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): November 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)	**(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.**

Aquestive Therapeutics, Inc. (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 Exhibit 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 Events and Presentations Page of the Investors section of 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 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 9.01 **Financial Statements and Exhibits**

(d) Exhibits.

Exhibit Number	Description
99.1	Aquestive Therapeutics, Inc. Corporate Presentation dated November 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: **November 6, 2024**

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Aquestive®

Corporate Presentation

November 2024

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 through clinical development and approval by the U.S. Food and Drug Administration (FDA), including the timing of submission of supporting and pediatric clinical studies, holding a pre-New Drug Application (NDA) meeting with the FDA and filing the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; that Anaphylm will be the first and only oral administration of epinephrine and accepted as an alternative to existing standards of care, if Anaphylm is approved by the FDA; the expected growth of the U.S. epinephrine market including in value and the opportunity such growth presents to the Company should Anaphylm be approved by the FDA; the advancement and related timing of our Adrenaverse™ pipeline epinephrine prodrug product candidates, including AQST-108, through clinical development and FDA regulatory approval process, including holding a pre-IND meeting with the FDA for AQST-108 and the following launch of AQST-108, if approved by the FDA; the advancement and related timing of our product candidate Libervant® (diazepam) Buccal Film for the indicated epilepsy patient population aged between six and eleven years through clinical development and FDA regulatory approval and the following launch of Libervant for this patient population if approved by the FDA; the approval for U.S. market access of Libervant for this patient population aged six 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 Libervant for these epilepsy patients six years of age and older, based upon an approval by the FDA of Libervant for this patient population of six to eleven years old; the advancement, growth and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel, through clinical development including design and timing of clinical studies including those necessary to support the targeted indication of alopecia areata for AQST-108, and holding a pre-investigational new drug application meeting (IND) with the FDA and the following launch of AQST-108, if approved by the FDA; the commercial opportunity of Libervant, Anaphylm, and AQST-108, including potential market growth and revenues (including projected peak annual sales) generated for the Company from commercialization of these products and product candidates should these product candidates be approved by the FDA; the potential growth of our patent portfolio including the extension of patent protection for Anaphylm should the pending patents be approved by the U.S. Patent and Trademark Office (PTO); the potential benefits our products and product candidates could bring to patients and acceptance by patients, prescribers and payors of our product candidates as an alternative to existing standards of care for the targeted medical indication of these product candidates; our cash and financial position, including with respect to our 2024 financial outlook; and business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm (including for pediatric patients), AQST-108, and the Company's 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 aged two to five for Libervant; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs for such product candidates, including for Anaphylm, AQST-108, Libervant for patients aged between six and eleven years and our other product candidates, or failure to receive FDA approval at all of any of these product candidates; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our submission of pharmacokinetics and pharmacodynamics comparability studies 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 that we may not overcome the seven year orphan drug market exclusivity granted by the FDA for the approved nasal spray product of another company in the U.S. in order for Libervant to be granted U.S. market access for patients aged six years and older until the expiration of the orphan drug market exclusivity period of the nasal spray product due to expire in January 2027, or for other reasons; risk of loss of U.S. market approval of Libervant for patients aged between two and five resulting from a legal challenge by the sponsor of the FDA approved nasal spray product relating to its granted U.S. orphan drug market exclusivity for these patients aged six years and older, or for other reasons; 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 commercialization of our product Libervant and other product candidates, including Anaphylm and AQST-108; 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 patients between two and five years of age and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, AQST-108 and Libervant for patients aged between six and eleven, should these product candidates be approved by the FDA, and for Libervant patients of six years and older upon expiration of the orphan drug marketing exclusivity period of the FDA approved nasal spray product; risk that our manufacturing capabilities will be sufficient to support demand for Libervant for patients between two and five years of age and for older patients, should Libervant receive U.S. market access for these older patients, and for demand for our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® and its risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance in the U.S. and abroad of Libervant for epilepsy patients between two and five years of age, and for older epilepsy patients if approved for U.S. market access and after the expiration of the orphan drug market exclusivity period; risk of the rate and degree of market acceptance in the U.S. and abroad of Libervant and Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of the success of any competing products including generics; risk of the size and growth of our product and product candidates respective commercial 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 and product candidates; risk that our patent applications for our product candidates, including for Anaphylm and AQST-108, will not be timely issued, or issued at all, by the PTO; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and 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, 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 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® Libervant 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

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

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.*

Our products

Aquestive is the go-to formulation development and commercial manufacturing partner for oral thin film products worldwide

Validation from 5 proprietary and licensed commercial products, supplying over 95% of the world's prescription oral thin films

1. Libervant approved by U.S. Food and Drug Administration (FDA) for patients aged 2-5. 2. Ondif collaboration with Hypera-Pharma (Brazil). 3. Sympazan collaboration with Otter Pharmaceuticals (worldwide). 4. Libervant collaboration with Pharmanovia (Ex-U.S.). 5. Emylif collaboration with Zambon (EU). 6. Suboxone collaboration with Indivior (worldwide).

