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): September 9, 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.

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. Copies 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 Company's website located at www.aquestive.com, although the Company reserves the right to discontinue that availability at any time.

A copy of the Company's investor presentation given to investors, analysts an others at the H.C. Wainwright 26th Annual Global Investor Conference on September 9, 2024 is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The H.C. Wainwright 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 and Exhibit 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 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 September 2024
99.2	Aquestive Therapeutics, Inc. H.C. Wainwright 26th Annual Global Investor Conference Presentation dated September 9, 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: **September 9, 2024**

Aquestive Therapeutics, Inc.

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

Aquestive®

Corporate Presentation

September 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-Investigational New Drug (IND) application meeting with the FDA and filing the New Drug Application (NDA) for Anaphylm, 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; the commercial opportunity of Libervant, Anaphylm, AQST-108 and our other product candidates, including potential revenues generated 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; the potential benefits our products and product candidates could bring to patients; 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, including for Anaphylm, AQST-108, Libervant for patients aged between six and eleven and 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 data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's 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; 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 a nasal spray product approved by the FDA 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 relating to U.S. orphan drug market exclusivity by the owner of the approved nasal spray product with respect to the FDA's approval for U.S. market access of Libervant for this pediatric patient population 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; 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 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 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 in January 2027; risk of the rate and degree of market acceptance in the U.S. and abroad of 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 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 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 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 the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 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.

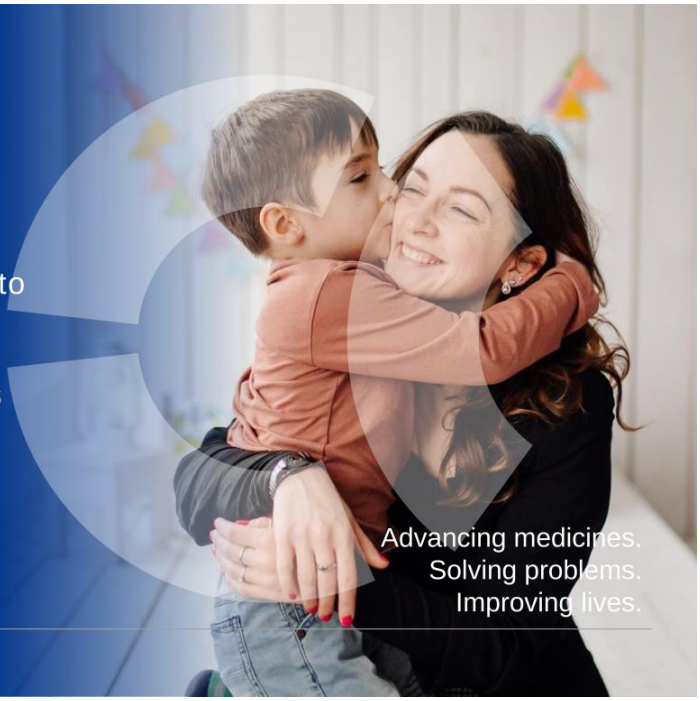
This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

PharmFilm® 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



Advancing medicines.
Solving problems.
Improving lives.

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

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. Ondif collaboration with Hypera-Pharma (Brazil). 2. Sympazan collaboration with Otter Pharmaceuticals. 3. Libervant FDA Approval. 4. Libervant collaboration with Pharmanovia (Ex-US). 5. Emylif collaboration with Zambon (EU). 6. Suboxone collaboration with Indivior.

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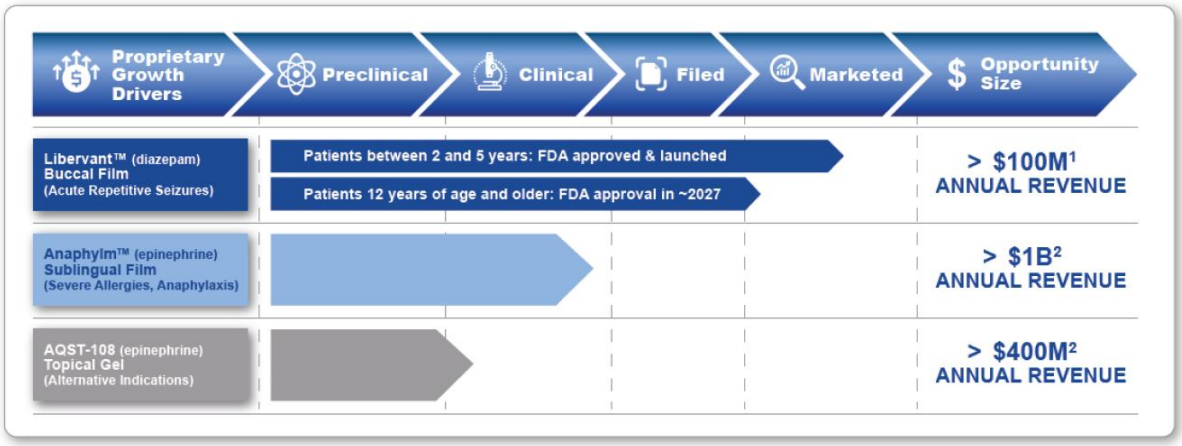
Diversified pipeline



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

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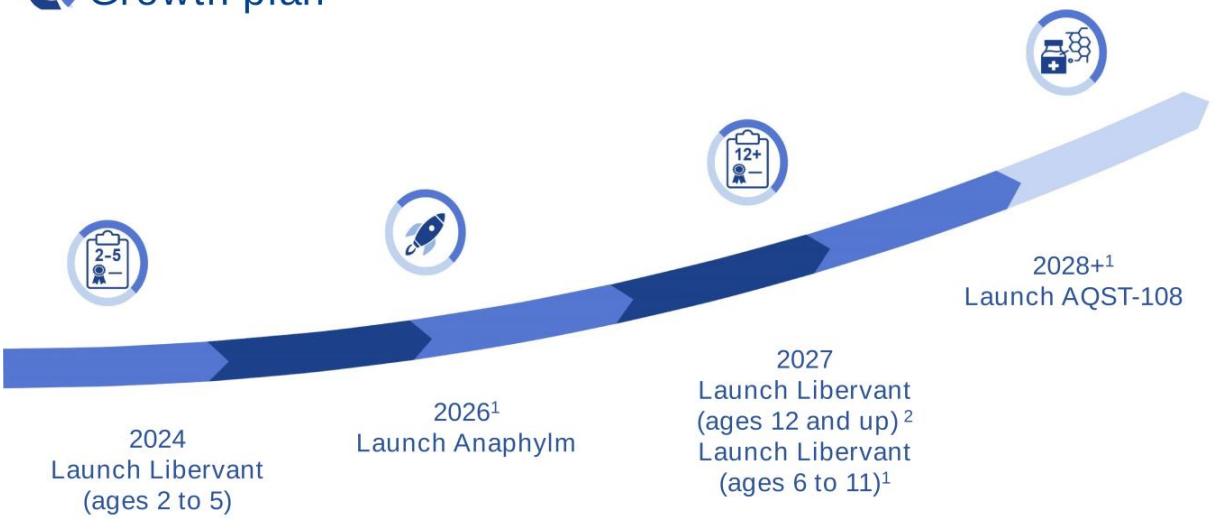
Growth plan



