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): June 6,2024

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

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, 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 Company's investor presentation is attached hereto as Exhibits 99.1 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 Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Exchange Act, 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 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Aquestive Therapeutics, Inc. Corporate Presentation dated June 6, 24

SIGNATURE

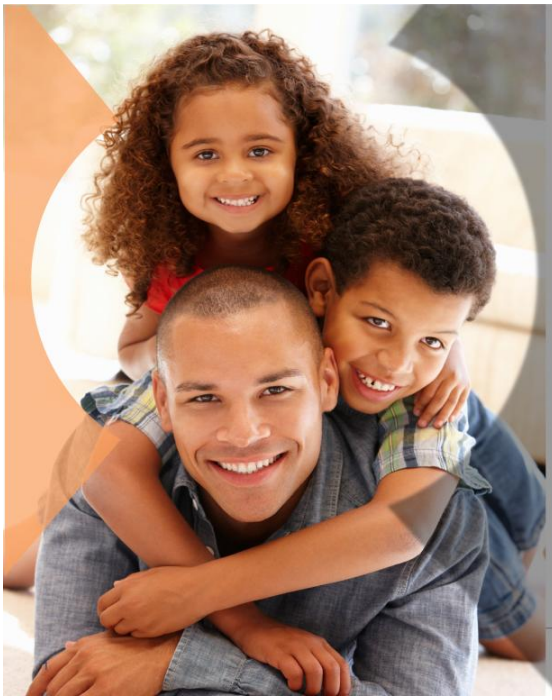
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: June 6, 2024

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.
Title: Chief Financial Officer
(Principal Financial Officer)



Aquestive®

Corporate Presentation

June 2024

Advancing medicines.
Solving problems.
Improving lives.

Aquestive®
Advancing medicines.
Solving problems.
Improving lives.

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 filing of our pivotal pharmacokinetic (PK) clinical trial and other supporting clinical studies for Anaphylm; regarding the advancement and relating timing through clinical development and approval by the FDA of the Company's other product candidates, including AQST-108 (epinephrine) Prodrug Topical Gel and our Adrenaverse™ epinephrine prodrug pipeline platform; the advancement of commercialization of our product Libervant™ (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy between two and five years of age; regarding the approval for U.S. market access of Libervant for these epilepsy patients aged 6 years and older, and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for this age group of the patient population; regarding the potential benefits our products and product candidates could bring to patients; regarding the ability to bring our product candidates, including Anaphylm, Libervant, AQST-108 and our other product candidates to market and achieve market acceptance and profitability for these products; regarding the rate and degree of market acceptance and demand for our licensed products; regarding the 2024 financial outlook of the Company and its growth and future financial and operating results and financial position; and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of global business and macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, and geopolitical conflicts, including the wars in Ukraine and Israel, and the impact of global pandemics on the Company's business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials, on the Company's commercialization activities for our products and regulatory submissions and regulatory reviews and approval of Anaphylm and our other product candidates, 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 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, AQST-108 and other product candidates; risks associated with the Company's distribution work for Libervant, including any delays or changes to the timing, cost and success of Company's distribution activities and expansion of market access to patients for Libervant; risk of the success of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product for pediatric epilepsy patients between 2 and 5 years of age; risk of delays in regulatory advancement through the FDA of Anaphylm, AQST-08 and our other drug candidates or failure to receive FDA approval at all; risk of the Company's ability to generate sufficient data in its pharmacokinetic (PK) and pharmacodynamic (PD) comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's future clinical trials and other 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 the success of any competing products; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for future commercialization of our product candidates; 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 Libervant for pediatric patients between 2 to 5 years of age and to fund future clinical development activities for Anaphylm, AQST-108 and our other product candidates and commercial activities should any such product candidates be approved by the FDA; risk that our manufacturing capabilities will be sufficient to support demand for Libervant and our licensed products in the U.S. and abroad; 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 any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; 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 Libervant for epilepsy patients between 2 to 5 years of age, Anaphylm, AQST-108 and our other products and product candidates and 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 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 adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; risks related to pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 2023 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, readers 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. We assume no obligation to update forward-looking statements, or outlook or guidance after the date of presentation, whether as a result of new information, future events or otherwise, except as may be required by applicable law.

