm) considered sufficient and reasonable for future NDA filing
Nonclinical Study Plans *(October 11, 2022)*	• Aligned with FDA on NDA, enabling nonclinical toxicology package
EOP2 Meeting *(November 15, 2022)*	• Reaffirmed 505(B)(2) regulatory approval pathway acceptable (no efficacy trials required) • Modified bracketing strategy to compare PK performance to IM and autoinjectors • Use during conditions of anaphylaxis to be considered in overall risk/benefit profile
FDA Response to General Correspondence *(March 1, 2023)*	• FDA agreed to review pivotal protocol • FDA agreed to separate meeting to align on risk/benefit characterization after pivotal study alignment
FDA Response to Pivotal Study Protocol *(October 9, 2023)*	• Received positive feedback from FDA • Proposed endpoints sample size, and statistical analysis found reasonable • Utilizes final dosing instructions from Study AQ109106
FDA Type C Meeting *(January 31, 2024)*	• Completed Q1 2024 • Addressed EOP2 open items and pediatric studies

Projected clinical timeline



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Plan for allergen-induced study

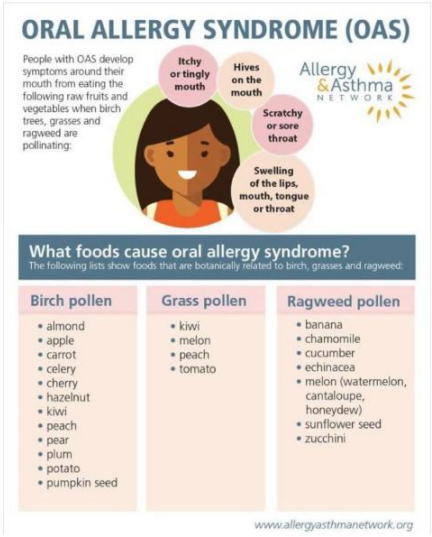
Utilize known OAS population to conduct allergen-challenge study

- Step 1: introduce allergen to patient
- Step 2: monitor for symptoms (minimum 15 minutes)
- Step 3: dose Anaphylm
- Step 4: conduct blood draws to assess Anaphylm pharmacokinetics

Note: a 2nd non-challenge arm will be performed to establish baseline

Model advantages

- Known population with localized response
- Study can be performed rapidly
- Isolates edema vs. confounding factors (such as congestion)



FDA Type C Meeting

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The Type C meeting was designed to address the open items from our End-of-Phase 2 meeting held in November 2022

Aquestive press release from December 22, 2022:

"The FDA also provided comments on potential issues the Company will need to address in regard to a sublingually delivered product including

(1) the impact of any product hold time,

(2) the potential for emesis (vomiting), and

(3) the impact of potential mouth conditions such as angioedema (swelling)."

(1) the impact of any product hold time

Our position	We removed hold time from our dosing administration thereby alleviating the issue.
Our interpretation of FDA meeting minutes	We have adequately addressed their concerns.
Additional information provided by FDA	For administration during pediatric studies, we should clarify film sizing and instructions.

(2) the potential for emesis (vomiting)

Our position	We will characterize events of emesis for consolidated analysis in the NDA.
Our interpretation of FDA meeting minutes	Recommended additional information (such as narratives for patients who require medical intervention) and reminded us that any impact on safety will be a review issue.

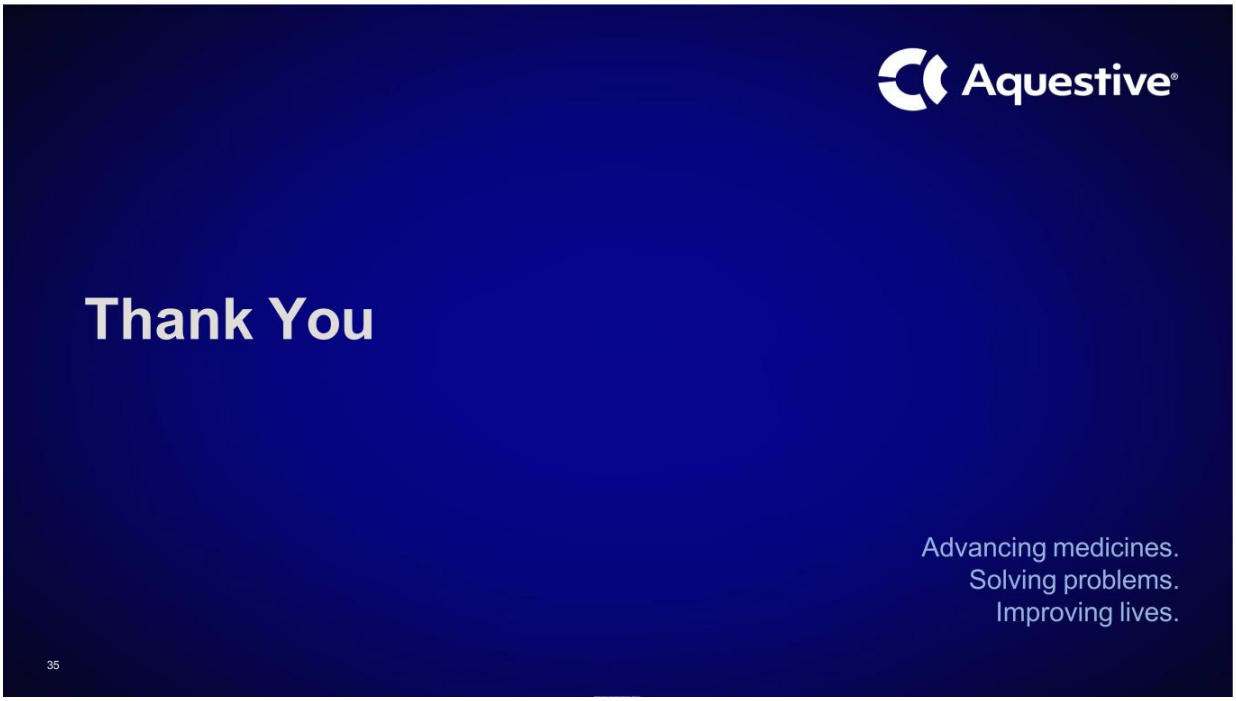
(3) potential for mouth conditions (such as angioedema)

Our position	We proposed a histamine study in healthy volunteers followed by the administration of Anaphylm.
Our interpretation of FDA meeting minutes	The FDA did not agree with this model. The FDA proposed a clinical model to assess the impact of allergen-induced oral physiological changes on the PK/PD of Anaphylm. We believe the FDA's proposal is a **SIGNIFICANTLY** easier study to perform and have agreed to move forward with this model.

Completeness of clinical development program

In addition to addressing the FDA comments from our EOP2 meeting, we requested the FDA provide feedback on the completeness of our overall program.

Our position	Completion of the planned clinical studies will be sufficient for filing an NDA.
Our interpretation of FDA meeting minutes	The FDA acknowledged that we have made "substantial progress" and reserved judgement until after they have reviewed our current clinical studies (i.e. the pre-NDA meeting). They reminded us that PK sustainability is an important issue for them and referenced the May 11 Ad Comm. They also reminded us that higher PK and PD profiles of the repeat dose must be justified to the extent we intend to rely on systemic safety of epinephrine injection products.
Additional information provided by FDA	We are aligned with the FDA with recommendation to initiate pediatric studies after completing our adult studies (pivotal study, self-administration, allergen study). (note: multiple nasal spray programs changed their dose strengths AFTER pediatric studies had been initiated)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