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

Aquestive

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

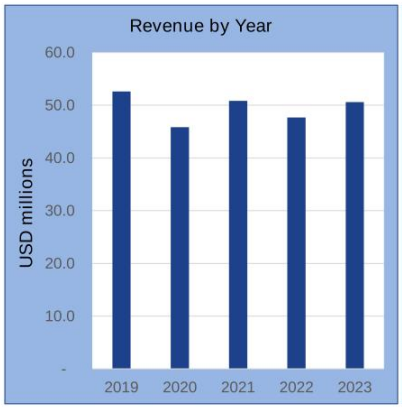
Production

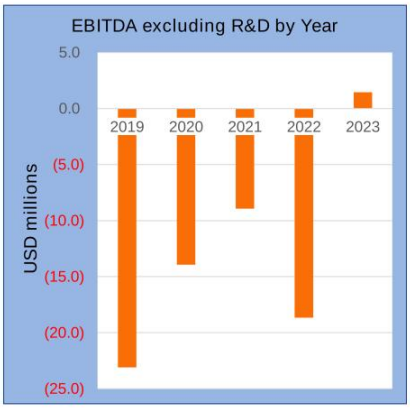
- Leading manufacturer of oral thin film technology (over 2 billion doses distributed for patient use)
- Two manufacturing and packaging facilities located in Indiana
- Comprehensive supply chain sourcing expertise

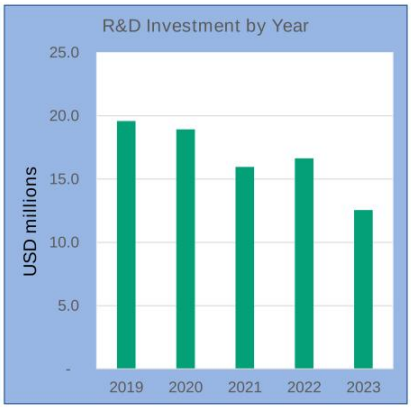
Commercialization

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

Financial snapshot







Aquestive

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
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 U.S. by 2027
Over
$1.5 billion1
in potential peak annual net sales from pipeline assets
1. Aquestive Therapeutics data on file.
11

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.

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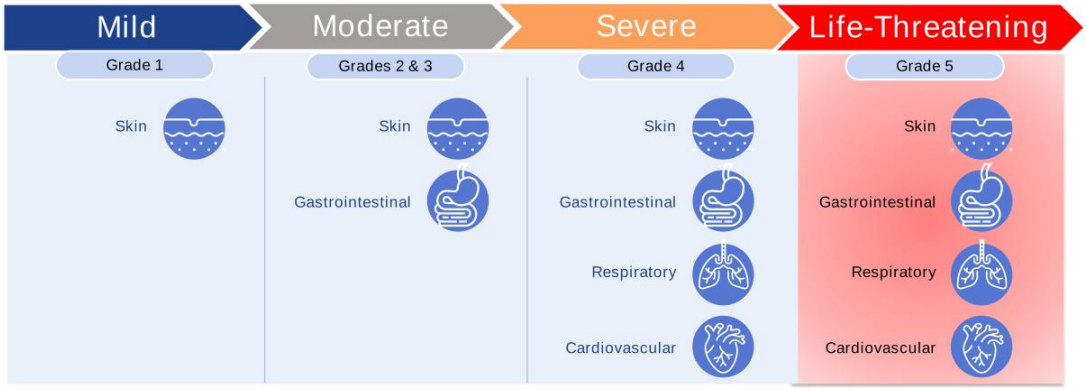
Stages of anaphylaxis: early intervention is critical[1]



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

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

Aquestive

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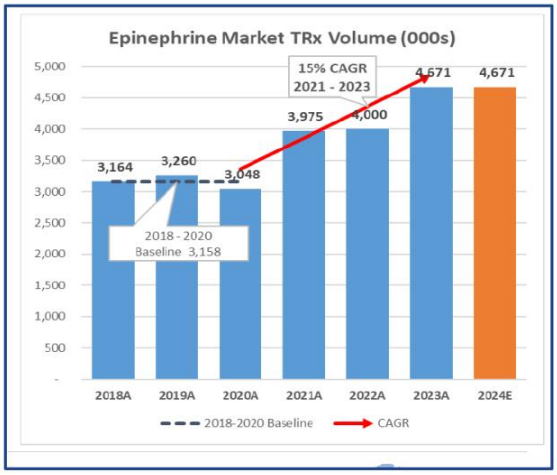
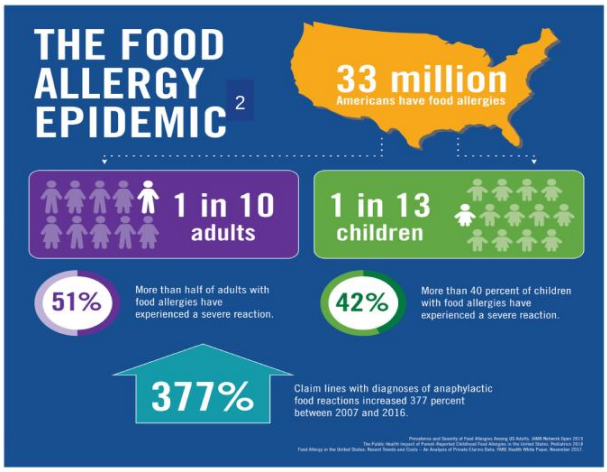
U.S. market has the potential to grow to ~$2B in value by 2031[1]





1. Aquestive Therapeutics data on file, scripts written for epinephrine autoInjectors have increased at a 15% compound annual growth rate (CAGR) from 2021- 2023.
2. https://foodallergy.org/resources/epidemic-infographic.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Lead Asset Anaphylm™ (epinephrine) Sublingual Film

Executive Summary

Anaphylm meets all predetermined primary and secondary endpoints of program clinical studies to support 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

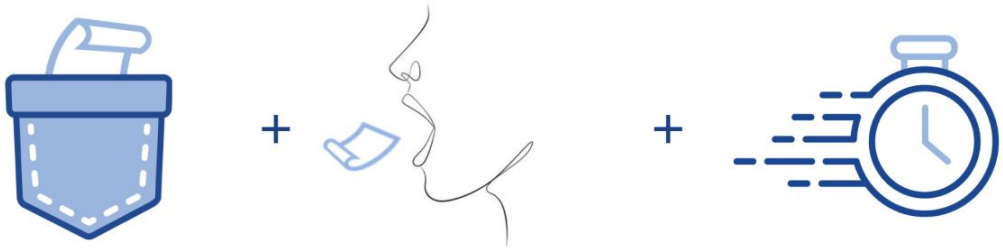
Path to Launch

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

1. Aquestive Therapeutics data on file.

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 result reflect autoinjectors only.

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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.

