



# H.C. Wainwright 26th Annual Global Investor Conference

September 9, 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 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 sunset 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.

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.



## 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.*

**6**



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

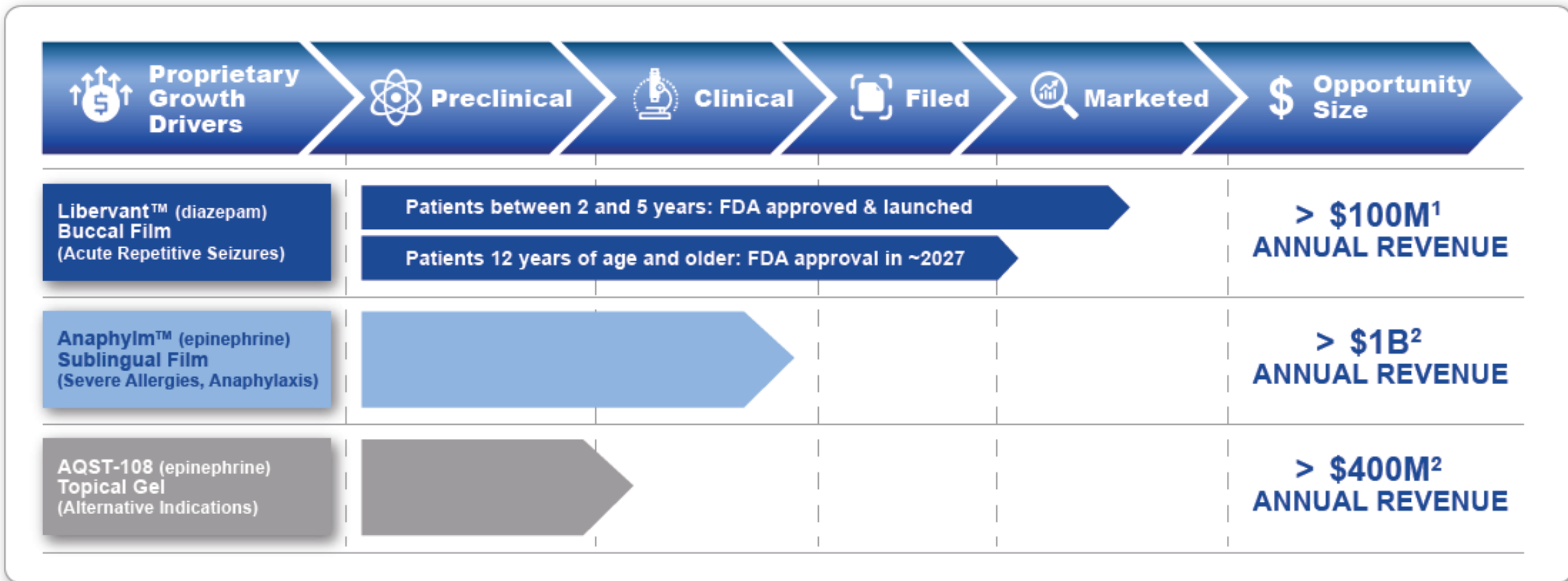
**\$1.5 billion<sup>1</sup>**

in potential peak annual net sales from pipeline assets



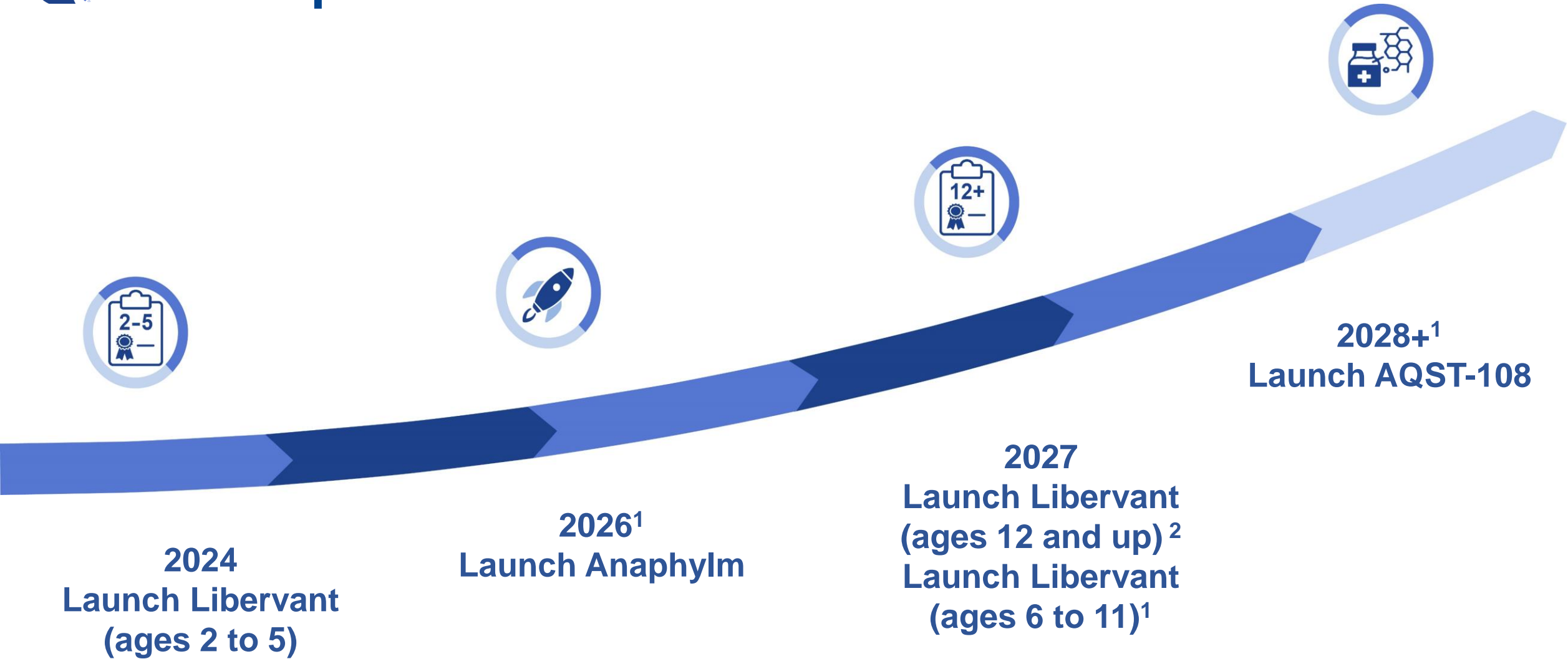
1. Aquestive Therapeutics data on file.