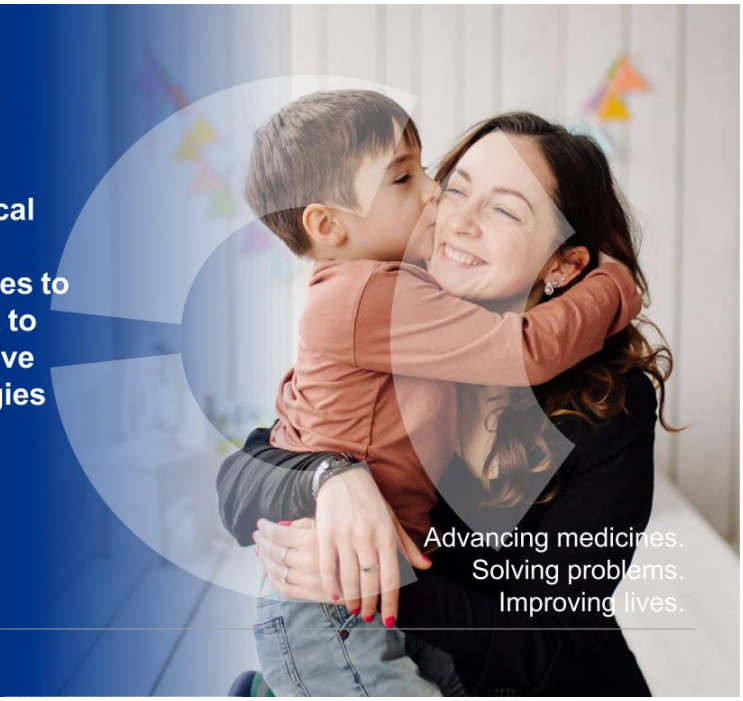
This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification 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 "Anaphylm" 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
Advancing medicines.
Solving problems.
Improving lives.

Who we are…

A publicly traded pharmaceutical company (NASDAQ: AQST) focused on advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies



Our drug delivery technologies

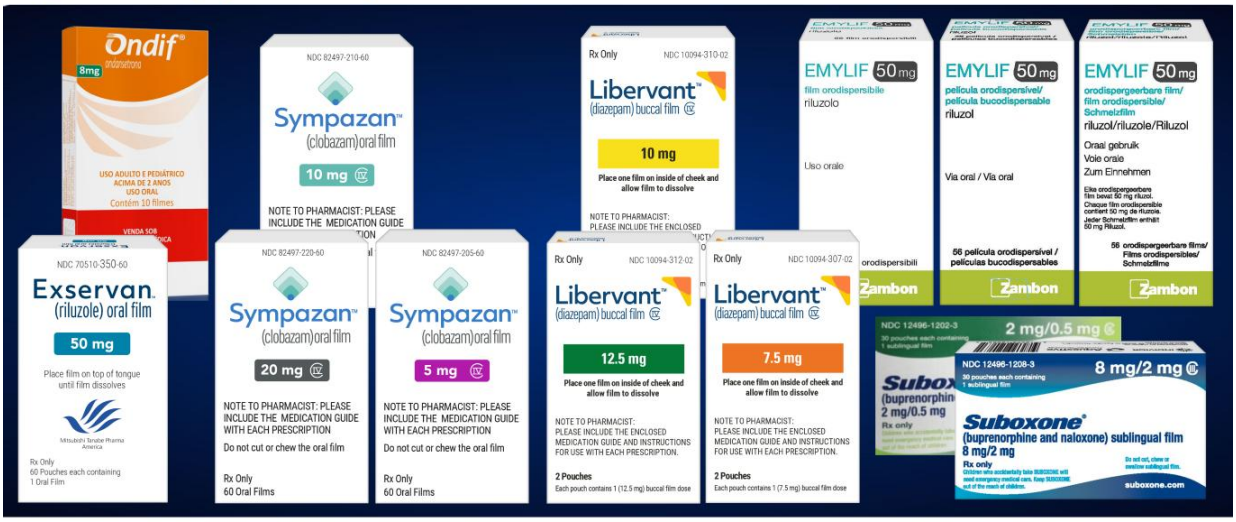
PharmFilm®

Adrenaverse™ Prodrug Platform

Adrenaverse platform contains a library of over 20 epinephrine prodrugs *that demonstrate control of absorption and conversion rates across a variety of dosage forms and delivery sites, including allergy, topical (dermatological), and more.*