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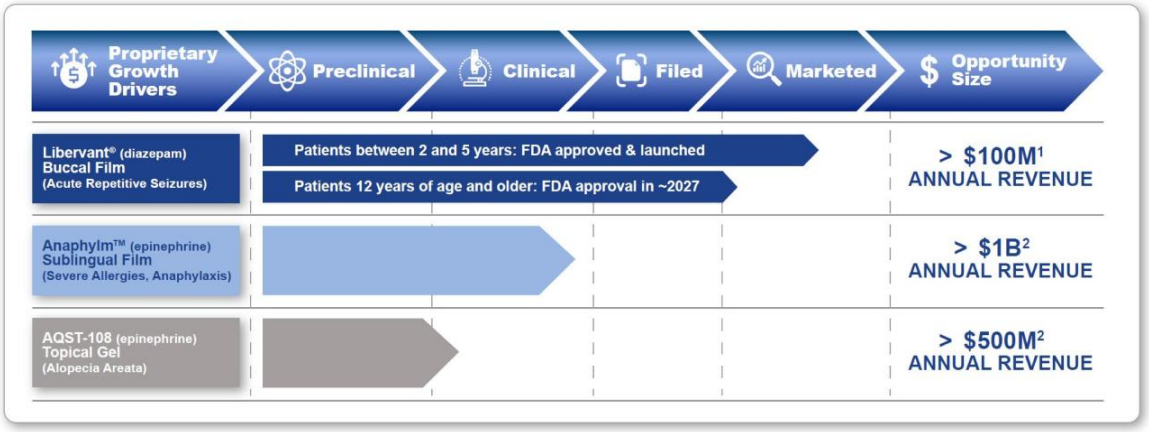
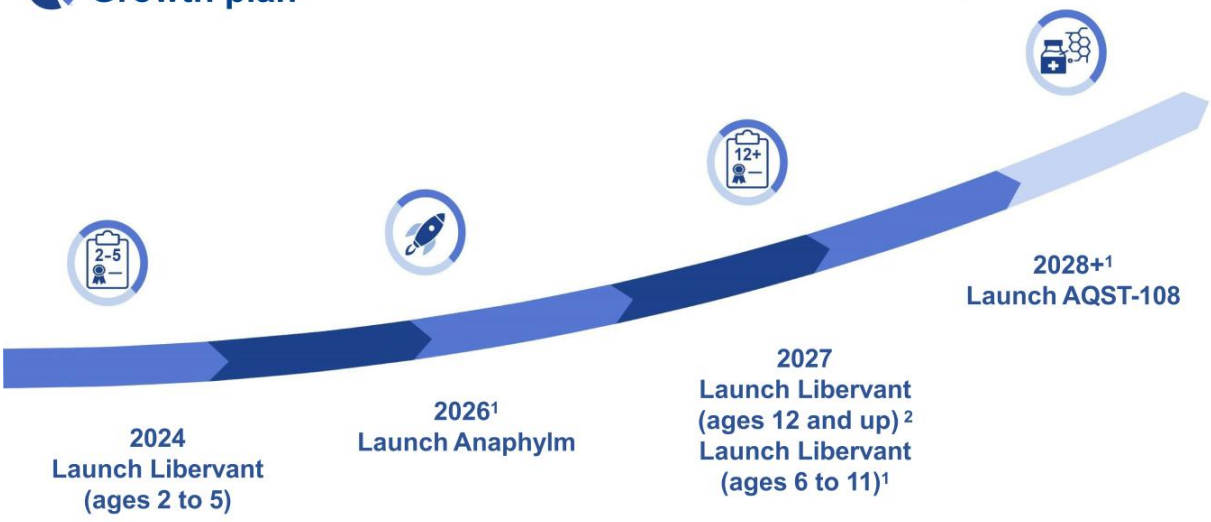
Diversified pipeline



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

Growth plan



1. Assumes satisfaction of all predetermined clinical endpoints and approved by FDA. 2. Estimate is based on an orphan drug market exclusivity block until January of 2027 by an FDA approved nasal spray product.

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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

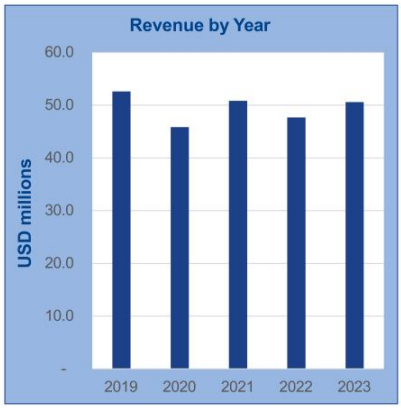
Production

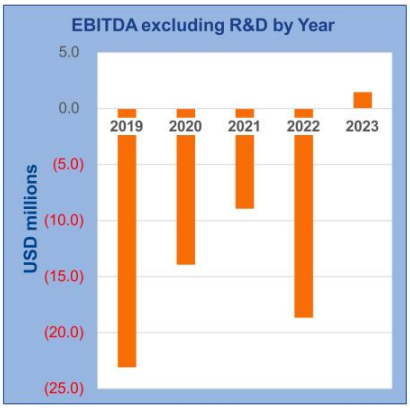
- Leading manufacturer of oral thin film technology (over 2 billion doses distributed for patient use)
- Two manufacturing and packaging facilities located in Indiana
- Comprehensive supply chain sourcing expertise

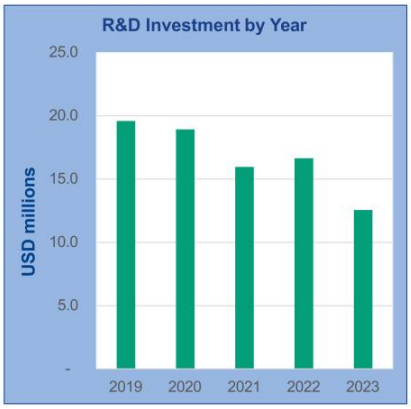
Commercialization

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

Financial snapshot







Dedicated and experienced leadership team

Daniel Barber
President, CEO & Director

Peter Boyd
SVP, HR & IT

Lori J. Braender
Chief Legal Officer, Chief Compliance Officer, Corporate Secretary

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

6 FDA drug approvals

More than
2 billion
PharmFilm® doses shipped worldwide

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 U.S. by 2027

Over
$1.5 billion[1]
in potential peak annual net sales from pipeline assets

1. Aquestive Therapeutics data on file.

Anaphylaxis and Unmet Needs

Anaphylaxis: a potentially fatal allergic reaction[1]

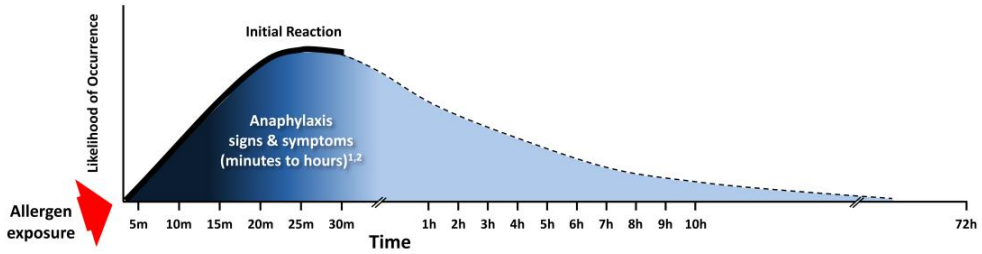
Severe systemic hypersensitivity allergic reaction that is rapid in onset and can cause death

- 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.

During an allergic reaction, time is the enemy

Medical Guidelines: Use epinephrine auto-injector promptly[2-4]



- Benefits of epinephrine far outweigh the risks of unnecessary dosing[2]
- Doctors advise to use epinephrine in a life-threatening situation regardless of contraindications[3]
- Delayed epinephrine injection may increase the risk of life-threatening outcomes[4]
- Symptoms not immediately life-threatening may progress rapidly[2,3]

1. Sampson HA et al. J Allergy Clin Immunol. 2006;117(2):391-397. 2. Lieberman P et al. J Allergy Clin Immunol. 2010;126:477-480. 3. Boyce JA et al; NIAID-Sponsored Expert Panel. J Allergy Clin Immunol. 2010;126(6 suppl):S1-S58. 4. Simons FE. J Allergy Clin Immunol. 2010;125(suppl 2):S161-S181.