# 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 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.

# 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



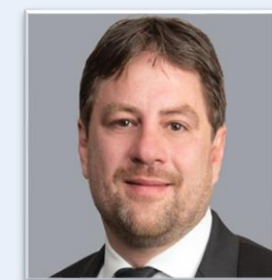
**Carl Kraus**  
Chief Medical Officer



**Mark Schobel**  
Chief Innovation &  
Technology Officer



**Ernie Toth**  
Chief Financial Officer



**Steve Wargacki**  
Chief Science Officer



# Anaphylaxis: a potentially fatal allergic reaction<sup>1</sup>



**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**

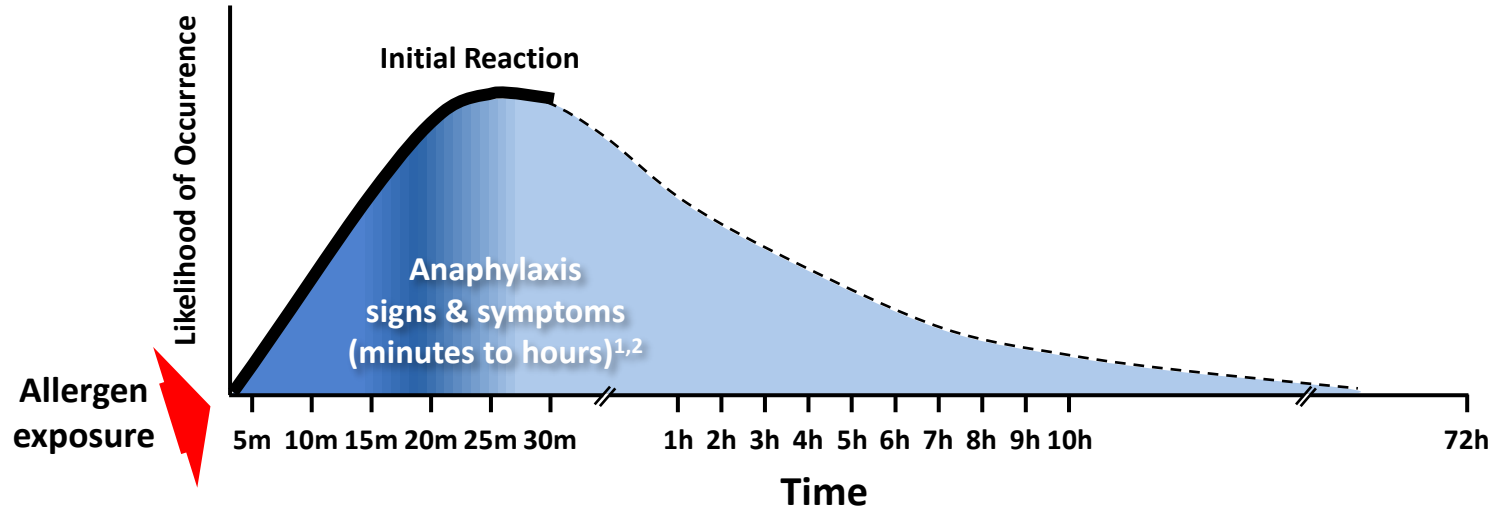