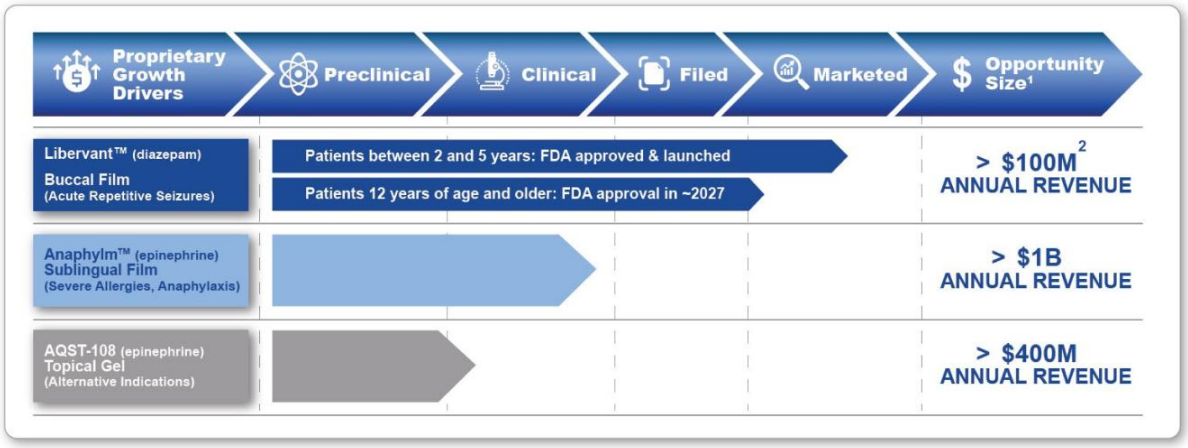
Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Our approved products and collaborations



Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Diversified pipeline



1. Aquestive Therapeutics data on file. 2. Annual revenue includes revenue for patients 12 and up after launch in 2027

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Our end-to-end capabilities

Development

- Formulation & analytical chemistry (CMC) leaders
- Regulatory experts with 6 FDA approvals
- Clinical trial design and execution
- Intellectual property know-how with 150+ patents worldwide

Production

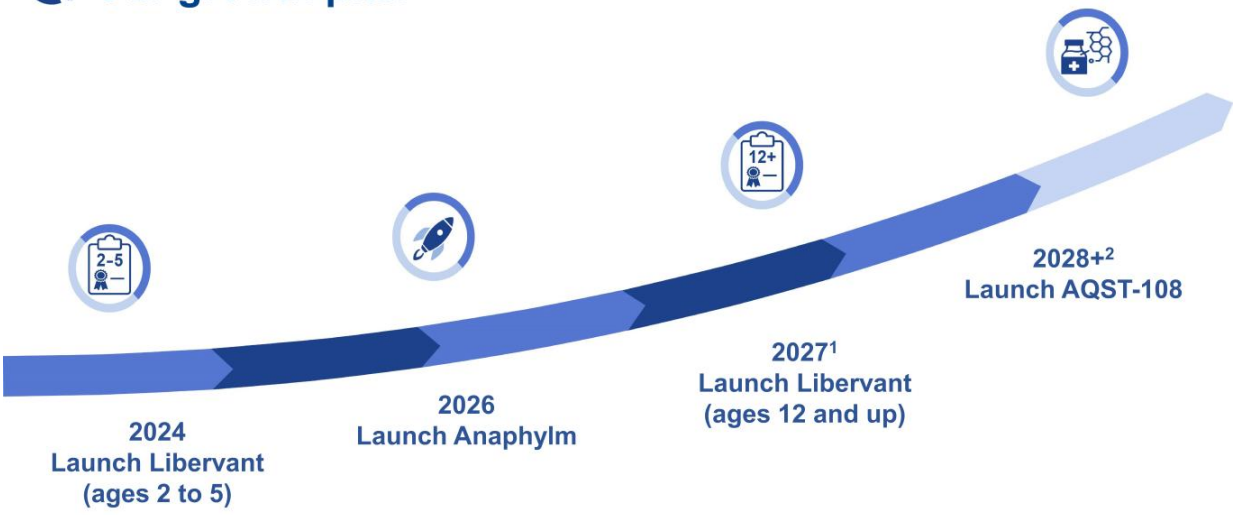
- Leading manufacturer of oral thin film technology (over 2 billion doses distributed for patient use)
- Two manufacturing and packaging facilities located in Indiana
- Comprehensive supply chain sourcing expertise