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What is happening in the allergy rescue space

Multiple epinephrine medical devices (EMDs)

- Epinephrine, the only medication proven to stop a life-threatening allergic reaction, is the first-line treatment for anaphylaxis
- No oral products are available
- By nature, EMDs would be put in a carrying case

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Several factors influence epinephrine administration during anaphylaxis

- **Comorbidities**
  - Rhinitis: 10% - 30%[1,2]
  - Chronic rhinosinusitis: 12%[3]
- **Psychological issues**
  - Needle phobia: 50%[4,5,6]

- Anaphlym has the potential to address these issues:
  - Orally administered – not affected by rhinitis
  - No needle or device

1. Nature Reviews Disease Primers on Allergic Rhinitis (2020). 2. Decker et. al. J All Clin Imm (2008). 3. Palmer et. al. All Asthma Proc (2019). 4. Warren et. al. Ann All Asthma Imm (2018). 5. Brooks et. al. Ann All Asthma Imm (2017). 6. Asthma and Allergy Foundation of America Patient Survey Report (2019).

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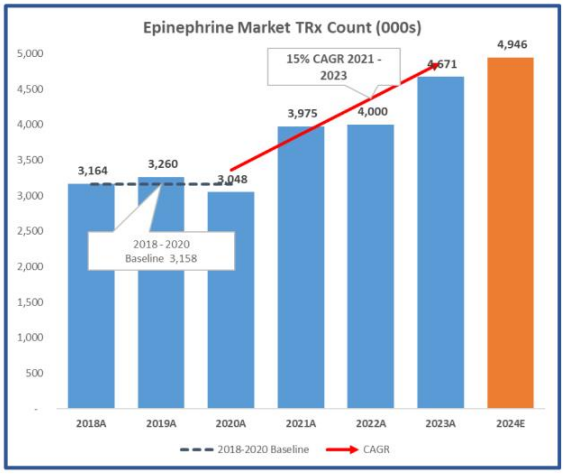
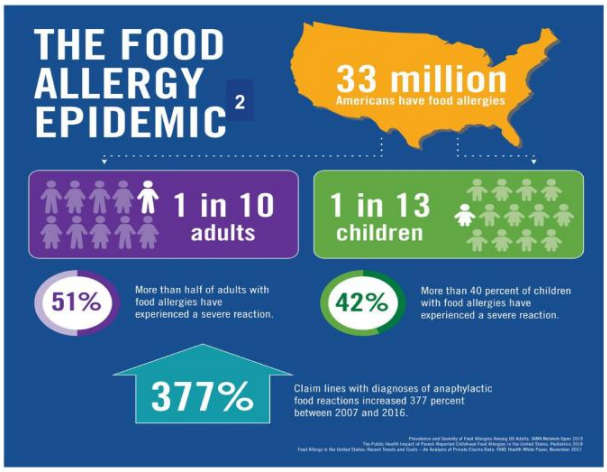
U.S. market has the potential to grow to ~$2B in value by 2031[1]





1.Aquestive Therapeutics data on file, scripts written for epinephrine (EAIs) have increased at a 15% compound annual growth rate (CAGR) from 2021- 2023.

2. https://foodallergy.org/resources/epidemic-infographic.

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Lead Asset Anaphylm™ (epinephrine) Sublingual Film

Anaphylm executive summary

Anaphylm meets all predetermined primary and secondary endpoints of program adult clinical studies planned to support New Drug Application (NDA) submission

Large Market Opportunity

- **~$2B anaphylaxis market in value by 2031** with high unmet meet[1]

Novel Oral Product

- **First and only oral epinephrine product candidate** in development for anaphylaxis, with patent protection potentially into **2044**
- World leader in oral thin film delivery, with **proprietary PharmFilm® technology** having been commercialized across six FDA approved products

Path to Launch

- Recently completed planned adult studies and **met all predetermined primary and secondary endpoints**[1]
- Positive FDA Type C meeting provided path to **NDA submission by Q1 '25**

1. Aquestive Therapeutics data on file.

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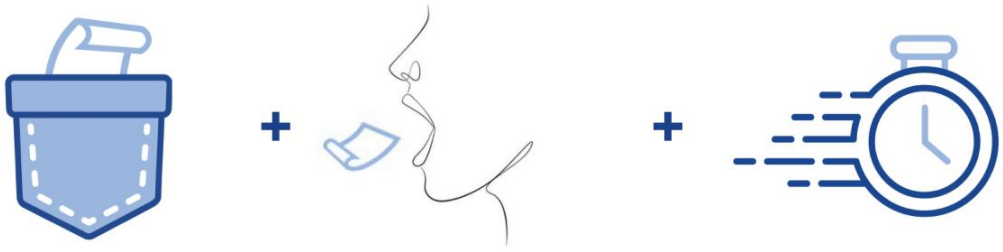
Anaphylm™ (epinephrine) Sublingual Film

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



Easy To Carry	Easy To Administer	Works Quickly[1]

1. *Aquestive Therapeutics data on file.*

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Most common reasons that people don't carry their epinephrine medical devices (EMDs)[1]

- Inconvenience
- Forgetfulness
- Cost
- Availability at other places, such as the home, car or school
- Expiration of the previous prescription
- Complacency if there has been no accidental exposure in a long time
- Did not understand that they were supposed to carry it at all times

1. https://community.kidswithfoodallergies.org/blog/new-epinephrine-study-shows-alarming-results; survey results reflect EAIs only.

Incorporating Anaphylm into patients' daily lifestyle routine

Anaphlym, if approved by the FDA, has the potential to be carried on the back of a phone.

1. https://www.reviews.org/mobile/cell-phone-addiction; July 2023.

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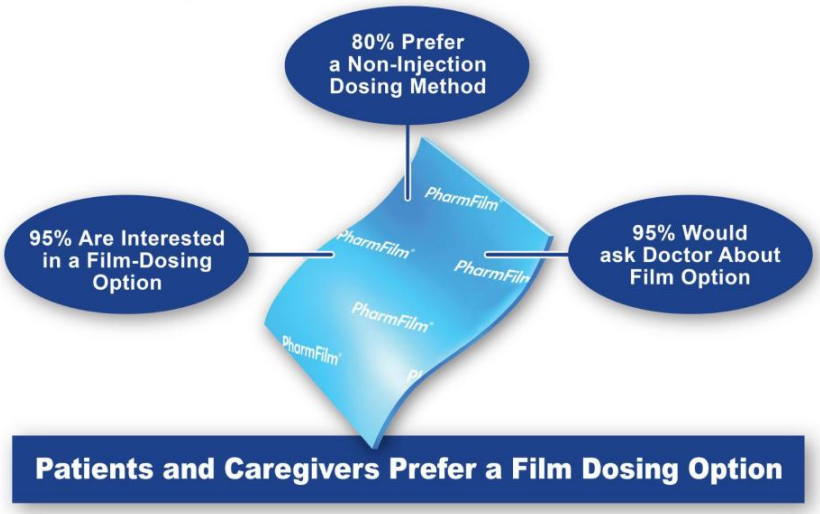
High epinephrine prescribing physicians have spoken[1]