**Patients at risk for anaphylaxis should have a long-term allergy-management plan**

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

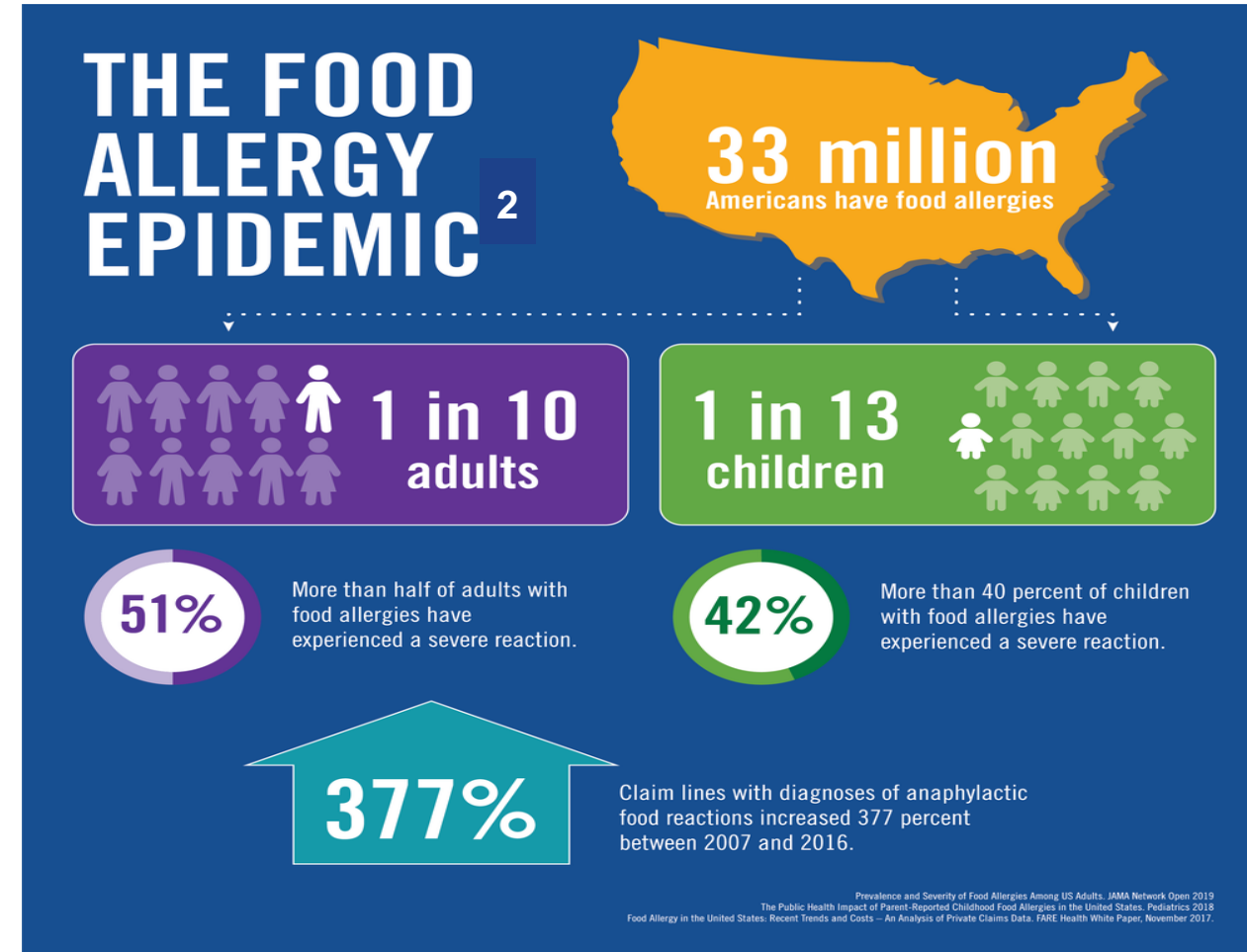
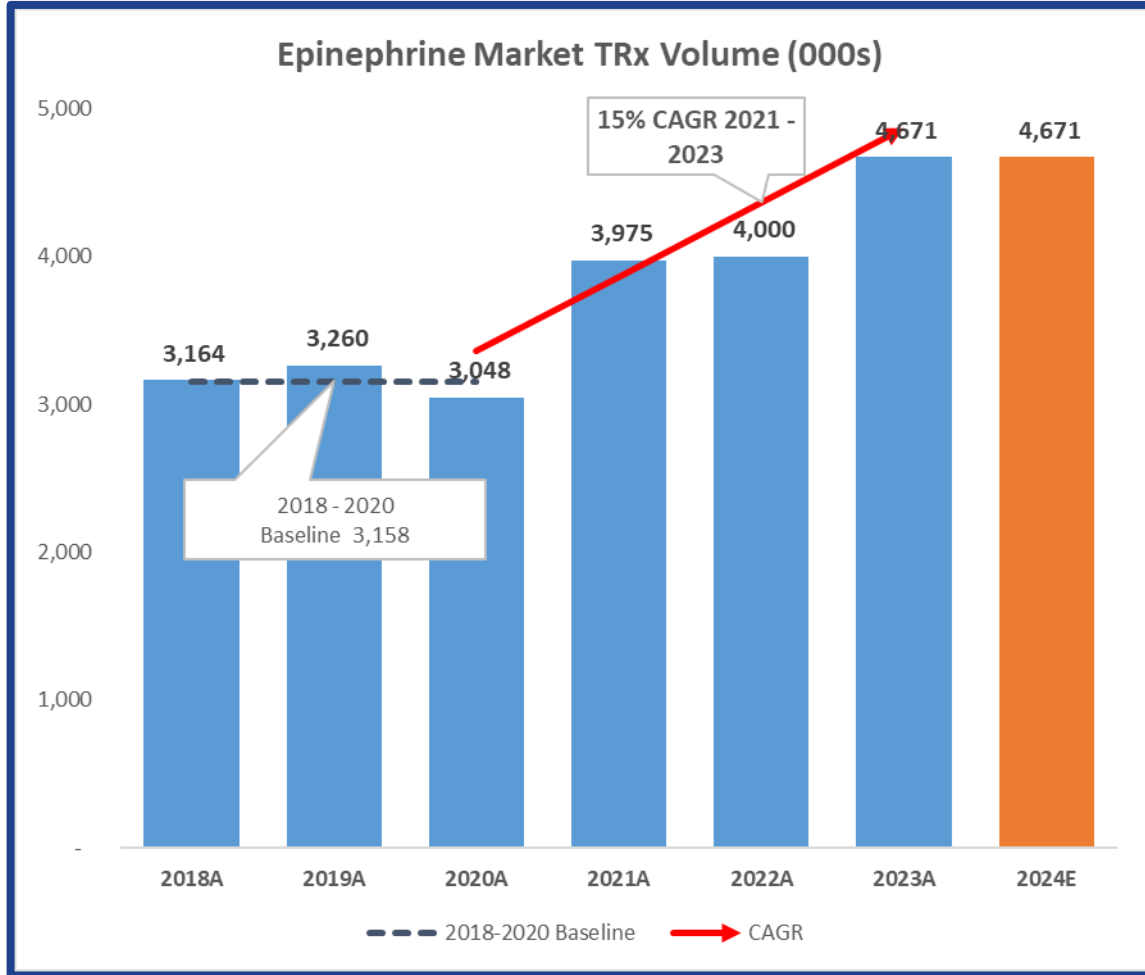
# During an allergic reaction, time is the enemy

Medical Guidelines: Use epinephrine auto-injector promptly<sup>2-4</sup>



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

# U.S. market has the potential to grow to ~\$2B in value by 2031<sup>1</sup>



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>.