Distribution

- Sales, marketing, and market access
- Direct to consumer capabilities
- Licensing and collaboration expertise

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

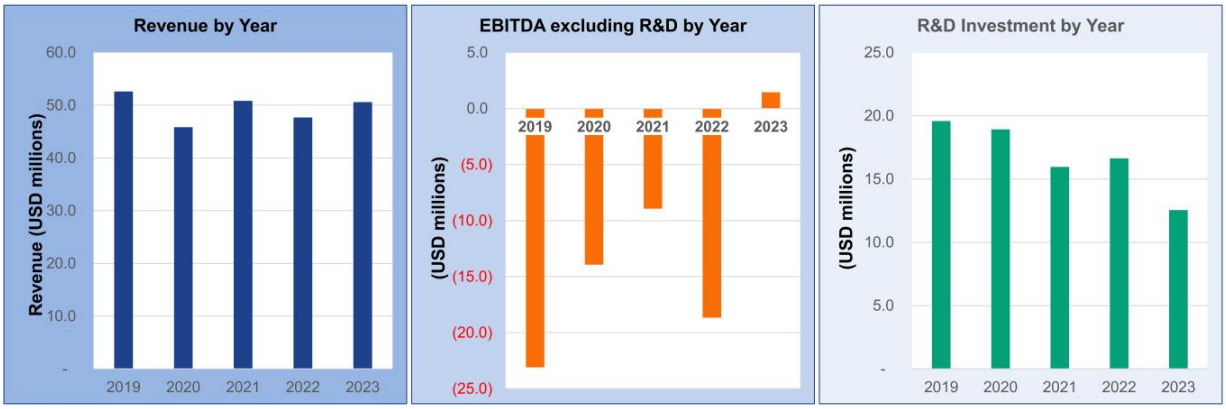
Our growth plan



1. Estimate is based on an orphan drug market exclusivity block until January of 2027 by an FDA approved nasal spray product.; 2. If we meet all clinical endpoints and if filed with and approved by the FDA.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Financial results



Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Dedicated and experienced leadership team

Daniel Barber
President, CEO & Director

Peter Boyd
SVP, HR & IT

Lori J. Braender
General Counsel, Chief Compliance Officer

Cassie Jung
Chief Operating Officer

Sherry Korczynski
SVP, Sales & Marketing

Carl Kraus
Chief Medical Officer

Mark Schobel
Chief Innovation & Technology Officer

Ernie Toth
Chief Financial Officer

Steve Wargacki
Chief Science Officer

Aquestive
Advancing medicines.
Solving problems.
Improving lives.


6
FDA
drug approvals
More than
2 billion
PharmFilm doses shipped worldwide
PharmFilm
19+
years since the company was founded
Aquestive®
(NASDAQ: AQST)
$50M+
of revenue in 2023
150+
employees based in Indiana and New Jersey
Products are available on
6
continents
2
Product launches are expected in the US by 2027
Over
$1.5 billion
in potential peak annual net sales from pipeline assets

Advancing medicines.
Solving problems.
Improving lives.