~90%	expressed concern that their at-risk patients don't consistently have an epinephrine auto injector (EAI) with them when away from home
85%	articulated that "A sublingual film is more likely to be carried, thereby protecting more at-risk patients"
>75%	believe their at-risk patients too often and inappropriately carry oral antihistamines as a first-line treatment for a severe allergic reaction
55%	stated that "My overall Rx'ing of epinephrine would increase if the film were available." Average anticipated increase: >30%

1. *Aquestive Therapeutics 2024 Survey data on file.*

Patients and caregivers have spoken[1]



1. Aquestive Therapeutics 2024 Survey data on file.

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Intellectual Property
25

Anaphylm's patented technology is broad, deep and constantly evolving with patent protection potentially extending into 2044[1]

ANAPHYLM Patent Title	Status
ENHANCED DELIVERY EPINEPHRINE COMPOSITIONS	▸ 2 US patents granted ▸ 2 US applications ▸ 3 Foreign patents ▸ 8 Foreign applications ▸ **Priority date:** May 5, 2016 ▸ Possible patent term to 2037
ENHANCED DELIVERY EPINEPHRINE AND PRODRUG COMPOSITIONS	▸ 2 US applications ▸ 8 Foreign applications ▸ **Priority date:** May 5, 2016 ▸ Possible patent term to 2037
PRODRUG COMPOSITIONS AND METHODS OF TREATMENT	▸ 1 US application ▸ 10 Foreign applications ▸ **Priority date:** November 1, 2019 ▸ Possible patent term to 2040
PHARMACEUTICAL COMPOSITIONS WITH ENHANCED STABILITY PROFILES	▸ 1 US application ▸ 8 Foreign applications ▸ **Priority date:** October 22, 2021 ▸ Possible patent term to 2042
ENHANCED DELIVERY EPINEPHRINE COMPOSITIONS	▸ 1 US application ▸ 1 Foreign application ▸ **Priority date:** July 20, 2023 ▸ Possible patent term to 2044

1. The issued patents have a current expiry of 2037 and 2042. If the current patents applications are issued by the U.S. Patent and Trademark Office, patent coverage would be extended to 2044.

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Anaphylm Clinical Program

Anaphylm program overview

Pivotal study meets predetermined endpoints for single dose and repeat dose

All planned adult supportive studies are now complete and have met predetermined endpoints

Pre-NDA meeting with FDA scheduled in Q4 2024

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

Consistent pharmacokinetics (PK) demonstrated across 5 administration procedures:

- Performed consistently in the presence of food (clinically), drink, temperature, and local swelling (clinically)
- Same peak concentration levels as EAIs of epinephrine

Safety and tolerability:

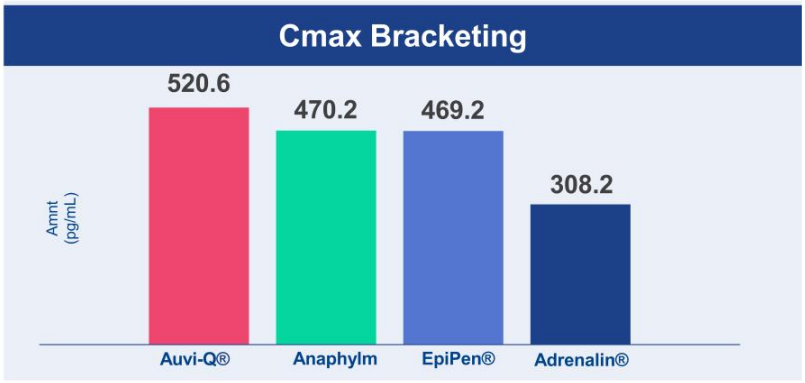
- Adverse events (AEs) were generally mild, all were transient and resolved without medical intervention

1. *Aquestive Therapeutics data on file.*

Anaphylm Pivotal Study Results

12mg single dose study meets primary endpoints of Cmax, demonstrating biocomparability 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 (removal of baseline effect) and geometric means; $spAUC_{0\text{-}20min}$ not statistically different ($p > 0.05$) (comparison to EpiPen); Aquestive Therapeutics data on file.

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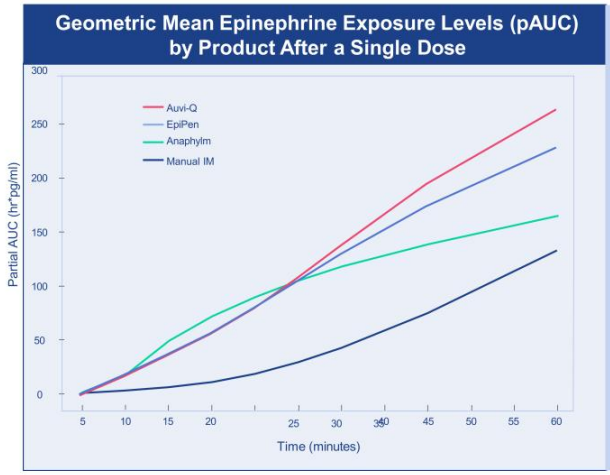
Primary predetermined endpoint of pAUC, demonstrating biocomparability to SOC[1]



Anaphylm's pAUC values demonstrate comparability to EAIs for 30 minutes post-dosing and remain bracketed beyond 60 minutes after dosing

1. Aquestive Therapeutics data on file.

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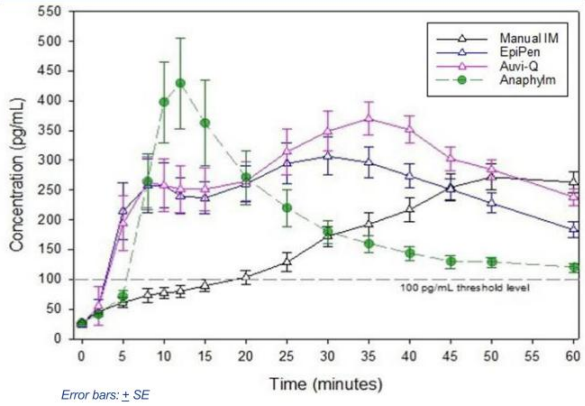
Anaphylm demonstrated a rapid and robust PK profile[1]