# 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**

# 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<sup>1</sup>

**60%**

of respondents in same patient survey did not have an epinephrine auto-injector currently available<sup>1</sup>

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)<sup>1</sup>

- **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<sup>1</sup>



- **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<sup>1</sup>**
- **Carrying methods for EMDs include diaper bags (30%), lunch boxes (11%), fanny packs (20%) and backpacks (20%)<sup>1</sup>**





# Sherry Korczynski

SVP, Sales & Marketing



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# Anaphylm™ (epinephrine) sublingual film

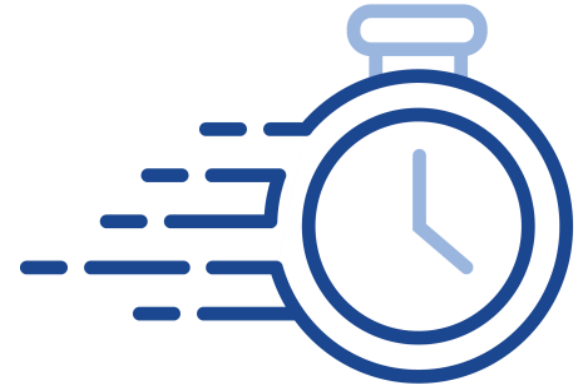
First and only non-device based, orally delivered epinephrine product candidate



Easy To Carry



Easy To Administer



Works Quickly<sup>1</sup>

1. Aquestive Therapeutics data on file.

# Anaphylm is simple to use



Autoinjectors	Neffy®	Anaphylm™ <sup>7</sup>
<ul style="list-style-type: none"><li>• Due to needle reluctance, 60% of patients/caregivers often delay treatment<sup>1</sup></li><li>• 25-50% often refuse treatment with EpiPen®<sup>2,3,4</sup></li><li>• Highly temperature sensitive due to aqueous epinephrine formulations (98% water content)<sup>5</sup><ul style="list-style-type: none"><li>• becomes completely unusable when frozen</li><li>• cannot be exposed to significantly elevated temperatures</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Multiple factors that could compromise efficacy of the treatment<sup>6</sup>:<ul style="list-style-type: none"><li>• Sniffing during or after the dose</li><li>• Dripping of the liquid from the nose</li><li>• Angling of the nozzle</li><li>• Accidental priming</li><li>• Non-room temperature storage (can only last a few days at 122°F / if frozen, must thoroughly thaw before use)</li></ul></li></ul>	<ul style="list-style-type: none"><li>• <b>Sublingual</b> application</li><li>• <b>Maintains shelf life at high temperature</b> for extended period of time (over 4 months at 104°F and up to one month at 122°F)</li><li>• <b>Does not freeze</b>, works in sub-zero °C temperatures, due in part to minimal water content (2%)</li></ul>

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.

# Fast-acting and well-tolerated, with a safety profile comparable to standard of care (SOC)<sup>1</sup>

1

**Rapid absorption as demonstrated by:**

**Consistent time to peak drug concentration (T<sub>max</sub>) 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<sup>1</sup>

