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): May 31, 2023

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 May 31, 2023, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing topline results from its recent pilot studies for Anaphylm™ (epinephrine) Sublingual Film that were completed following the End-of-Phase 2 meeting with the FDA (the "Pilot Studies") 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. A copy of the press release and investor presentation are attached to this Current Report on Form 8-K as Exhibits 99.1 and 99.2, respectively, and incorporated into this Item 7.01 by reference. The Company reserves the right to discontinue the availability of the investor presentation 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 Exchange Act, nor shall it be deemed to be incorporated by reference in any filing under the 33 Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

On May 31, 2023, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing topline results from its recent pilot studies for its product candidate Anaphylm™ (epinephrine) Sublingual Film for the treatment of severe allergic reactions, including anaphylaxis, which were completed following the End-of-Phase 2 meeting with the FDA (the "Pilot Studies").

The Pilot Studies included examining (1) differences in pharmacokinetic (PK) results based on changes to administration instructions for Anaphylm, (2) additional repeat dose data on Anaphylm, and (3) the differences between Anaphylm and several FDA approved auto-injectors and a 0.3mg manual injection of epinephrine. The Pilot Studies consisted of a single dose PK study of Anaphylm 12mg in healthy subjects, 1-period, 3 cohorts, n=12 for each cohort, with revised administration instructions to eliminate hold time periods. Anaphylm was applied to the sublingual mucosa and held in place until dissolved with no prescribed salivary hold time. The Pilot Studies included results demonstrating a geometric mean maximum epinephrine concentration (Cmax) of 400pg/mL and a median Tmax of 10 minutes, with a Tmax range of 5 minutes to 20 minutes, the fastest median Tmax result to date for the Anaphylm development program. These results demonstrate improvements from previous administration instructions as the Company continues to optimize film administration in the development program of Anaphylm.

Data from the Pilot Studies showed that epinephrine levels for Anaphylm were higher than epinephrine levels from a epinephrine 0.3mg manual injection, at all timepoints within the first 10 minutes following dosing. Based on interactions with the FDA, the Company continues to believe that similarity to approved auto-injectors during the first 10 minutes following administration of Anaphylm is preferred. All but one of the subjects receiving Anaphylm exceeded epinephrine concentrations of 100 pg/mL by 15 minutes following dosing. Given that manual epinephrine injections are rarely used outside of a clinical setting, the Company conducted the Pilot Studies to compare three different auto-injectors to a 0.3mg manual injection. These auto-injectors were Auvi-Q® (epinephrine) 0.3mg auto-injector, EpiPen® (epinephrine) 0.3mg auto-injector, and a generic equivalent to EpiPen. The geometric mean Cmax levels for EpiPen, generic epinephrine auto-injector, and Auvi-Q were 628, 573, and 646pg/mL, respectively, while the median Tmax times were 10, 15, and 30 minutes, respectively. As a comparison in the same study, the geometric mean Cmax level for epinephrine 0.3mg manual injection was 344pg/mL with a median Tmax of 50 minutes. These data will be used to help identify the appropriate auto-injector(s) and PK values for comparing Anaphylm' s performance in the Company's expected upcoming pivotal study.

In addition, in the Pilot Studies multiple pharmacodynamic markers were monitored, including systolic blood pressure, with a median increase of 22mmHg in systolic blood pressure being observed at 2 minutes following dosing, and a change from baseline maintained for 1 hour following dosing. Public data shows that injected epinephrine produces moderate increases in SBP and pulse with no measurable effect on DBP.

In another arm of the Pilot Studies, the Company completed a repeat dose study with subjects given a second dose 25 minutes after the initial dose. Importantly, minimal administration instructions were utilized, potentially simulating non-compliance with the expected administration instructions for Anaphylm. Consistent with the Company's previous repeat dose study, Anaphylm produced a median Tmax of 8 minutes when re-administered after 25 minutes. Cmax and overall exposure were comparable to the auto-injectors demonstrating that a second dose of Anaphylm can be used effectively at a later time period, as needed.

Consistent with previously reported trial results, Anaphylm was observed to be well-tolerated with no serious adverse events reported.

The Company expects to refine administration instructions in its ongoing pilot study (AQ109103), finalize its pivotal study protocol for submission to the FDA for review and alignment in Q3 2023, and begin execution of its pivotal study in Q4 2023.