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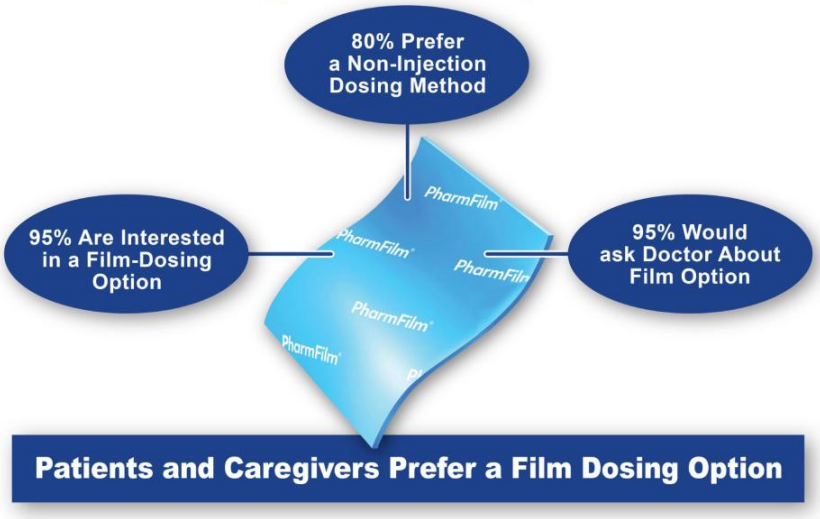
Patients and caregivers have spoken[1]



1. Aquestive Therapeutics 2024 Survey data on file.

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Aquestive
Intellectual Property
25

Patented Technology is Broad, Deep and Constantly Evolving, with Anaphylm-Specific 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, patent coverage would be extended to 2044.

Anaphylm Clinical Program

Program overview

Pivotal Study meets predetermined endpoints for single dose and repeat dose

Temperature/pH Study and Self-Administration Study meet predetermined endpoints; Oral Allergy Syndrome Study underway

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

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 Consistent pharmacokinetics (PK) demonstrated across 5 administration procedures:

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

3 Safety and tolerability:

- **Adverse events (AE's) were** generally mild, all were transient and resolved without intervention

1. Aquestive Therapeutics data on file.

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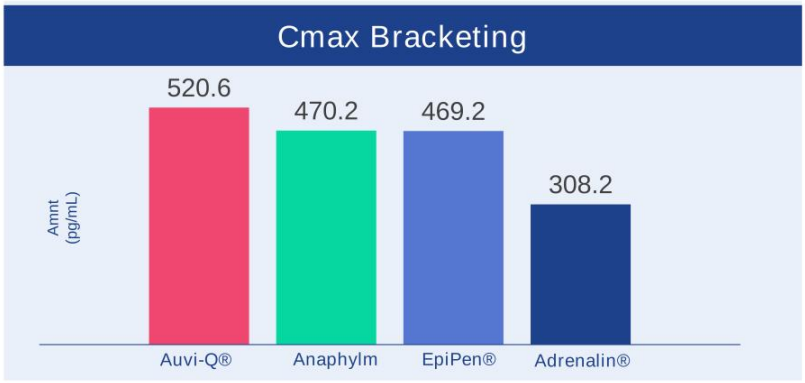
Anaphylm Pivotal Study Results

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; $pAUC_{0\text{-}20min}$ not statistically different ($p > 0.05$) (comparison to EpiPen); Aquestive Therapeutics data on file.

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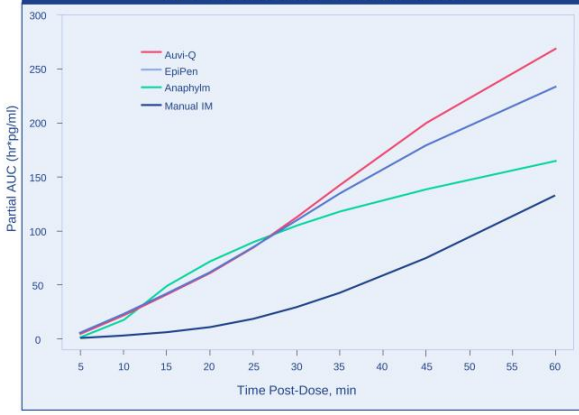
Primary predetermined endpoint of pAUC, demonstrating biocomparability to SOC

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



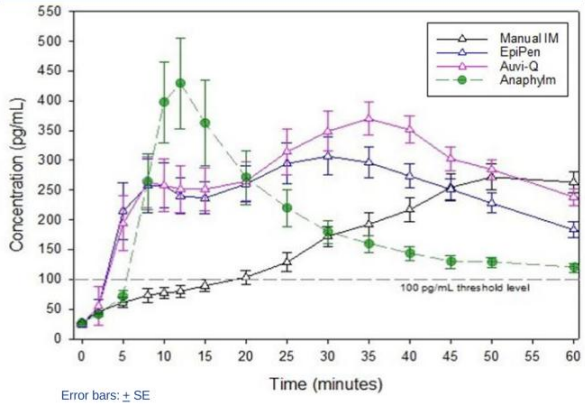
Anaphylm's partial AUC values demonstrate comparability to autoinjectors for 30 minutes post-dosing and remain bracketed beyond 60 minutes after dosing

1. Aquestive Therapeutics data on file.

Aquestive®

Anaphylm demonstrated a rapid and robust PK profile[1]

Geometric Mean Epinephrine Concentrations by Product After a Single Dose



Error bars: ± SE

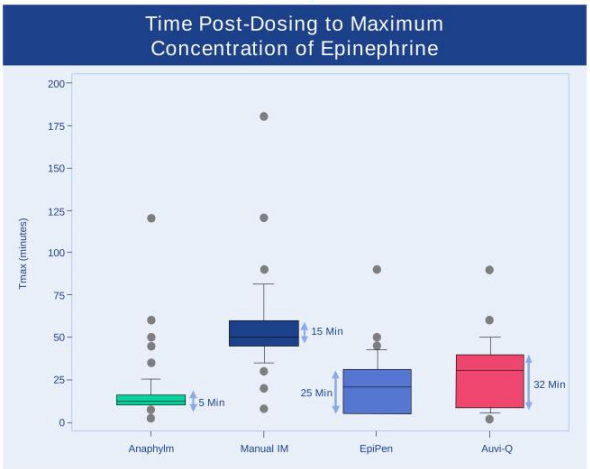
Anaphylm's epinephrine concentration:

- Exceeds Adrenalin beginning at 2 minutes
- **Matches EAI's by 10 minutes**
- Sustains levels above Adrenalin intramuscular 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 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 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.