Geometric Mean Epinephrine Concentrations by Product After a Single Dose



Error bars: ± SE

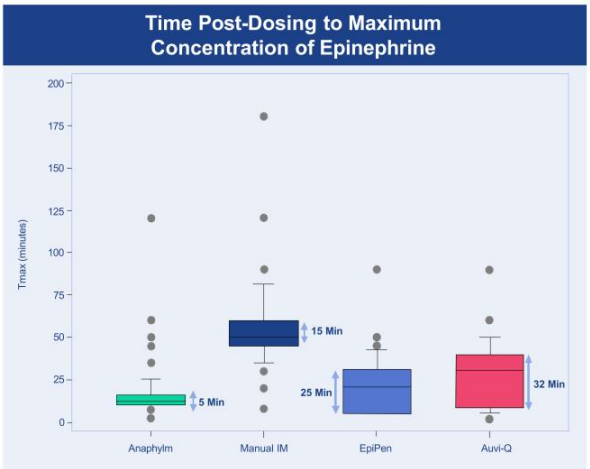
Anaphylm's epinephrine concentration:

- **Exceeds Adrenalin manual intramuscular (Manual IM) beginning at 2 minutes**
- **Matches EAIs by 10 minutes**
- **Sustains levels above Manual IM out to 35 minutes**
- **Remains above 100 pg/mL for the relevant period of time, which is 60 minutes**

1. Aquestive Therapeutics data on file.

Aquestive

Time to maximum concentration (Tmax) of Anaphylm demonstrates more consistency[1]



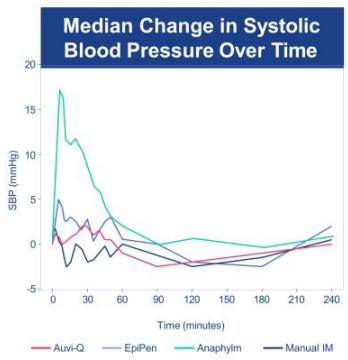
- Tmax is a surrogate for speed of absorption, a critical factor in treating anaphylaxis
- Tmax consistency is an important measure of clinical performance
- Anaphylm Tmax interquartile range (5 min) is more consistent than EpiPen, Auvi-Q, and Manual IM
- Anaphylm median Tmax of 12 minutes is faster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

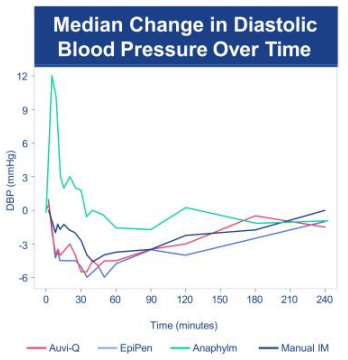
1. *Aquestive Therapeutics data on file.*

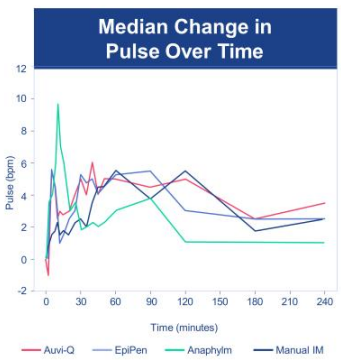
Aquestive

Anaphylm demonstrates rapid pharmacodynamic (PD) effects[1]

- Epinephrine is administered during anaphylaxis to quickly raise heart rate and blood pressure to normal levels
- PD results were consistent with previous Anaphylm clinical study results







1. *Aquestive Therapeutics data on file.*

Aquestive

Anaphylm Supportive Studies Results and Clinical Timeline

Anaphylm temperature/pH study PK results[1]

Test Condition	Cmax (Test Condition/Room Temperature Water)	AUC0-60min (Test Condition/Room Temperature Water)
Cold water	106%	98%
Hot water	104%	107%
Lemon water (target pH: 3)	98%	99%
Baking soda water (target pH:8)	123%	132%

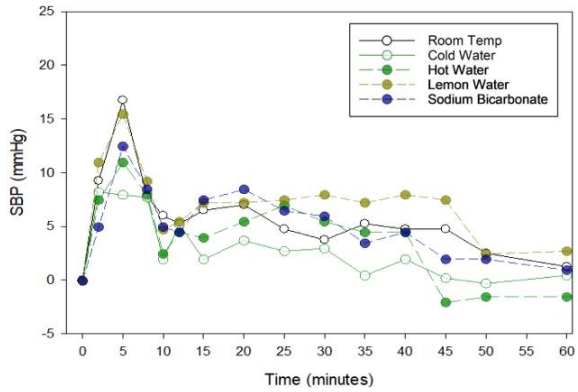
Key Takeaways:

- **No significant difference in PK results based on changes in temperature and pH**

1. *Aquestive Therapeutics data on file.*

Anaphylm temperature/pH study PD results[1]

Median Change in Systolic Blood Pressure Over 60 Minutes Following Administration of Anaphylm



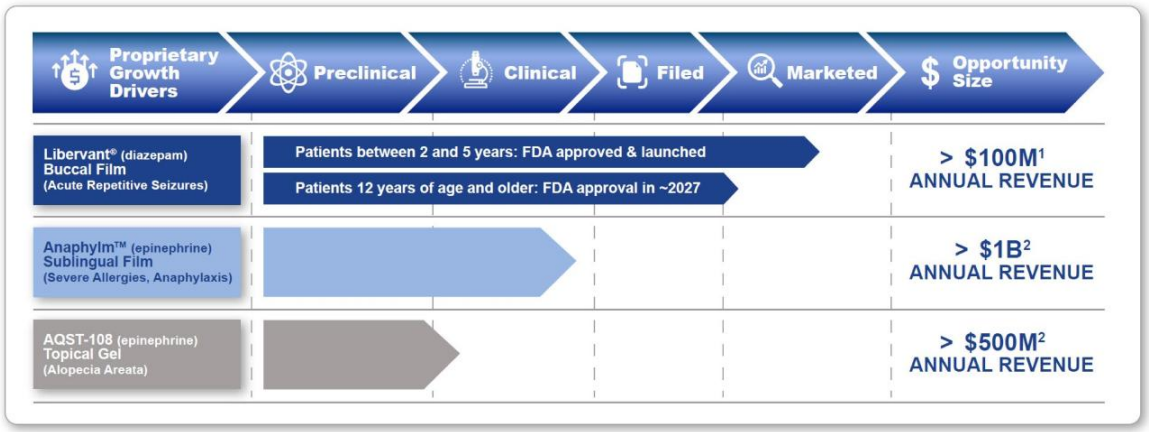
Key Takeaways:

- **Topline results demonstrate no statistically significant difference in the maximum increase in systolic blood pressure due to temperature/pH conditions**
- **PD results for this study are in alignment with prior Anaphylm clinical study results**