The product profile, data from our trials, and related statements regarding Anaphylm have not been approved by the FDA. Aquestive has received conditional acceptance of the use of the trade name Anaphylm, which is subject to final FDA approval of the product candidate.

Cautionary Note Regarding 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; the potential benefits Anaphylm could bring to patients, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on the Company's business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

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; risk of the Company's failure to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for FDA approval of Analphylm; risk of delays in or the failure to receive FDA approval of Anaphylm and there can be no assurance that we will be successful in obtaining FDA approval of Anaphylm; 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; risk of the rate and degree of market acceptance of our product candidate Anaphylm; risk of the success of any competing products; uncertainties related to general economic, political, 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 its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed with the Securities and Exchange Commission.

In addition, topline and interim data from clinical trials may not be indicative of final results, and the results of early clinical trials may not be indicative of the results of later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the FDA or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available. 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 Current Report on Form 8-K, whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely upon this information as current or accurate after its publication date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	
99.1	Aquestive Therapeutics, Inc. Press Release dated May 31, 2023.
99.2	Aquestive Therapeutics, Inc. Anaphylm™ (epinephrine) Sublingual Film Pilot Clinical Studies Supplemental Materials Dated May 2023

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: May 31, 2023

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.

Title: Chief Financial Officer

(Principal Financial Officer)

Aquestive Therapeutics Reports Positive Results from Latest Clinical Studies Evaluating Pharmacokinetic and Pharmacodynamic Performance of Anaphylm ™ (epinephrine) Sublingual Film and Provides Findings from Recent Auto-Injector Clinical Study

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

- *Time to maximum blood concentration (median Tmax) for Anaphylm was 10 minutes with a range of 5 to 20 minutes*
- *Early drug exposure at 10 minutes (partial area under the curve, or $pAUC_{0\text{-}10min}$) for Anaphylm was similar to Auvi-Q® (epinephrine injection) auto-injector 0.3mg and over 4 times higher than epinephrine 0.3mg manual injection, while lower than both EpiPen® (epinephrine) auto-injector 0.3mg and the generic equivalent product*
- *Pharmacodynamic effects were observed as early as 2 minutes for both Anaphylm and the auto-injectors*
- *Target range for comparing Anaphylm to approved epinephrine formulations was successfully identified for upcoming pivotal study*
- *Company continues to expect to submit the protocol for the pivotal study to the FDA in third quarter 2023*

WARREN, N.J., May 31, 2023 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) (the "Company" or "Aquestive"), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today released topline clinical data from recent pilot studies that were completed following the End-of-Phase 2 meeting with the FDA. The studies included examining (1) differences in pharmacokinetic (PK) results based on changes to administration instructions, (2) additional repeat dose data on Anaphylm, and (3) the differences between approved auto-injectors.

"These data continue to show rapid absorption of epinephrine during the critical first ten minutes following administration of Anaphylm. As our scientific advisors and the FDA have previously stated, anaphylaxis is a serious condition that must be treated quickly. Simply put, every minute matters during a severe allergic reaction," said Daniel Barber, Chief Executive Officer of Aquestive. "We are pleased to share the latest clinical results from our recent pilot studies confirming the rapidity of epinephrine delivery as we continue the progression of our Anaphylm development program. We expect to submit the protocol for our pivotal PK trial to the FDA during the third quarter 2023 for the Agency's review and comments."

David Golden, M.D., allergist-immunologist and Associate Professor of Medicine at Johns Hopkins University, stated, "The latest clinical data for Anaphylm demonstrate that the sublingual film continues to deliver the pharmacokinetic and pharmacodynamic effects needed for the most effective treatment of anaphylaxis and to prevent the progression of anaphylactic reactions. We know that early and high levels of epinephrine are critical in the treatment of this life-threatening condition."

Single Administration Pilot PK Study

The Company recently completed a single dose PK study of Anaphylm 12mg in healthy subjects with revised administration instructions. Anaphylm was applied to the sublingual mucosa and held in place until dissolved with no prescribed salivary hold time. The study resulted in a geometric mean maximum epinephrine concentration (Cmax) of 400pg/mL and a median Tmax of 10 minutes, with a Tmax range of 5 minutes to 20 minutes. This is the fastest median Tmax result to date for the Anaphylm development program. These results demonstrate meaningful improvements from previous administration instructions as the Company continues to optimize film administration.