Anaphylaxis: a potentially fatal allergic reaction[1]

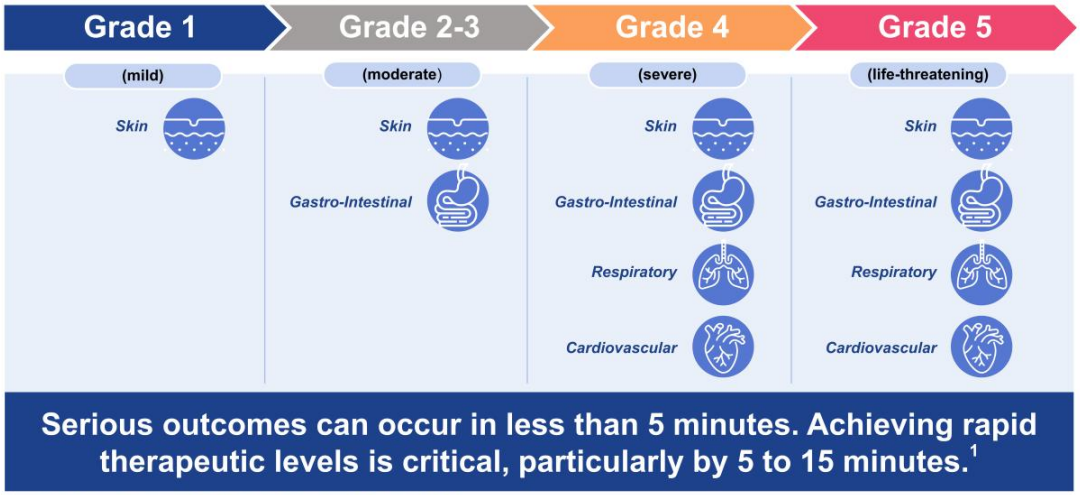
Anaphylaxis is a severe systemic hypersensitivity allergic reaction that is rapid in onset and can cause death

- **Poses serious consequences for at-risk patients**
- **Often occurs in the community setting**
- **Patients at risk for anaphylaxis should have a long-term allergy- management plan**

[1]Turner PJ, et al. *World Allergy Org J.* 2019;12100066

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Stages of anaphylaxis: earlier intervention is critical



Serious outcomes can occur in less than 5 minutes. Achieving rapid therapeutic levels is critical, particularly by 5 to 15 minutes.[1]

[1]Dribin et al., J Allergy Clin Immunol, 2021; Xu et al., Allergy Asthma Clin Immunol. 2014

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Treatment of Anaphylaxis: epinephrine[1]

- Epinephrine, the only medication proven to stop a life-threatening allergic reaction, is the first-line treatment for anaphylaxis
- All devices currently on the market are needle-based
- A second dose of epinephrine may be needed

[1]EpiPen® Package Insert.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

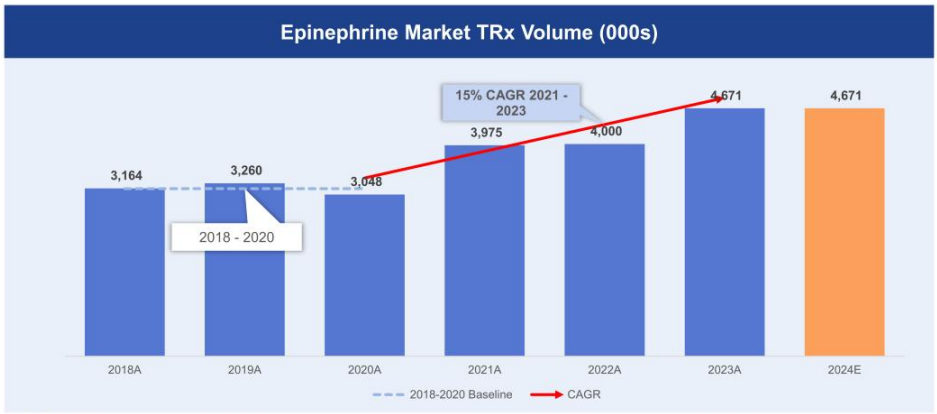
The numbers on Anaphylaxis

32M	**At chronic risk for acute anaphylactic episodes in the United States[1]**
1.2B	**Direct costs of anaphylaxis[2]**
52%	**of patients surveyed who had previously experienced anaphylaxis had never received an epinephrine auto-injector prescription[2]**
60%	**of respondents in same patient survey did not have an epinephrine auto-injector currently available[2]**