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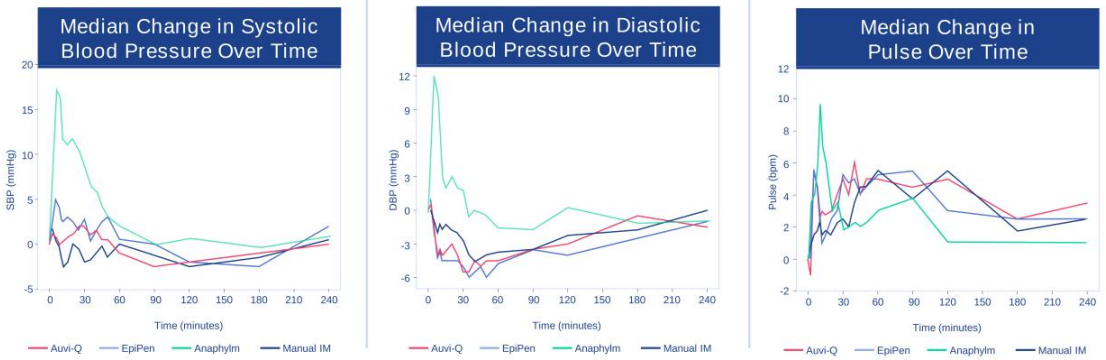
Anaphylm demonstrates rapid pharmacodynamic (PD)

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



1. Aquestive Therapeutics data on file.

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Supportive Studies and Clinical Timeline

Temperature/pH study 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%

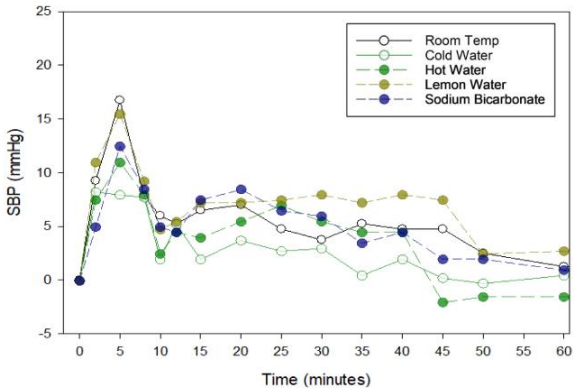
Key Takeaways:

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

1. Aquestive Therapeutics data on file.

Temperature/pH study pharmacodynamic (PD) results[1]

Median Change in Systolic Blood Pressure Over 60 Minutes Following Administration of Anaphylm (epinephrine) Sublingual Film



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 study results

1. Aquestive Therapeutics data on file.

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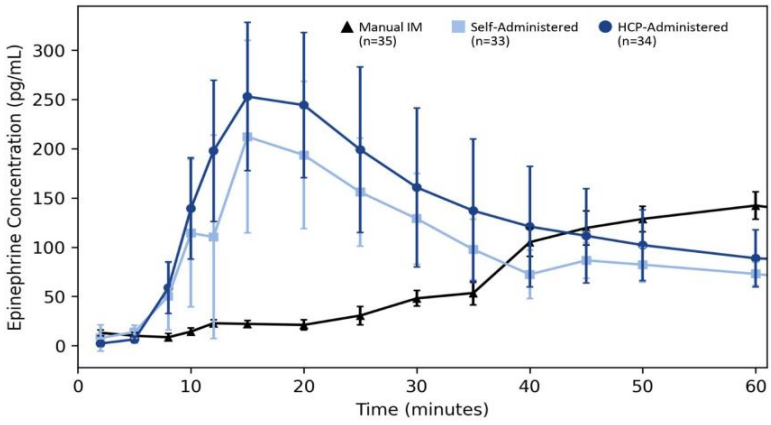
Self-administration PK study results[1]



Key Takeaways:

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

1. Aquestive Therapeutics data on file.

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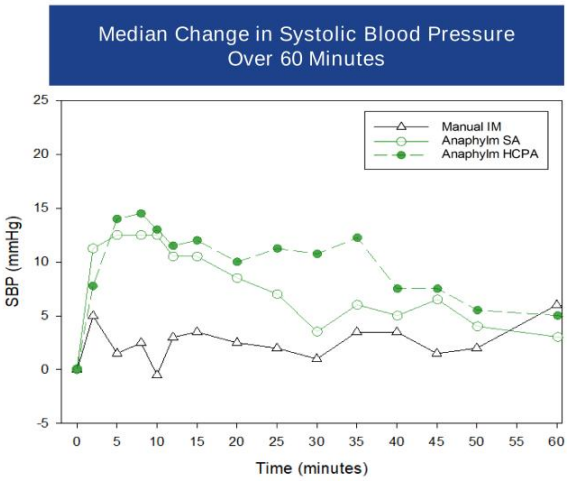
Self-administration study PD results[1]



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.

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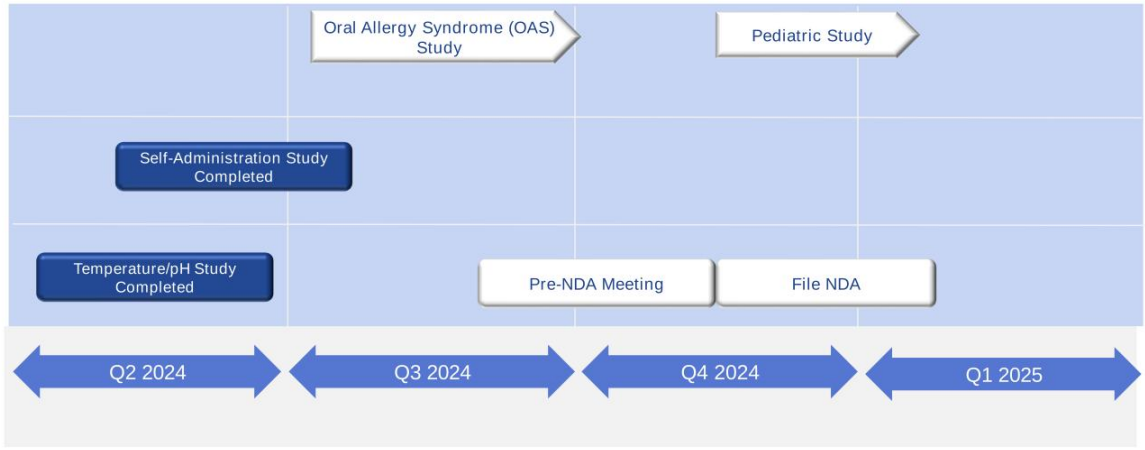
Expected clinical timeline for Anaphlym



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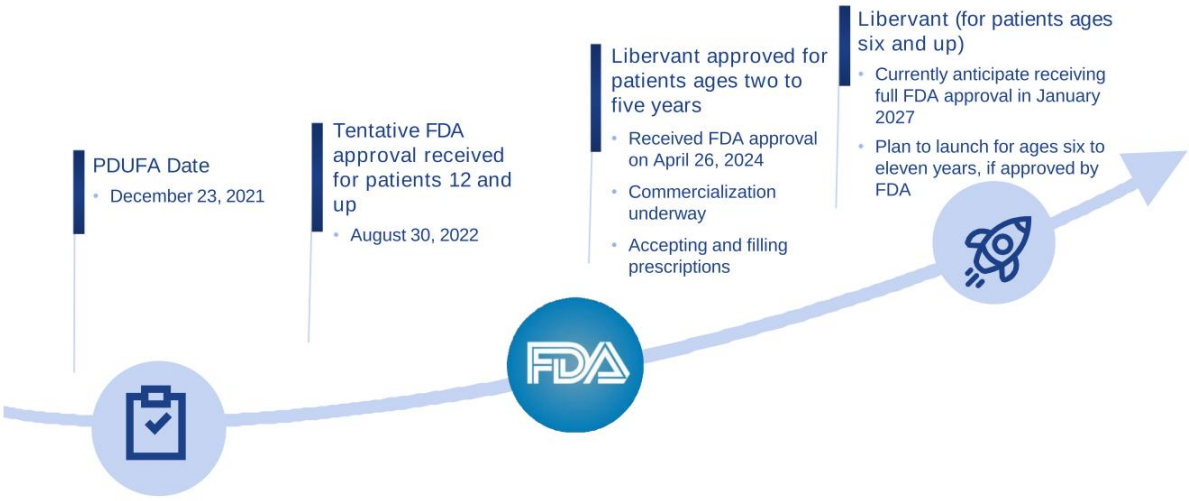
Pipeline Products