1. *Aquestive Therapeutics data on file.*

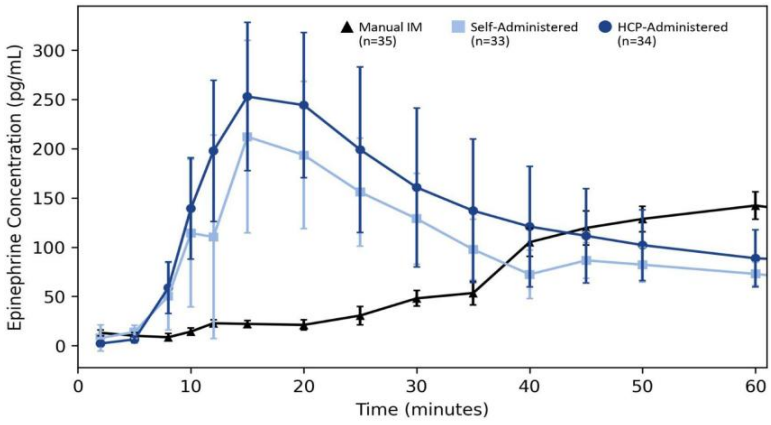
Aquestive

Diversified pipeline



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

Anaphylm self-administration PK study results[1]



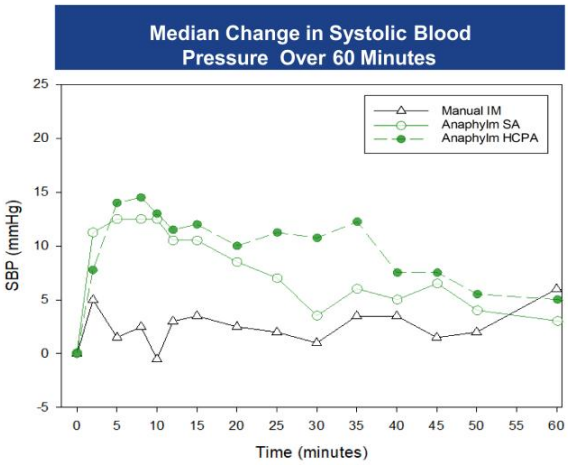
Key Takeaways:

- Cmax was not statistically different whether Anaphylm was self-administered or administered by a healthcare provider (HCP)
- Median Tmax was 15 minutes for Anaphylm whether self-administered or administered by an HCP
- Median Tmax for the Manual IM injection was 50 minutes after dosing

1. Aquestive Therapeutics data on file.

Aquestive

Anaphylm self-administration study PD results[1]



Key Takeaways:

- **Topline PD results demonstrate no significant difference in the median increase in systolic blood pressure whether Anaphylm is self-administered or HCP-administered**
- **PD results for this study are in alignment with prior study results**

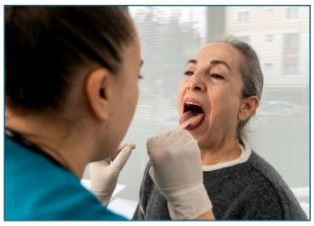
1. *Aquestive Therapeutics data on file.*

Aquestive

Oral allergen challenge study (OASIS) induced subject reactions

Step #1:
Oral cavity of OAS subjects exposed to allergen

Step #2:
Assessment of symptom severity[1]



First subject visit

Screening
Clinician tracks symptoms until resolution

Second subject visit

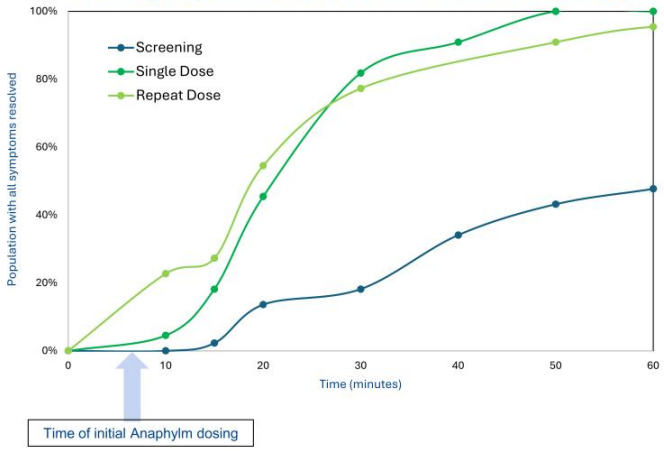
Dosing
1. Subjects received either single dose or repeat dose of Anaphylm
2. Clinician tracks symptoms from time of dosing until resolution

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

Aquestive

OASIS study - complete symptom resolution occurs rapidly after Anaphylm administration[1]

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



Key Takeaways:

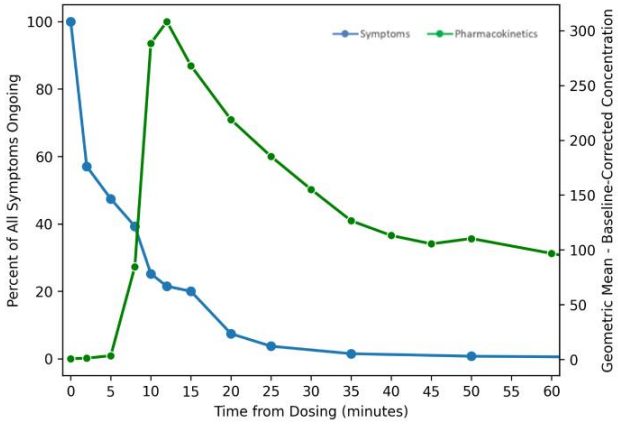
- **Median time to complete symptom resolution was 12 minutes after Anaphylm administration**
- **Median time to resolution was 74 minutes without Anaphylm administration**

1. Aquestive Therapeutics data on file.

Aquestive

OASIS study - symptom relief correlates to Anaphylm PK levels[1,2]

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



Key Takeaways:

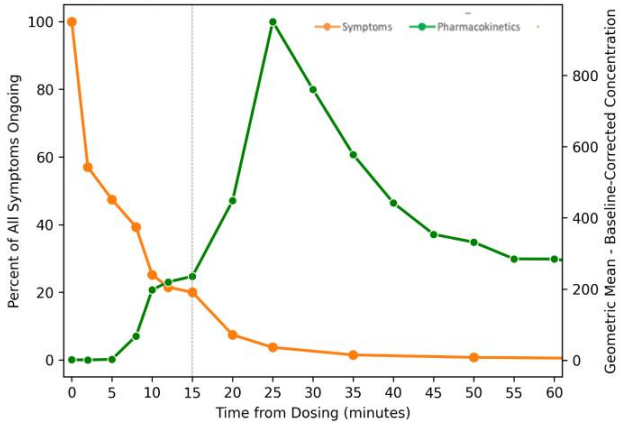
- **Symptom resolution was observed as early as 2 minutes in some subjects**
- **Median symptom resolution was 5 minutes**

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

Aquestive

OASIS study - symptom relief was also observed with repeat dosing of Anaphylm[1,2]