[1]FARE, 2022; https://www.foodallergy.org/resources/facts-and-statistics; [2]Fromer L. The American Journal of Medicine (2016);129, 1244-1250.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Epinephrine market continues to grow[1]



[1] Aquestive Therapeutics data on file.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

High levels of dissatisfaction combined with unmet need

Current patient option is large, needle-based injectors. Numerous studies and Patient Surveys articulate significant dissatisfaction with current offerings[1]

Oversized, bulky devices

- Burdensome to carry (must carry 2) [1]
- <50% of patients carry their EpiPen®, often due to "hassle" factor [1]

Needle-based

- Due to needle reluctance;
  - 60% of patients/caregivers often delay treatment [1]
- 25-50% often refuse treatment with EpiPen [2,3,4]

Not always intuitive to use

- 23-35% of patients and caregivers fail to administer correctly[5]

1.KOL feedback; Aquestive Market Research.; [2]Warren et al. Ann Allergy Asthma Immunol (2018).; [3]Brooks et al. Ann Allergy Asthma Immunol (2017).; [4]Asthma and Allergy Foundation of America Patient Survey Report (2019).; [5]El Turki et al. EmergMed J (2017).

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Anaphylm™ (epinephrine) Sublingual Film

The first and only non-device based, orally delivered epinephrine product candidate

Portability + **Non-device administration** + **Fast absorption into the bloodstream**

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Anaphylm program overview

Pivotal Study meets endpoints for single dose and repeat dose

Positive FDA Type C meeting provides clarity on path to filing

Continue to anticipate a pre-NDA meeting with FDA prior to filing

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Anaphylm is fast-acting and well-tolerated, with a safety profile comparable to standard of care (SOC) [1]

1 Rapid absorption as demonstrated by:

- Consistent time to peak drug concentration (Tmax) of 12-15 minutes
- Onset of pharmacodynamics (PD) effects within 2-5 minutes

2 Local adverse events (AE's) were generally mild (1 moderate), all transient and resolved without intervention

- Fewer cardiac AEs than EpiPen® in comparative trial

3 Consistent pharmacokinetics (PK) across 5 administration procedures

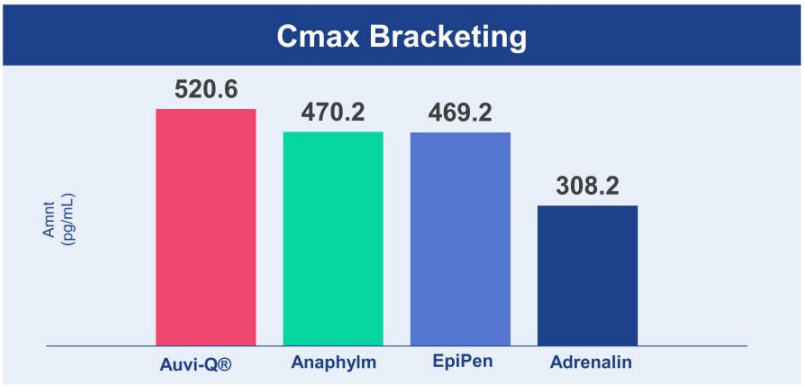
- Performed consistently in the presence of food (clinically), drink, temperature, and local swelling (non-clinically)
- Same maximum exposure levels as autoinjectors of epinephrine

[1] Aquestive Therapeutics data on file.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Anaphylm 12mg single dose study meets primary endpoints of Cmax, demonstrating comparability to current SOC[1]

Primary endpoints predefined as Anaphylm values bracketed between injectable products for (1) Maximum drug concentration (Cmax) and (2) Area under the curve (AUC)0-10min, AUC0-20min, AUC0-30min, AUC0-45min.