Expected full launch path for Libervant™(diazepam) buccal film



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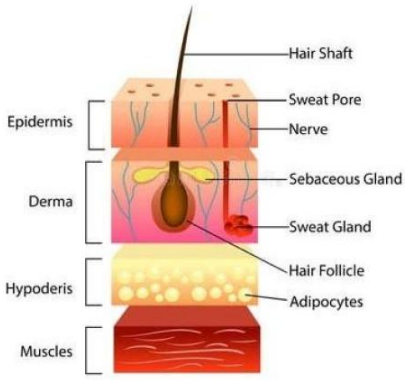
AQST-108 (epinephrine) topical gel

Human Skin Structure

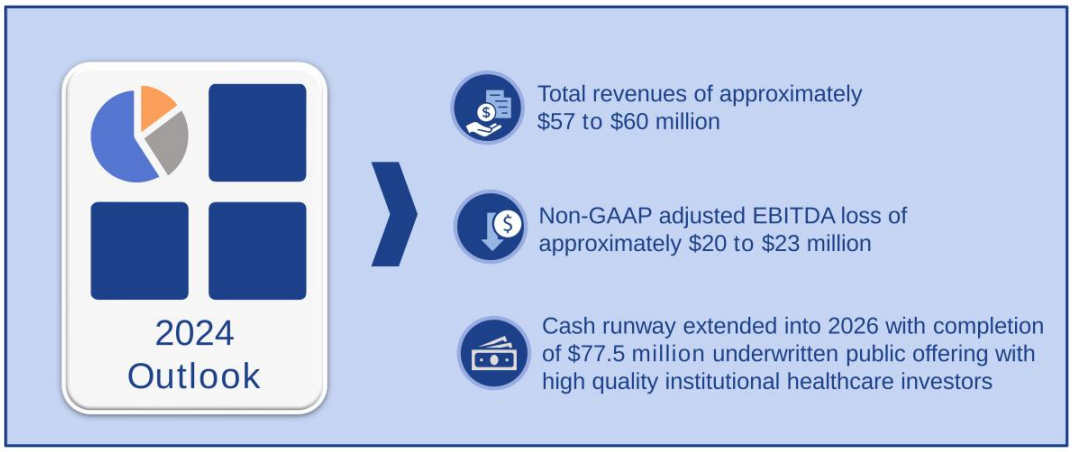


- Topical delivery of epinephrine has been limited due to poor permeability and rapid clearance[1]
- Adrenaverse prodrug platform demonstrates targeted delivery of epinephrine without systemic effects[2]
- First human study completed
- IND-enabling ex-vivo / non-clinical program ongoing

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). 2. Aquestive Therapeutics data on file.

Financial Guidance

2024 expected outlook as of August 6, 2024



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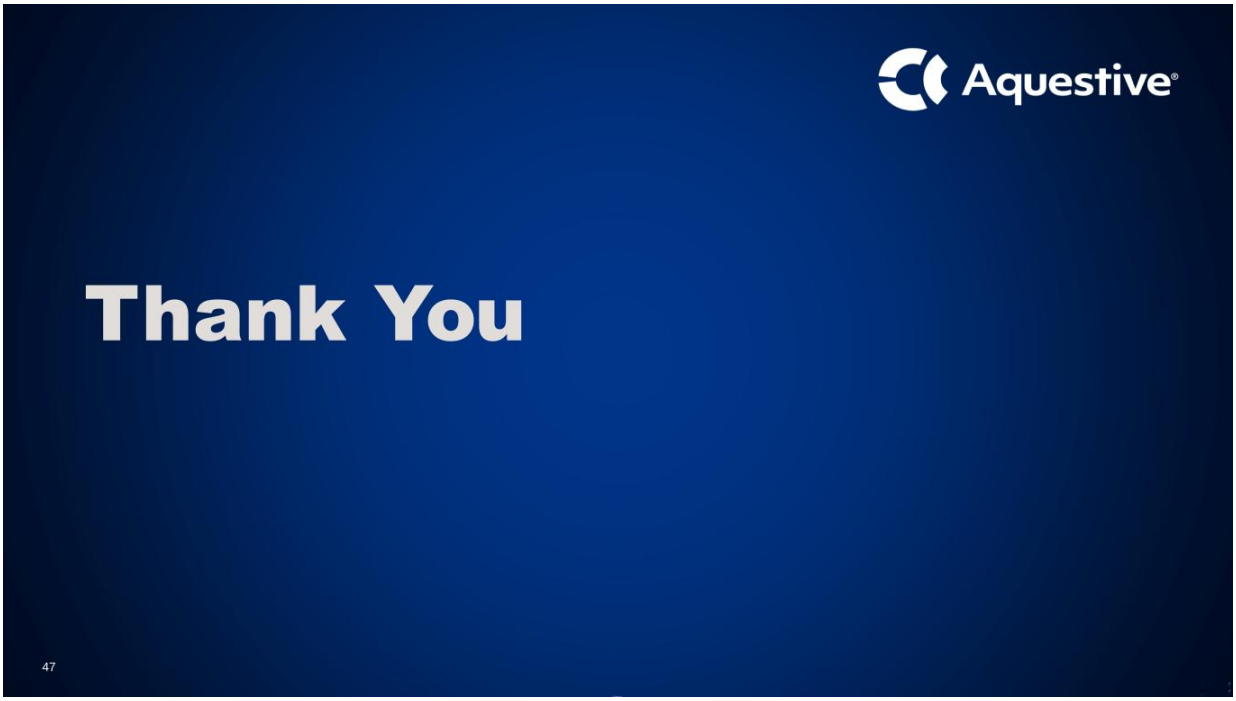
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Thank You
47


Aquestive
H.C. Wainwright 26th Annual Global Investor Conference
September 9, 2024
Advancing medicines.
Solving problems.
Improving lives.