Importantly, Anaphylm's epinephrine levels were significantly higher than epinephrine levels from the epinephrine 0.3mg manual injection from previous study data, at all timepoints within the first 10 minutes following dosing. Based on interactions with the FDA, the Company continues to believe that similarity to approved auto-injectors during the first 10 minutes following administration is preferred. All but one of the subjects receiving Anaphylm exceeded epinephrine concentrations of 100pg/mL by 15 minutes following dosing.

In the same study, multiple pharmacodynamic markers were monitored including systolic blood pressure. A median increase of 22mmHg in systolic blood pressure was observed at 2 minutes following dosing, with a significant change from baseline maintained for 1 hour following dosing. There were no significant adverse events reported during the study and Anaphylm continues to be safe and well-tolerated by subjects.

Pilot Crossover PK Study Comparing Different Auto-injectors and Epinephrine 0.3mg Manual Injection, Including a Repeat Dose of Anaphylm

Given that manual epinephrine injections are rarely used outside of a clinical office setting, the Company conducted a pilot PK study to compare three different auto-injectors to the 0.3mg manual injection (Belcher Pharmaceuticals). These auto-injectors were Auvi-Q (epinephrine) 0.3mg auto-injector, EpiPen (epinephrine) 0.3mg auto-injector, and the generic equivalent to EpiPen (Teva Pharmaceutical USA). These data will also be used to help identify the appropriate auto-injector(s) and PK values for comparing Anaphylm's performance in the upcoming pivotal study.

The geometric mean Cmax levels for EpiPen, generic epinephrine auto-injector, and Auvi-Q were 628, 573, and 646pg/mL, respectively, while the median Tmax times were 10, 15, and 30 minutes, respectively. As a comparison in the same study, the geometric mean Cmax level for epinephrine 0.3mg manual injection was 344pg/mL with a median Tmax of 50 minutes.

In another arm of this study, the Company also completed a repeat dose study with subjects given a second dose 25 minutes after the initial dose. Importantly, minimal administration instructions were utilized potentially simulating non-compliance to Anaphylm's expected administration instructions. Consistent with the Company's previous repeat dose study, Anaphylm produced a median Tmax of 8 minutes when re-administered after 25 minutes. Cmax and overall exposure were comparable to the auto-injectors demonstrating that a second dose of Anaphylm can be used effectively at a later time period, as needed. There were no significant adverse events reported during any arms of this study.

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 Anaphylaxis

Anaphylaxis is a serious systemic hypersensitivity reaction 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 (AQST-109) is a polymer matrix-based epinephrine prodrug candidate product administered as a sublingual film that is applied under the tongue for the rapid delivery of epinephrine. The product is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The packaging for 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.

About Aquestive Therapeutics

Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. 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 our licensees in the U.S. and around the world. 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 proprietary product pipeline focused on treating diseases of the central nervous system and for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit Aquestive.com and follow us on LinkedIn.

Forward-Looking Statements

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submissions and regulatory reviews and approval of Anaphylm; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

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; risk of the Company's failure to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for FDA approval of Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm and there can be no assurance that we will be successful in obtaining FDA approval of Anaphylm; 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; risk of the rate and degree of market acceptance of our product candidate Anaphylm; risk of the success of any competing products; uncertainties related to general economic, political, 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 its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed with the Securities and Exchange Commission.

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Investor Inquiries:

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Aquestive®

Anaphylm™ (epinephrine) Sublingual Film

Pilot Clinical Studies Supplemental Materials

May 2023

Advancing medicines.
Solving problems.
Improving lives.

Forward Looking Statement

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The product profile, data from our trials, and related statements regarding Anaphylm have not been approved by the FDA. Aquestive has received conditional acceptance of the use of the trade name Anaphylm, which is subject to final FDA approval of the product candidate.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy the Company's securities, nor shall there be any sale of the Company's securities in any state or 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 jurisdiction.