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



Key Takeaway:

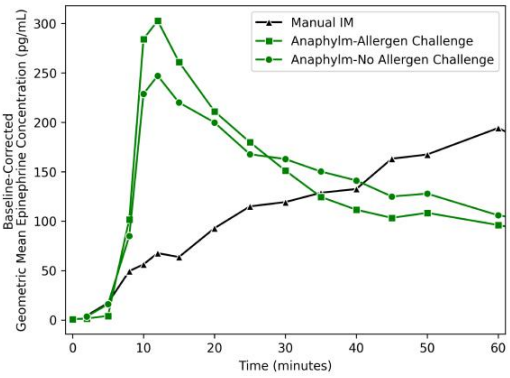
- **Repeat dose at 15 minutes resulted in rapid resolution of remaining symptoms**

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

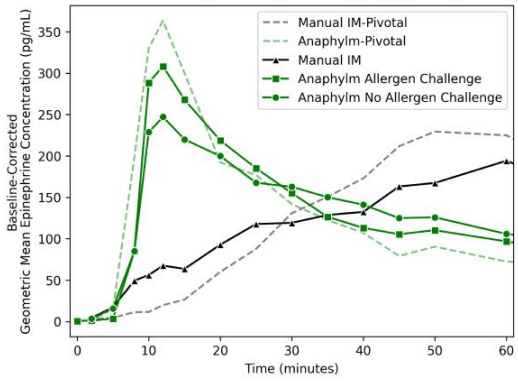
Aquestive

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

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



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



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

Aquestive

OASIS study - Anaphylm single dose meets predetermined primary endpoints[1,2]

- *Primary endpoints predefined as Anaphylm values above Manual IMs for (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.*
- *No significant difference of allergen challenge on key Anaphylm PK results*

Cmax and Tmax[3]

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

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

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

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

Aquestive

OASIS study - Anaphylm repeat dose meets predetermined primary endpoints[1,2]

- *Primary endpoints predefined as Anaphylm values above Manual IMs for (1) Cmax and (2) $AUC_{0\text{-}10min}$, $AUC_{0\text{-}20min}$, $AUC_{0\text{-}30min}$, $AUC_{0\text{-}45min}$.*
- *No significant difference of allergen challenge on key Anaphylm PK results*

Cmax and Tmax[3]

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

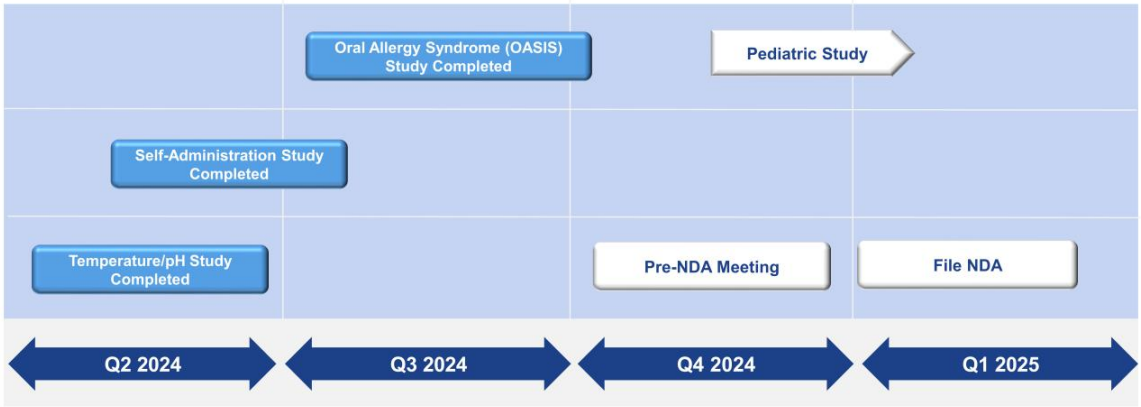
Partial AUC's (hr*pg/mL)[3]

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

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

Aquestive

Expected clinical timeline for Anaphylm

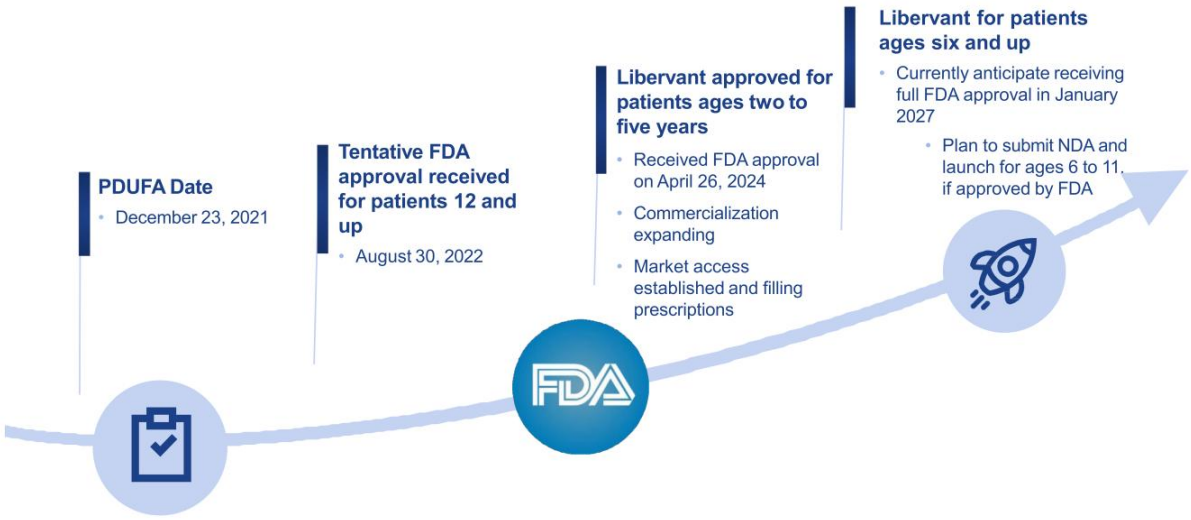


- **OASIS study:** Assessing PK profile for Anaphylm in the presence of oral physiologic change in subjects with oral allergen syndrome (OAS)
- **Self administration study:** Comparing PK and PD of Anaphylm self-administered, HCP-administered, and Manual IM HCP-administered
- **Temperature / pH study:** Comparing PK and PD of Anaphylm just after consuming water (hot, cold, and room temp.), low pH water, and high pH water
- **Pediatric study:** Pediatric PK study to commence following completion of the adult studies upon alignment with FDA