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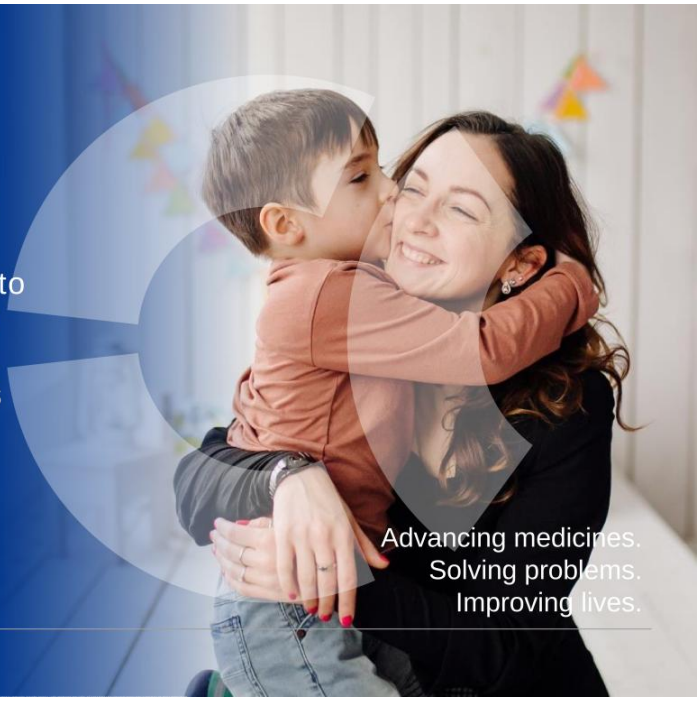
This presentation and the accompanying oral commentary have been prepared by Aquestive Therapeutics, Inc. ("Aquestive", the "Company", "our" or "us") and contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "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 FDA, including submission of supporting clinical studies and the NDA for Anaphylm with the FDA and the following launch of Anaphylm, if approved 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 advancement and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine)Topical Gel (and potential alternative indications), through clinical development and approval by the FDA, and the following launch of AQST-108, if approved by the FDA; the future commercial opportunity (including projected peak annual sales) of our products and product candidates, including Anaphylm and AQST-108, if approved by the FDA, and for Libervant™ (diazepam) Buccal Film for the indicated epilepsy patient population aged between two and five years and, if approved by the FDA for U.S. market access, Libervant for these epilepsy patients aged 6 and older; the continued expansion of U.S. market growth, access and coverage for epilepsy patients and the opportunity such growth presents to the Company, should Anaphylm be approved by the FDA; our ability to price Anaphylm competitively and to leverage our commercial and distribution capabilities and infrastructure for Anaphylm, if approved by the FDA; the advancement and related timing of Libervant for patients aged between six and eleven years through the clinical development and FDA regulatory approval process for U.S. market access; the approval for U.S. market access of Libervant for this patient population aged twelve 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; the potential benefits our products could bring to patients; and business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm (including for pediatric patients), AQST-108, Libervant for patients aged between six and eleven years, and the Company's other product candidates; risks associated with the Company's marketing and 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 litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved nasal spray product for pediatric epilepsy patients between two to five years of age relating to the approval by the FDA of Libervant for pediatric patients aged between two and five years; risk of delays in advancement of the regulatory approval process through the FDA of Anaphylm, including the filing of the NDA for Anaphylm, and for AQST-108 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 data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's 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; risk that we may not overcome the seven year orphan drug 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 between six and 11, if approved by the FDA, and for patients aged twelve years and older until the expiration of the exclusivity period in January 2027 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, if approved by the FDA; 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 Anaphylm, should Anaphylm be approved by the FDA, and for Libervant for older patients should Libervant receive U.S. market access for these older patients or after the expiration of the orphan drug exclusivity period in January 2027 for another company's nasal spray product granted by the FDA; 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 risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of default of our debt instruments; risk related to litigation claims against Indivior for which we license, manufacture and sell Suboxone; 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 our products and product candidates, including Anaphylm and AQST-108, should they be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of the success of any competing products including generics, risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk 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 the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 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 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.

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



Advancing medicines.
Solving problems.
Improving lives.

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.

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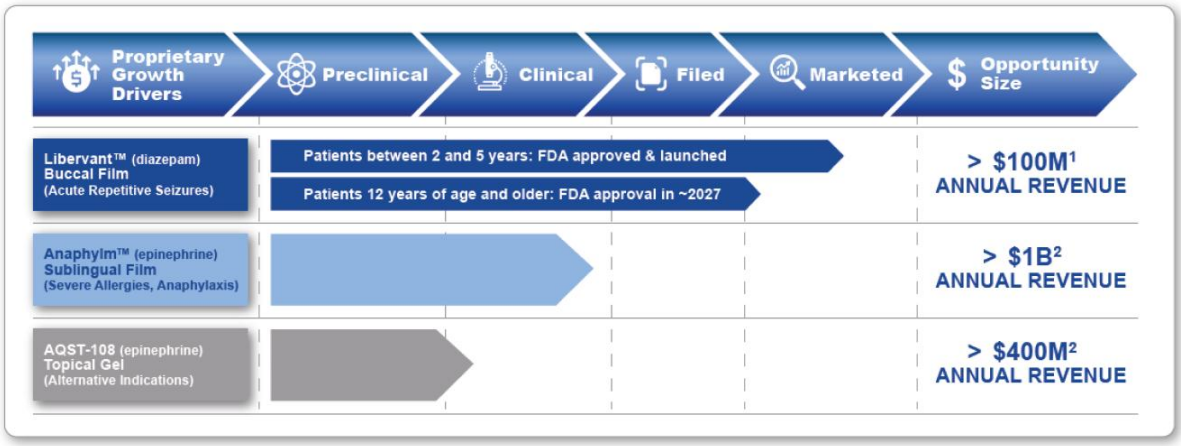
6
FDA
drug approvals
More than
2 billion
PharmFilm® doses shipped worldwide
PharmFilm
19+
years since the company was founded
Aquestive®
(NASDAQ: AQST)
$50M+
of revenue in 2023
150+
employees based in Indiana and New Jersey
Products are available on
6
continents
2
Product launches are expected in the U.S. by 2027
Over
$1.5 billion1
in potential peak annual net sales from pipeline assets
1. Aquestive Therapeutics data on file.
5

Diversified pipeline



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

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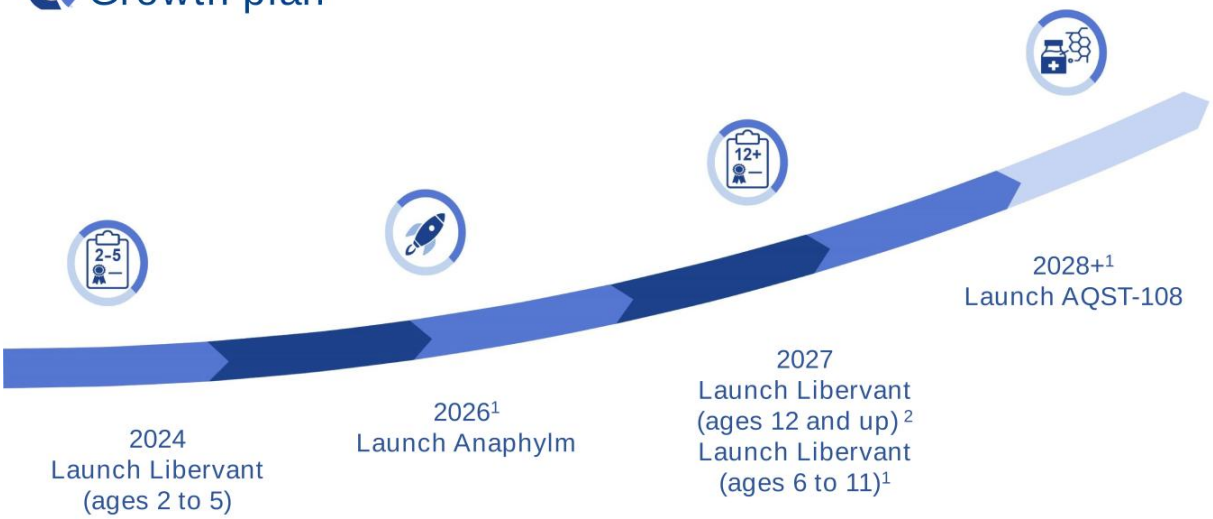
Growth plan