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Goals of Pilot Study Work Following FDA End-of-Phase 2 (EOP2) Meeting

- Analyze the pharmacokinetic (PK) performance of several epinephrine auto-injectors and the 0.3mg manual injection – identify comparators for planned pivotal study
- Simplify the Anaphylm administration instructions to eliminate hold time
- Characterize PK and pharmacodynamic (PD) performance under different administration conditions

Key Takeaways from the Post-EOP2 Meeting Pilot Studies

Anaphylm (epinephrine) Sublingual Film 12mg

- Revised administration demonstrated a 10-minute median time to maximum concentration (Tmax)
- PK bracketed between available comparators for proposed pivotal study endpoints –both geometric mean maximum epinephrine concentration (Cmax) and partial area under the curve (pAUC)
- Safety profile in line with previous studies – no severe or serious events were observed

Auto-injector and 0.3mg Manual Injection Characterization

- Established PK variability within and across available auto-injectors
- Highlighted similarities across auto-injectors and a target range (bracket) between IM and auto-injectors
- Data will be utilized to statistically power the pivotal study

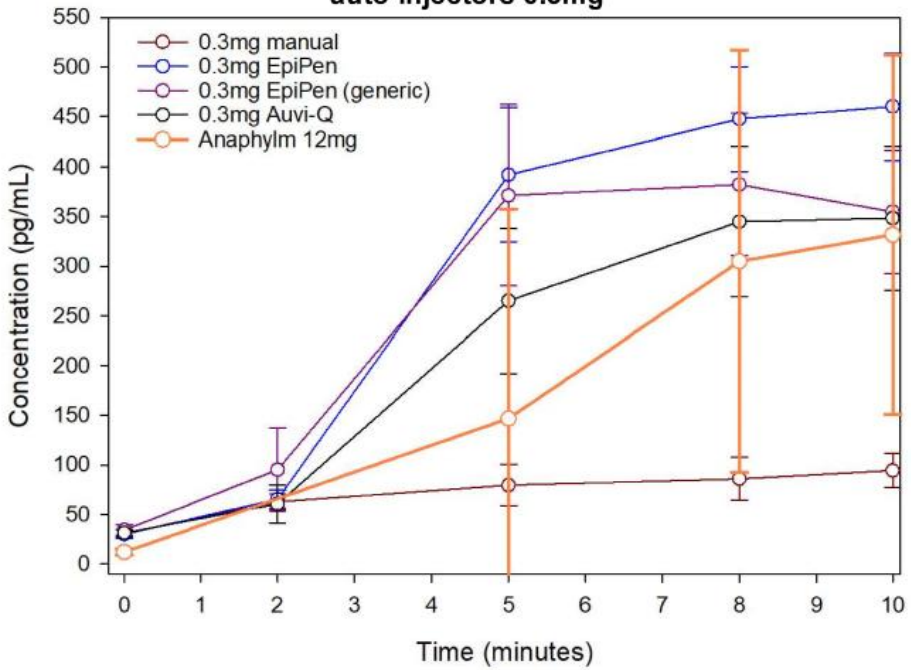
Pilot Study Designs

- Crossover Pilot PK Study Comparing Different Auto-injectors and 0.3mg Manual Injection to Anaphylm (Study AQ109102)
  - Healthy volunteers, 6-period, n=24
  - Designed to assess:
    - Variability of multiple epinephrine auto-injectors
    - Repeat dose of Anaphylm administered 25 minutes after the first dose
    - Anaphylm results providing minimal administration instruction

- Single Administration Pilot PK Study (Study AQ109106)
  - Healthy volunteers, 1-period, 3 cohorts, n=12 each cohort
  - Designed to assess:
    - Anaphylm performance utilizing updated administration instructions
    - Cross-study comparison to RLD bracket in AQ109102

Anaphylm: similar exposure to auto-injectors during the first 10 minutes following dosing*

Comparison of epinephrine plasma concentrations over time of Anaphylm 12mg to various approved auto-injectors 0.3mg



Comparison of epinephrine exposure at 10 minutes of Anaphylm 12mg to various approved auto-injectors 0.3mg