Aquestive

Pipeline Products

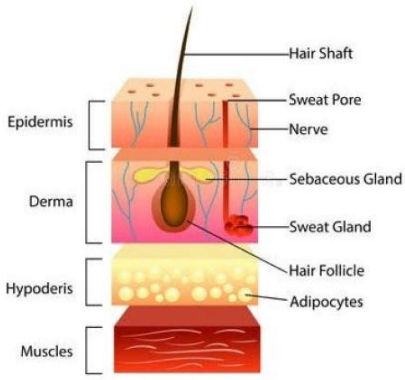
Expected full launch path for Libervant® (diazepam) Buccal Film



Aquestive

AQST-108 (epinephrine) Topical Gel

Human Skin Structure



- The utility of exogeneous epinephrine for the treatment of medical conditions has been limited due to the molecule's five-minute half-life as well as poor absorption capabilities[1]
- Aquestive's Adrenaverse™ technology unlocks the potential of epinephrine by addressing both problems[2]
- Completed First-in-Human Study (FIH)
- Pursing alopecia areata as an initial indication[3]

*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). 2. Aquestive Therapeutics data on file. 3. See Investor Day Presentation dated September 27 located at Aquestive.com/investors/eventsandpresentations for more detail on clinical development and the commercial overview.*

Aquestive

AQST-108 planned Phase 2a clinical study for alopecia areata[1]

A Phase 2a, multi-center, double-blind, dose-response, adaptive study to evaluate the safety and efficacy of AQST-108 in mild to moderate alopecia areata patients

Phase 2a Study Design
• **24-48 subjects, 4 doses** • **12 – 24 weeks[2]** • **Change from baseline ≥10% in Severity of Alopecia Tool (SALT) score at Week 12** • **Trichoscopy evaluations and labs at baseline**

Phase 2a Study Objectives:

- Assess the safety and efficacy of AQST-108 in alopecia areata patients following 12 weeks of treatment as determined by change from baseline ≥10% in SALT score at week 12

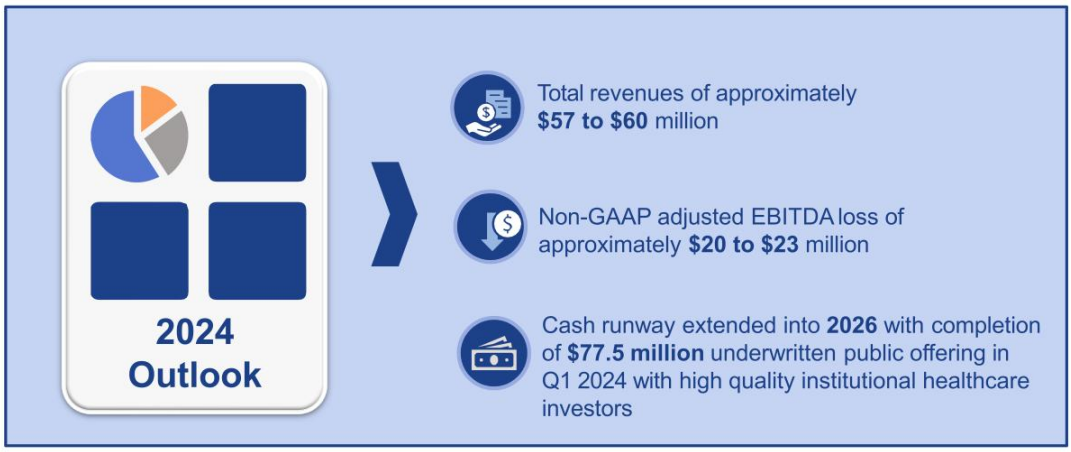
1. Plan on commencing study after alignment with the FDA. 2. Interim data expected to be available after 12 weeks and primary endpoint data expected to be available at 24 weeks.

Planned AQST-108 clinical and regulatory approval timeline[1]

1. End of phase 2 meeting with the FDA is planned for the fourth quarter of 2025 or the first quarter of 2026.

Financial Guidance

2024 expected outlook as of November 6, 2024



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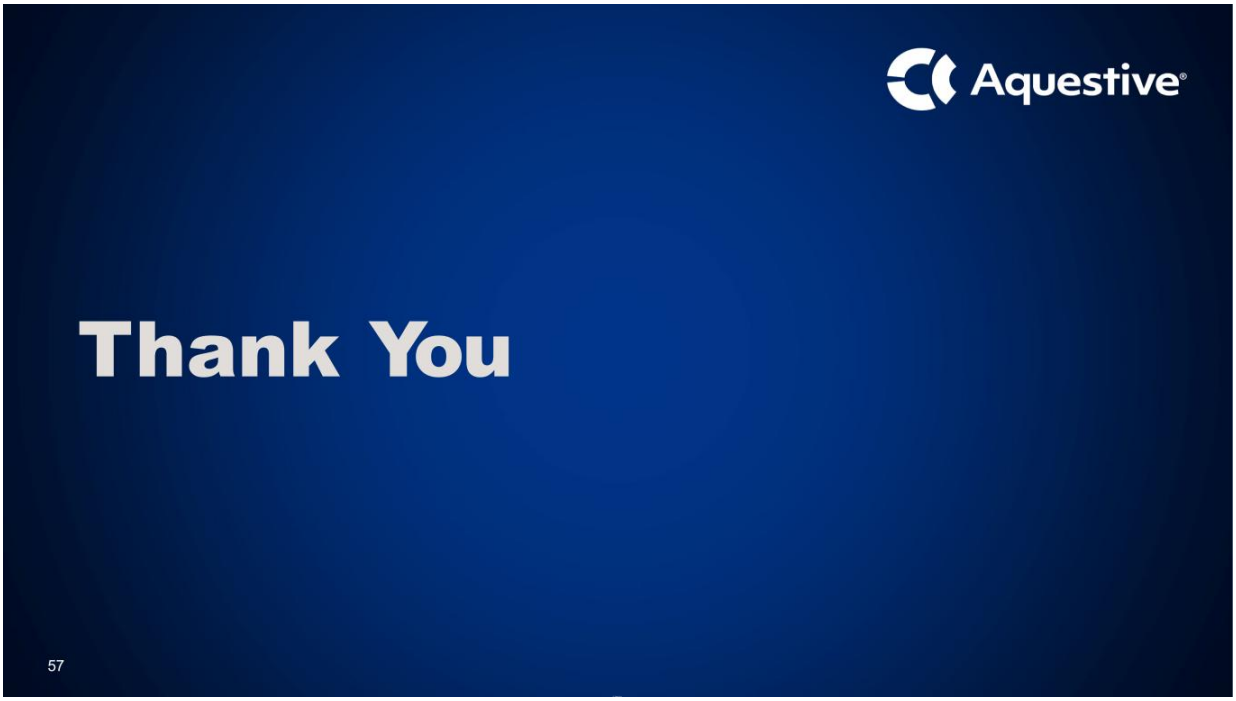
Aquestive
Thank You
57