1. Assumes satisfaction of all predetermined clinical endpoints and approved by U.S. Food and Drug Administration (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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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

Anaphylaxis: a potentially fatal allergic reaction[1]

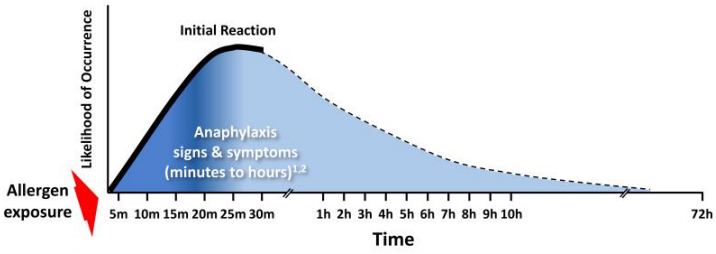
Severe systemic hypersensitivity allergic reaction
that is rapid in onset and can cause death

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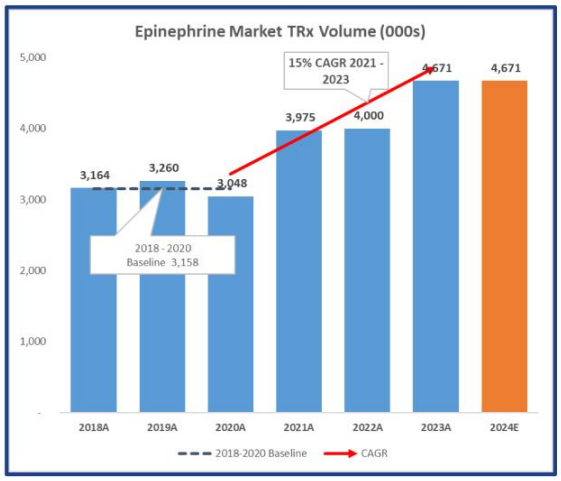
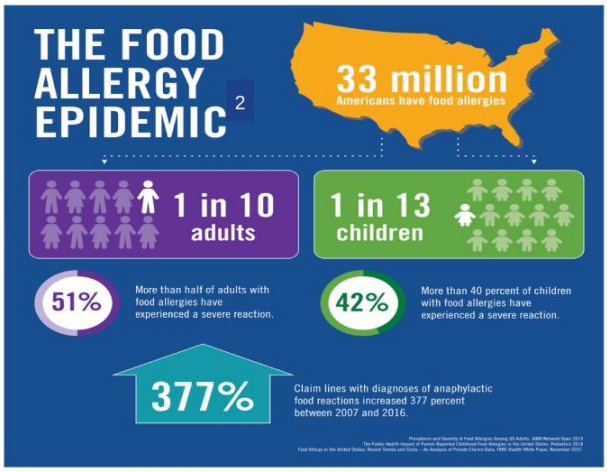
U.S. market has the potential to grow to ~$2B in value by 2031[1]





1. Aquestive Therapeutics data on file, scripts written for Epinephrine Auto-Injectors have increased at a 15% Compound Annual Growth Rate (CAGR) from 2021- 2023.
2. https://foodallergy.org/resources/epidemic-infographic.

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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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Epinephrine medical devices (EMDs) carry rates are low

52% of patients surveyed who had previously experienced anaphylaxis had never received an epinephrine auto-injector prescription[1]

60% of respondents in same patient survey did not have an epinephrine auto-injector currently available[1]

1. Fromer L. The American Journal of Medicine (2016);129, 1244-1250; data reflects carry rates for autoinjectors only.

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 autoinjectors only.

DoorDash® survey[1]

- The average person has to return home to retrieve four forgotten items per month
- 39% of people forget more than five items each month

1. https://nypost.com/2022/07/05/this-many-americans-forget-their-phones-more-before-travel/ n=2000.

Complacency in carrying an EMD is the norm

A recent published survey indicated that:

- 100% of respondents said that they would not return home if they had forgotten their epinephrine[1]
- Carrying methods for EMDs include diaper bags (30%), lunch boxes (11%), fanny packs (20%) and backpacks (20%)[1]

1. https://www.healio.com/news/allergy-asthma/20231211/customer-discovery-reveals-why-patients-do-not-carry-their-epinephrine-autoinjectors; survey results reflect autoinjectors only

Aquestive®

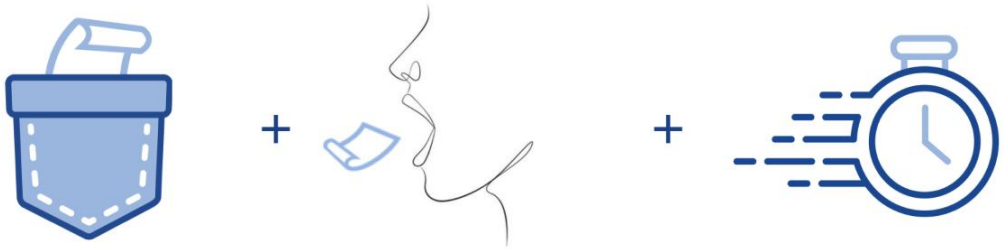
Sherry Korczynski

SVP, Sales & Marketing

Advancing medicines.
Solving problems.
Improving lives.

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.

Anaphylm is simple to use

Autoinjectors	Neffy®	Anaphylm™[7]

• Due to needle reluctance, 60% of patients/caregivers often delay treatment[1]
• 25-50% often refuse treatment with EpiPen®[2,3,4]
• Highly temperature sensitive due to aqueous epinephrine formulations (98% water content)[5]
  • becomes completely unusable when frozen
  • cannot be exposed to significantly elevated temperatures
	• Multiple factors that could compromise efficacy of the treatment[6]:
	  • Sniffing during or after the dose
	  • Dripping of the liquid from the nose
	  • Angling of the nozzle
	  • Accidental priming
	  • Non-room temperature storage (can only last a few days at 122°F / if frozen, must thoroughly thaw before use)
		• Sublingual application
		• Maintains shelf life at high temperature for extended period of time (over 4 months at 104°F and up to one month at 122°F)
		• Does not freeze, works in sub-zero °C temperatures, due in part to minimal water content (2%)

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. EpiPen® package insert. 6. neffy prescribing information and clinical studies. 7. Aquestive Therapeutics data on file.

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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 Consistent pharmacokinetics (PK) demonstrated across 5 administration procedures:

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

3 Safety and tolerability:

- **Adverse events (AE's) were** generally mild; all were transient and resolved without intervention

1. Aquestive Therapeutics data on file.

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.