**~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**

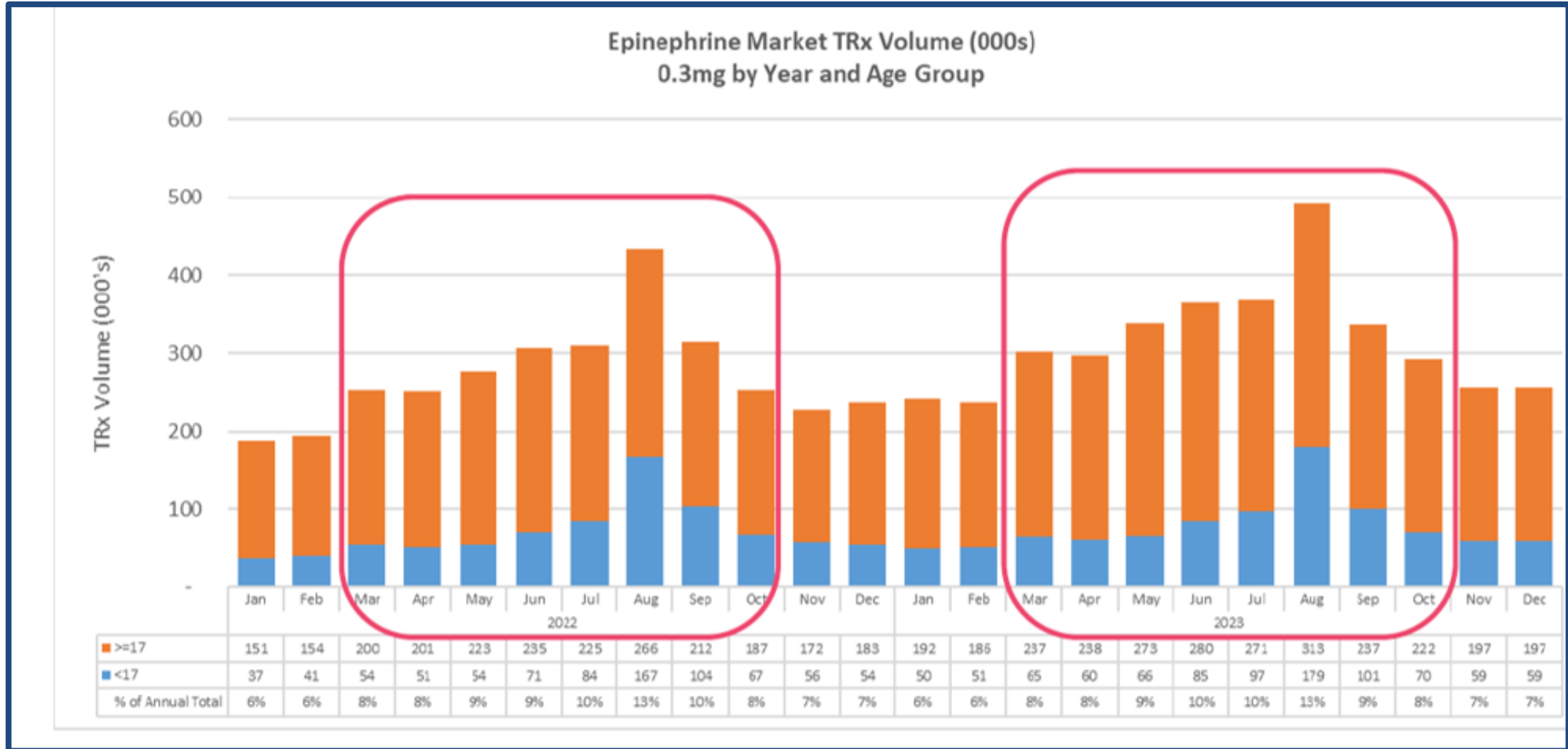
# Epinephrine prescribers: an addressable market opportunity<sup>1</sup>

- **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.