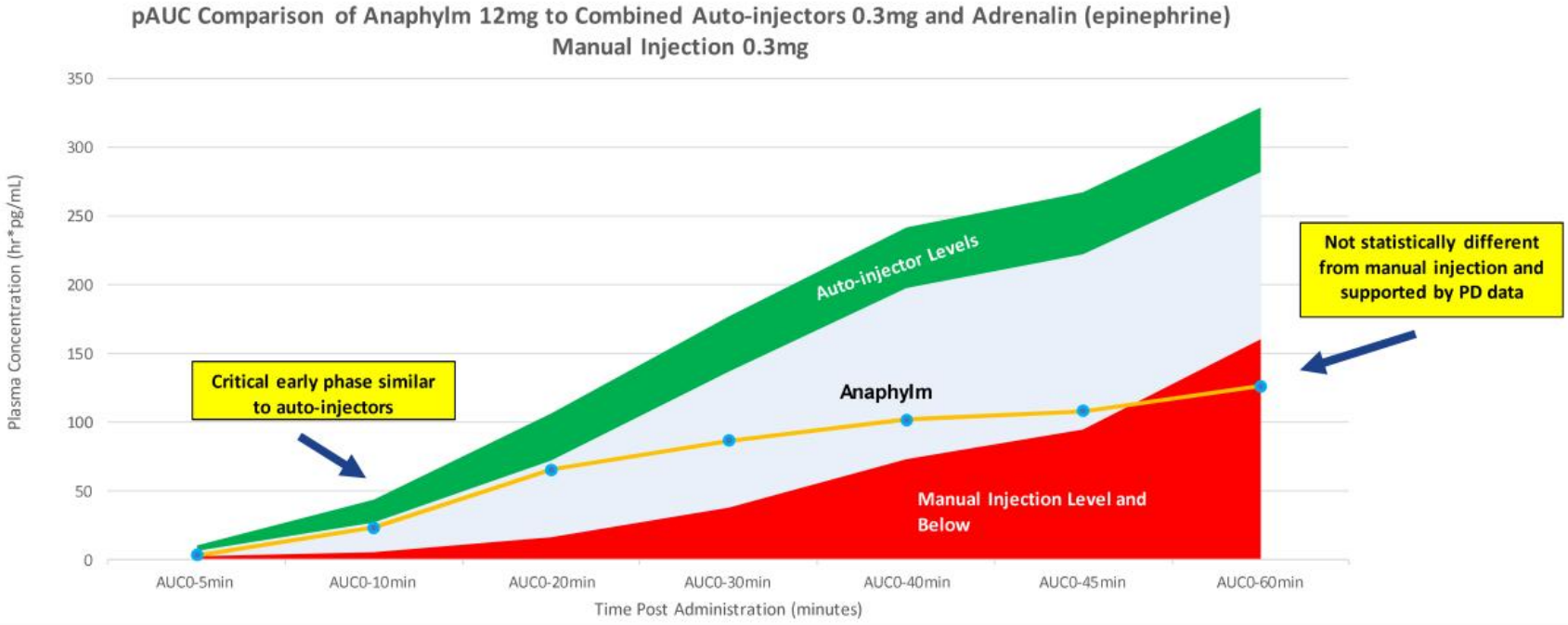
Parameter	0.3mg Manual (N=27)	Anaphylm (n=12)	Auvi-Q (N=29)	EpiPen (generic) (N=29)	EpiPen (N=27)
$AUC_{0\text{-}10min}$ (hr*pg/mL)	5.3	**23.1**	26.7	37.7	43.7

*Cross-study comparison from AQ109102 and AQ109106

Aquestive

Anaphylm data brackets existing products to 45 minutes*

FDA recommended bracketing between the exposures produced by auto-injectors and manual injection across a range of relevant time points characterized as pAUC.



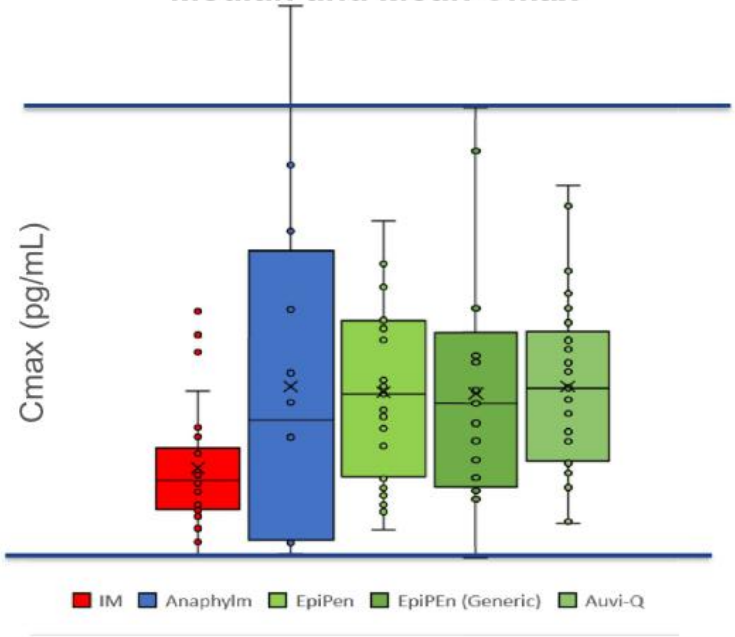
*Bracketing end points subject to alignment with FDA. Cross-study comparison from AQ109102 and AQ109106.