Planned Anaphylm launch strategy

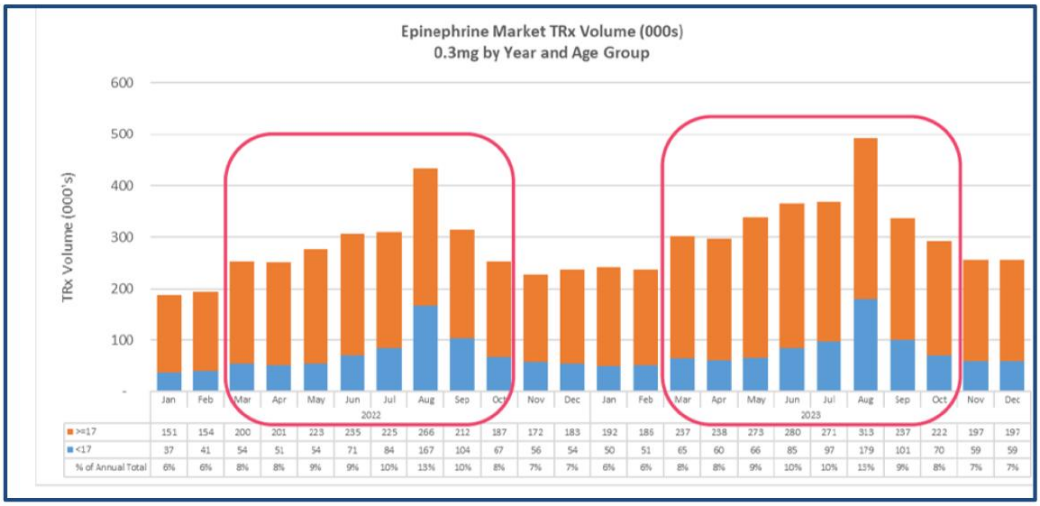
1	Focus on driving awareness among allergists and pediatricians
2	**Launch into the “warm weather” volume increase**
3	Price within the range of existing standards of care
4	Leverage existing commercial infrastructure

Epinephrine prescribers: an addressable market opportunity[1]

- Allergists are the most productive segment by far, averaging ~200 prescriptions per year
- Pediatricians are the second most productive segment, averaging ~16 prescriptions per year

1. Aquestive Therapeutics data on file.

Launch into the “warm weather” volume increase[1]

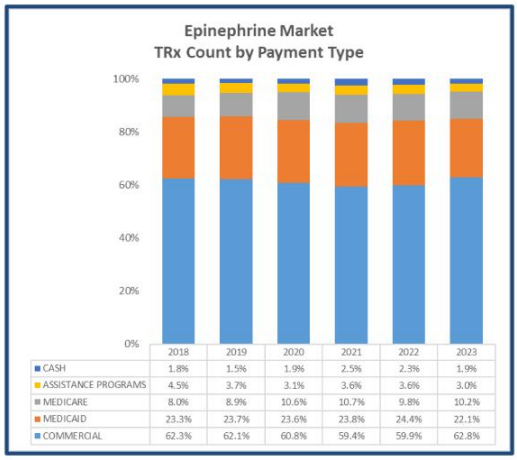


	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
>=17	151	154	200	201	223	235	225	266	212	187	172	183	192	186	237	238	273	280	271	313	237	222	197	197
<17	37	41	54	51	54	71	84	167	104	67	56	54	50	51	65	60	66	85	97	179	101	70	59	59
% of Annual Total	6%	6%	8%	8%	9%	9%	10%	13%	10%	8%	7%	7%	6%	6%	8%	8%	9%	10%	10%	13%	9%	8%	7%	7%

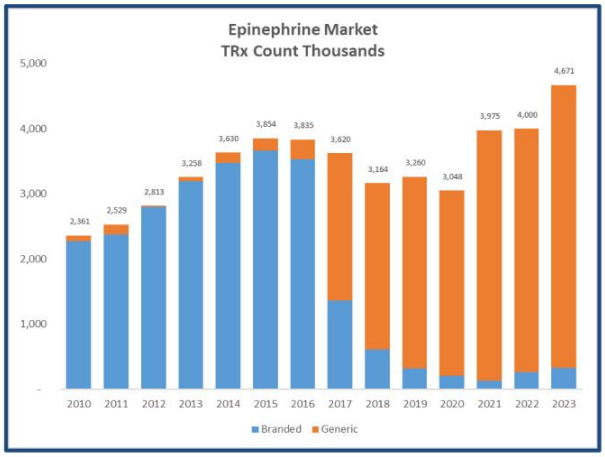
1. Aquestive Therapeutics data on file; all market data is limited to U.S. and its Territories.

Aquestive

Price within the current range of existing SOCs[1]



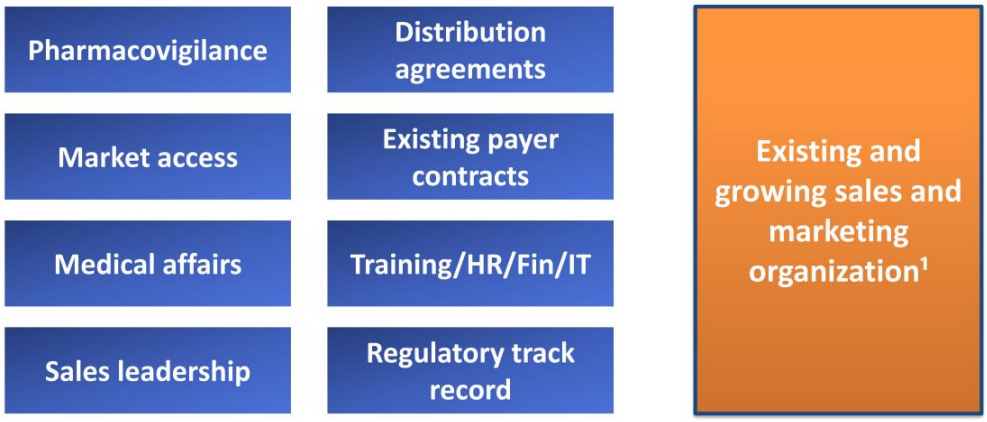
	2018	2019	2020	2021	2022	2023
CASH	1.8%	1.5%	1.9%	2.5%	2.3%	1.9%
ASSISTANCE PROGRAMS	4.5%	3.7%	3.1%	3.6%	3.6%	3.0%
MEDICARE	8.0%	8.9%	10.6%	10.7%	9.8%	10.2%
MEDICAID	23.3%	23.7%	23.6%	23.8%	24.4%	22.1%
COMMERCIAL	62.3%	62.1%	60.8%	59.4%	59.9%	62.8%



1. Aquestive Therapeutics data on file; all market data is limited to U.S. and its Territories.

Aquestive

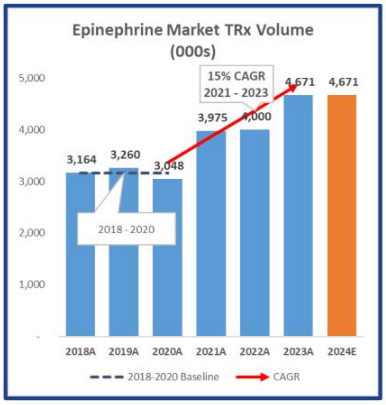
Leveraging our Libervant experience



1. Libervant (diazepam) Buccal Film FDA approved and marketed for Acute Repetitive Seizures (ARS) in pediatric patient ages between two and five years old.

Anaphylm summary

Large Market Opportunity



Novel Oral Product

Late-Stage Development

1. Aquestive Therapeutics data on file. 2. Scripts written for Epinephrine Auto-Injectors have increased at a 15% Compound Annual Growth Rate (CAGR) from 2021- 2023.

Aquestive

Thank You

Advancing medicines.
Solving problems.
Improving lives.