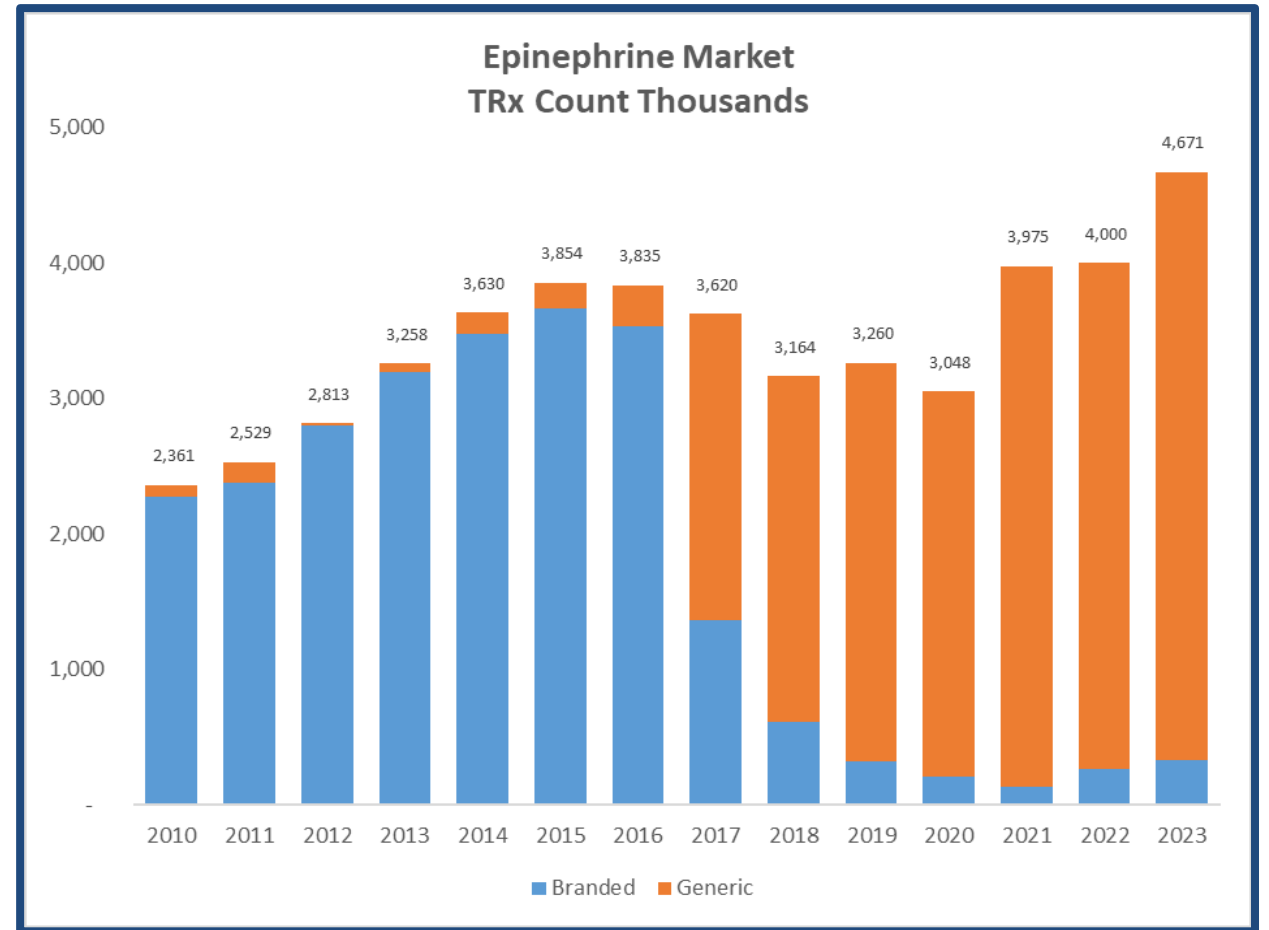
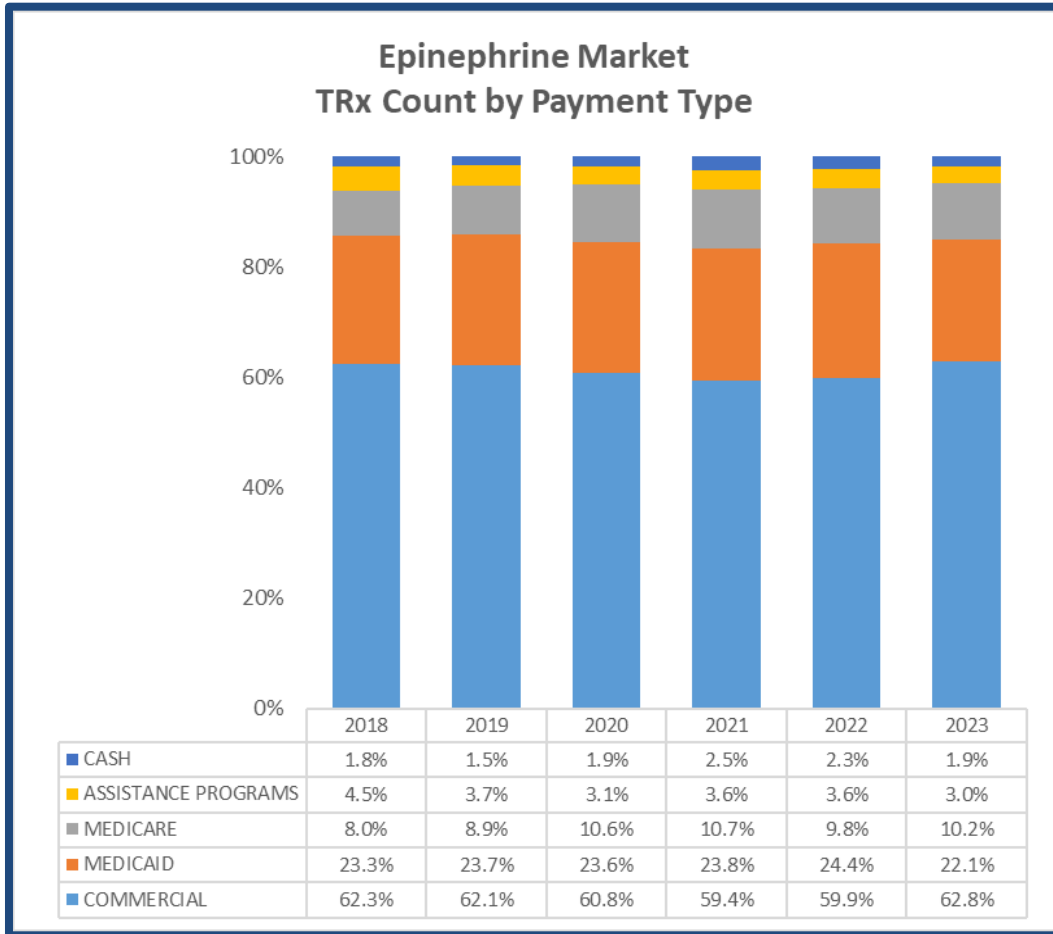
# Launch into the “warm weather” volume increase<sup>1</sup>