Aquestive

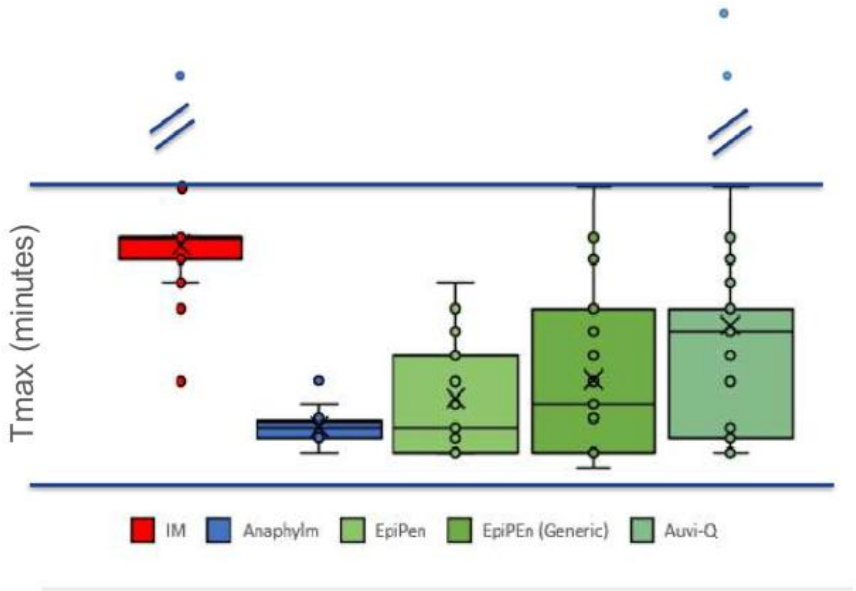
Key PK parameters compare favorably to existing treatments*

AnaphylIm 12mg provides a consistently fast Tmax with median and mean Cmax levels bracketed by the current FDA approved products.

Median and Mean Cmax



Median Tmax



Bars above show highest and lowest 75% quartile ranges of approved products

*Cross-study comparison of AQ109102 and AQ109106

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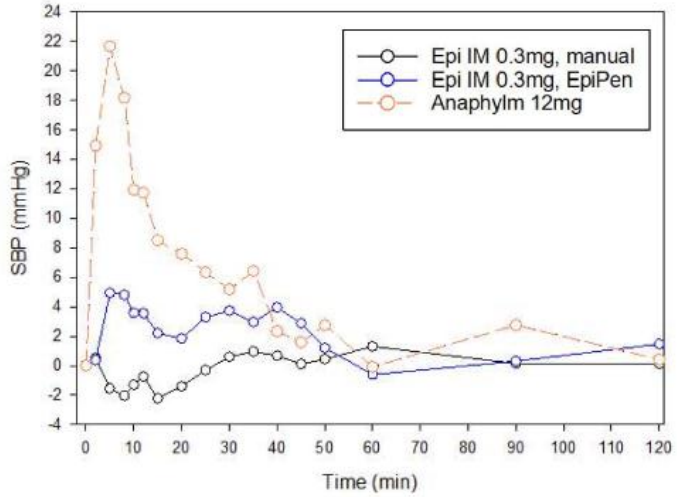
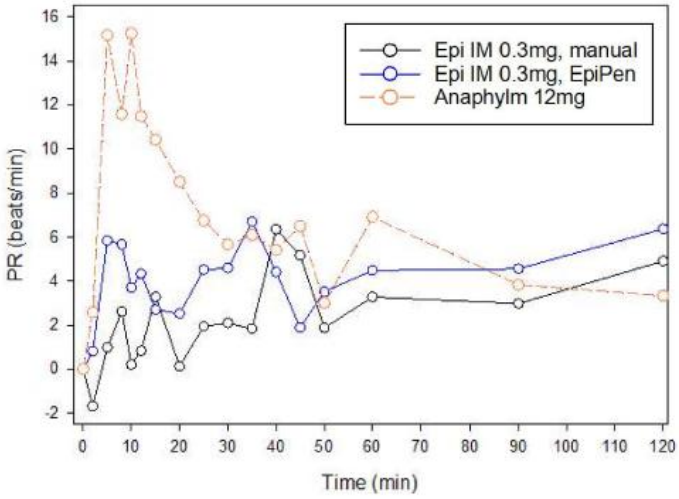
Clinically favorable PD from Anaphylm*