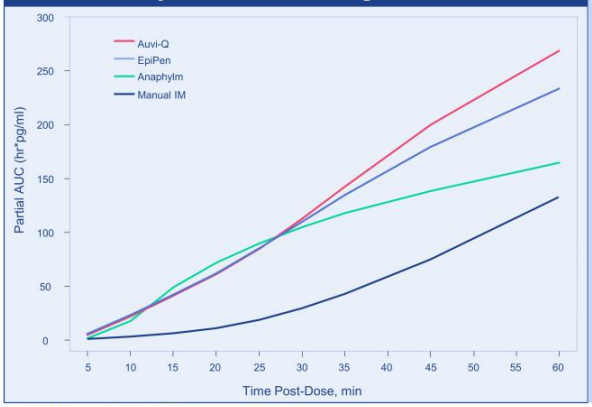


[1]All figures are baseline corrected and geometric means; $pAUC_{0\text{-}20min}$ not statistically different ($p > 0.05$) (comparison to EpiPen).

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Anaphylm meets secondary endpoint of AUC, demonstrating biocomparability to the current SOC[1]

Geometric Mean Epinephrine Exposure Levels (pAUC) by Product After a Single Dose



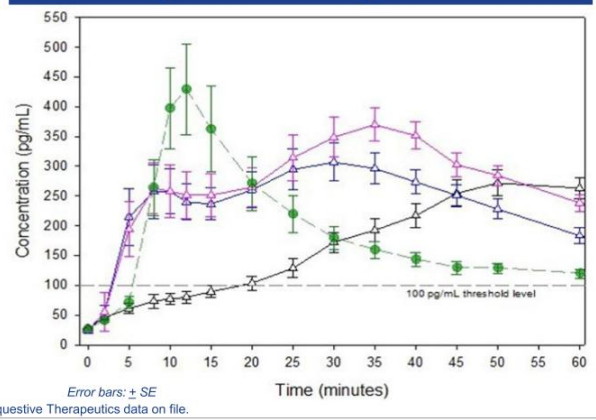
Similar to other measured values, Anaphylm's partial AUC values are comparable to autoinjectors for 30 minutes post-dosing and remain bracketed past 60 minutes after dosing

[1] Aquestive Therapeutics data on file.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Anaphylm matches and surpasses EAI: concentration remains above 100 pg/mL at 60 minutes after dosing[1]

Geometric Mean Epinephrine Concentrations by Product After a Single Dose



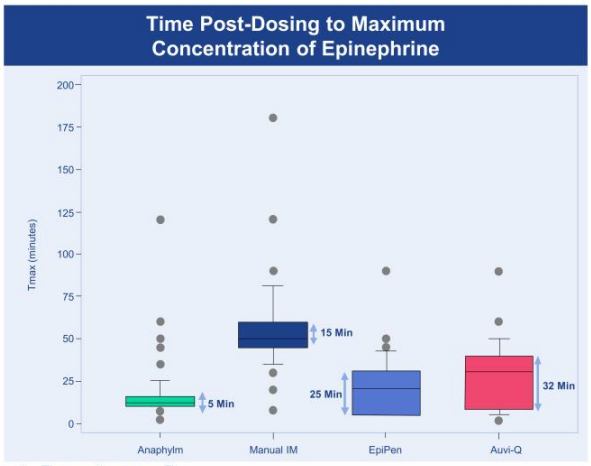
Error bars: ± SE

[1]Aquestive Therapeutics data on file.

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

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Time to maximum concentration of Anaphylm significantly more consistent compared to autoinjectors[1]



- 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)

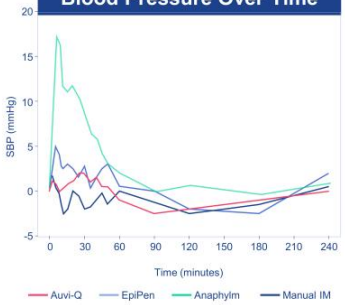
[1]Aquestive Therapeutics data on file.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

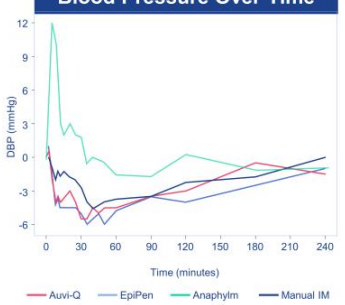
Anaphylm quickly addresses drop in heart rate and blood pressure[1]

- Epinephrine is administered during Anaphylaxis to quickly raise heart rate and blood pressure to normal levels
- Pharmacodynamics is consistent with our previous clinical results