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



# Price within the current range of existing SOC<sup>1</sup>s



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

# Leveraging our Libervant experience

Pharmacovigilance

Distribution agreements

Market access

Existing payer contracts

Medical affairs

Training/HR/Fin/IT

Sales leadership

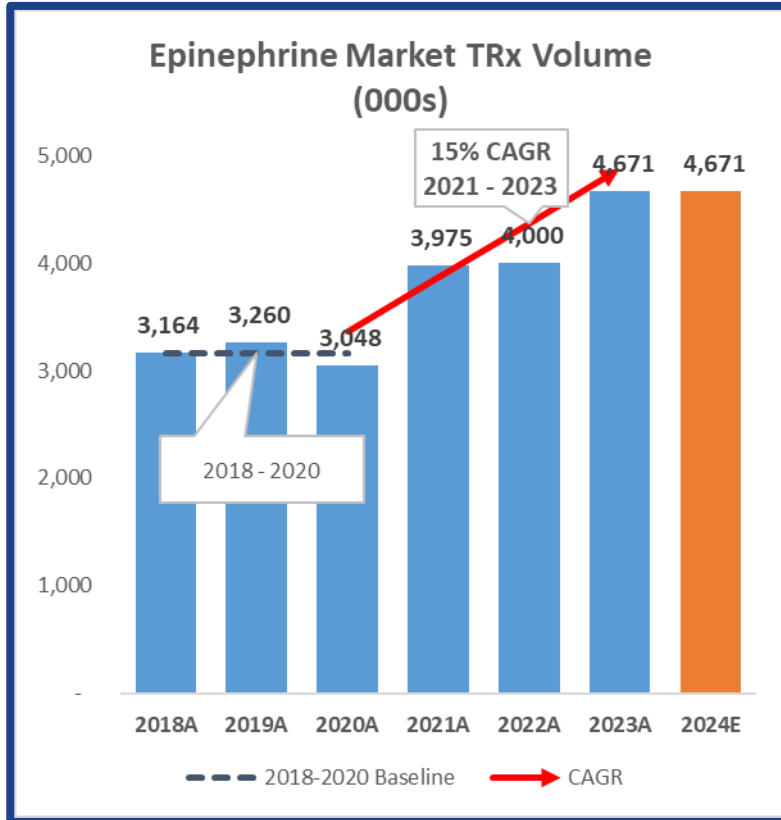
Regulatory track record

Existing and growing sales and marketing organization<sup>1</sup>

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.

# Thank You

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