*Anaphylm demonstrates a rapid increase in systolic blood pressure (SBP), pulse and diastolic blood pressure (DBP) within **2 minutes.** Injected epinephrine produces moderate increases in SBP and pulse with no measurable effect on DBP.*

Mean Baseline Adjusted Changes in Systolic Blood Pressure Following Administration



Mean Baseline Adjusted Changes in Pulse Following Administration



*Cross-study comparison from AQ109102 and AQ109106

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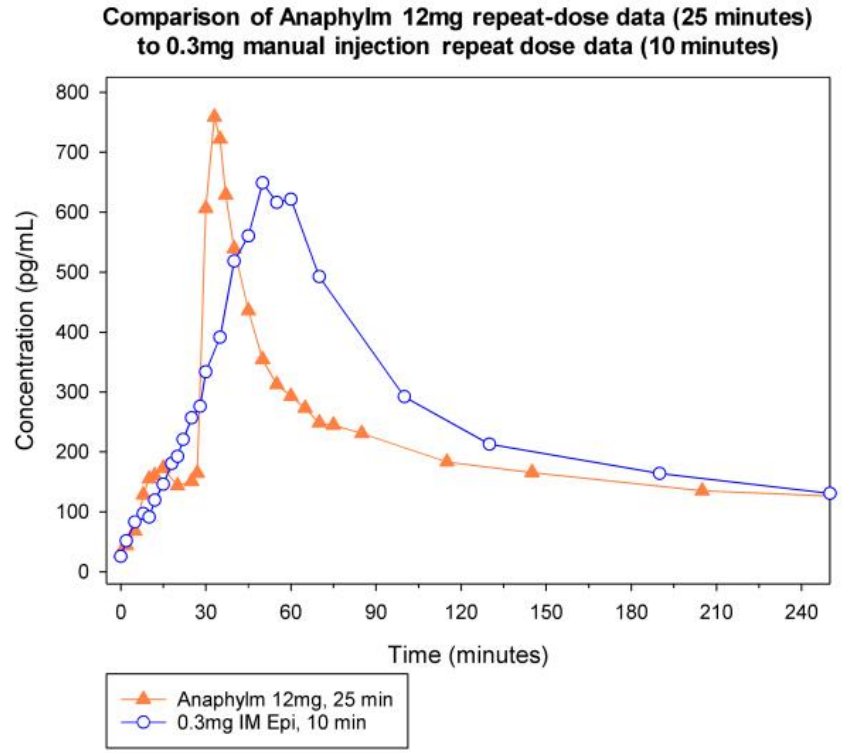
Repeat Dose – 25 Minutes*



Description	0.3mg Manual Injection Repeat Dose (10 min)	Anaphylm Repeat Dose (25 min)
# Subjects	23	27
C_{max} (pg/mL)	755	882
AUC_{0-t} (hr*pg/mL)	1300	776
AUC_{0-45} (hr*pg/mL)	181	207
Tmax (minutes)	50	33
Tmax Range (minutes)	30 - 70	10 - 70

Geometric Means presented for Cmax, AUC0-t, AUC0-45. Median Tmax.
Data presented from cross-study analysis of AQ109201 (0.3mg manual injection repeat dose at 10 min) and AQ109102 (Anaphylm repeat dose at 25 minutes - top-line results)

*Cross-study comparison from AQ109201 (EpiPhast II) and AQ109102

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Summary and Next Steps

- AQ109102 compared Anaphylm to multiple epinephrine auto-injectors
  - Confirmation of target range between existing reference listed drug (RLD) epinephrine injections
- AQ109106 focused on administration instructions
  - Confirmation of Anaphylm Cmax comparability
  - Confirmation that Anaphylm early pAUC parameters are bracketed by other RLDs
- Next Steps
  - Refine administration instructions in ongoing pilot study (AQ109103)
  - Finalize pivotal study protocol – expect to submit for FDA review/alignment in Q3 2023
  - Expect to begin execution of pivotal study in Q4 2023