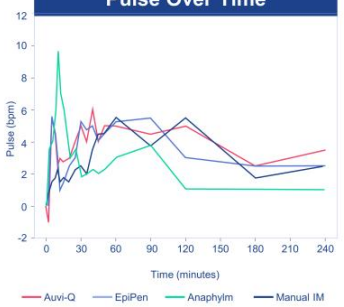
Median Change in Systolic Blood Pressure Over Time



Median Change in Diastolic Blood Pressure Over Time



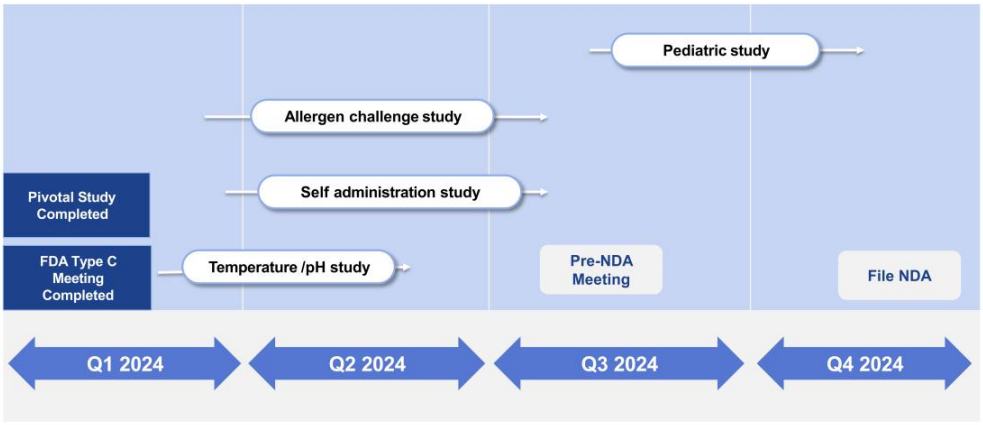
Median Change in Pulse Over Time



[1] Aquestive Therapeutics data on file.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Expected clinical timeline for Anaphlym



Advancing medicines.
Solving problems.
Improving lives.

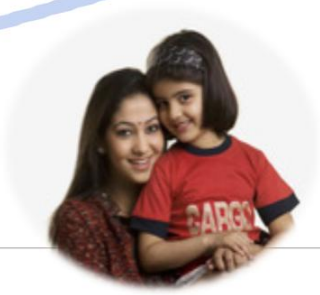
Libervant™ (diazepam) buccal film path to launch

PDUFA Date
- December 23, 2021

Tentative approval received
- August 30, 2022

Libervant (diazepam) buccal film approved for ages 2 to 5
- Received FDA approval on April 26, 2024
- Launch underway
- Accepting and filling non-Medicaid prescriptions

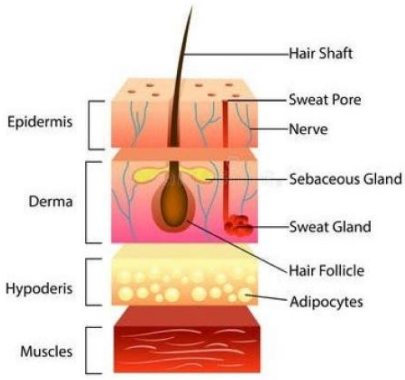
Libervant (ages 12 and up)
- Currently anticipate receiving FDA approval in January 2027



Aquestive
Advancing medicines.
Solving problems.
Improving lives.

AQST-108 (epinephrine) prodrug topical gel

Human Skin Structure



- Topical delivery of epinephrine has been limited due to poor permeability and rapid clearance[1]
- Adrenaverse prodrug platform allows for the targeted delivery of epinephrine without systemic effects
- First human study completed
- IND-enabling Ex-vivo / Non-Clinical program ongoing

1. Jeong, W.Y., Kwon, M., Choi, H.E. *et al.* Recent advances in transdermal drug delivery systems: a review. *Biomater Res* **25**, 24 (2021).

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Financial Guidance

Advancing medicines.
Solving problems.
Improving lives.

2024 outlook as of May 7, 2024

Thank You

Advancing medicines.
Solving problems.
Improving lives.