



# **Aquestive Therapeutics H.C. Wainwright**

September 2022

Advancing medicines.  
Solving problems.  
Improving lives.



# Forward-Looking Statement

This presentation includes 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 of Libervant™, AQST-109, and other product candidates through the regulatory and development pipeline; and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers’ ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

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 the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans for AQST-109 and our other drug candidates; risk of delays in FDA approval of our drug candidate Libervant, AQST-109, and our other drug candidates or failure to receive approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of loss of our orphan drug approval and failure to obtain resulting drug exclusivity for our products; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default thereof; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks 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 the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters and associated costs; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). 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 us or any person acting on our 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 press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

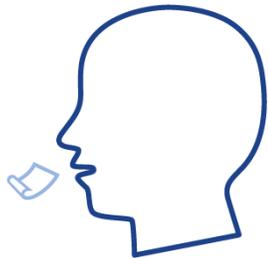
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This presentation shall not constitute an offer to sell or the solicitation of an offer to buy the Company's securities, nor shall there be any sale of the Company's securities in any state or jurisdiction in which such offer, solicitation or sale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

# Strategic Priorities

## Proven track record of success

- Technology-based pharmaceutical company
- 5 FDA-approved products
- 10+ years of product sales
- 200+ patents worldwide
  - 23 filed patents covering AQST-109
  - 19 patents covering Libervant™



## Near-term pipeline catalysts

- AQST-109 epinephrine sublingual film
  - First and only sublingual film using a novel prodrug of Epinephrine
  - End-of-Phase 2 meeting with FDA planned in 4Q22 and to commence pivotal PK study shortly thereafter
- Libervant™ (diazepam) buccal film\*
  - Tentative FDA approval granted
  - Expected launch January 2027

## Multiple cash-generating opportunities

- Cash flow positive manufacturing business
- Business performance and capital options support commercial operations and pipeline development



\*Libervant™ Buccal Film (Diazepam) is an investigational drug being evaluated for use in children and adults with refractory seizures, who remain on stable regimens of antiepileptic drugs, to control bouts of increased seizure activity. The product profile, data from our trials, and related statements have not been approved by the FDA. Aquestive has received conditional acceptance of the use of this trade name, which is subject to final FDA review and acceptance.

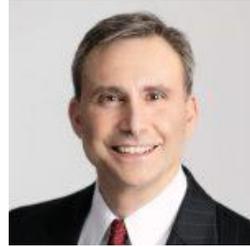
# PharmFilm® Technology – *Where You Need It, When You Need It™*



# Experienced Team



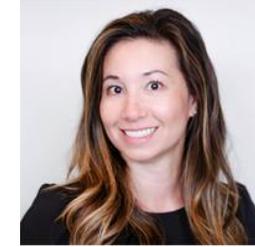
**Daniel Barber**  
President, CEO and  
Director



**Peter Boyd**  
SVP, Business Process &  
Information Technology



**Lori J. Braender**  
General Counsel and  
Chief Compliance Officer



**Cassie Jung**  
Vice President, Operations  
and Product Management



**Ken Marshall**  
Chief Commercial Officer



**Mark Schobel**  
Chief Innovation &  
Technology Officer



**Ernie Toth**  
Chief Financial Officer



**Ken Truitt**  
Chief Medical Officer



**Steve Wargacki**  
Vice President, Research  
and Development

# Scientific Advisory Board with Allergy Expertise



**David Bernstein, MD**

*University of Cincinnati*



**Carlos Camargo, MD**

*Harvard Medical School*



**David M. Fleischer, MD**

*Children's Hospital Colorado*



**David Golden, MD**

*Sinai Hospital, Baltimore*



**Matthew Greenhawt,  
MD**

*Children's Hospital Colorado*



**Ruchi Gupta, MD,  
MPH**

*Northwestern*



**Jay Lieberman, MD**

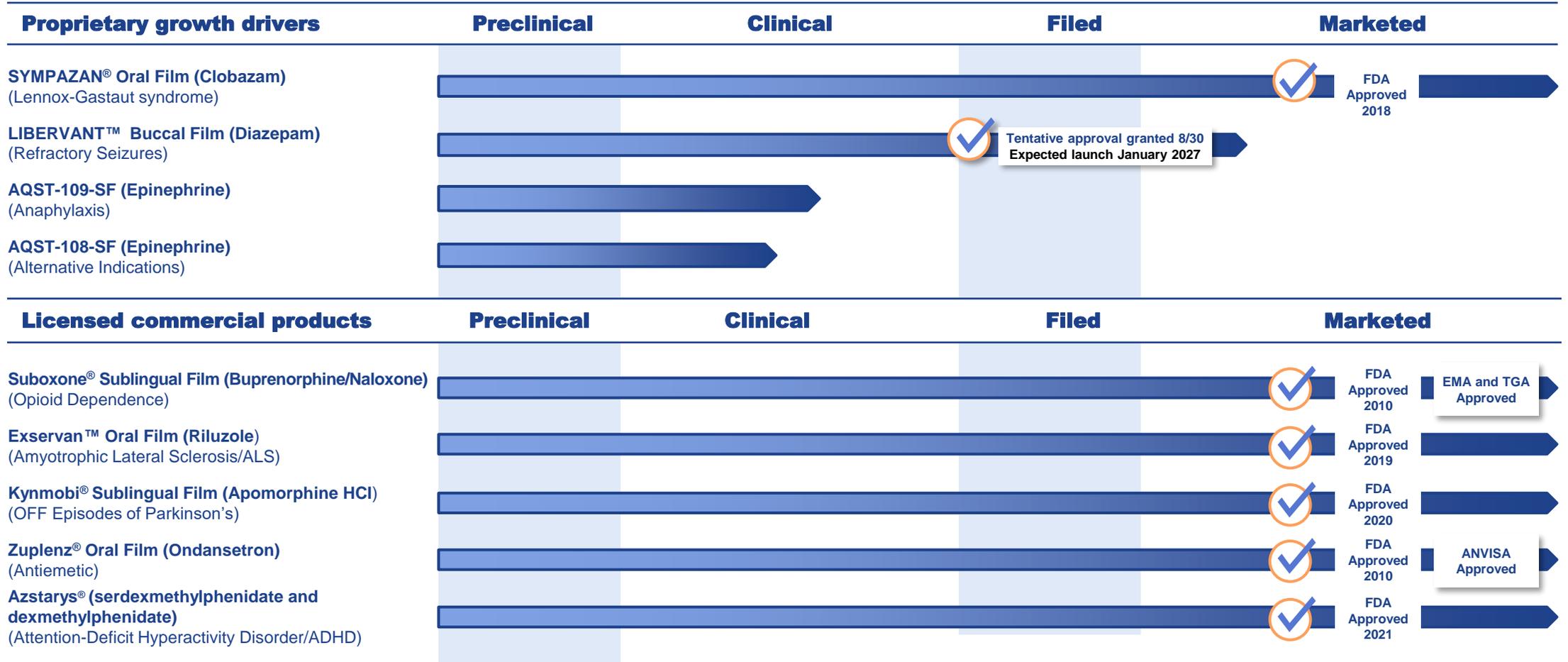
*University of Tennessee*



**John Oppenheimer,  
MD**

*UMDNJ - Rutgers*

# Product Portfolio



# AQST-109: Commercial Opportunity

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# Anaphylaxis: A Serious Systemic Hypersensitivity Reaction That is Usually Rapid in Onset And May Be Fatal<sup>1</sup>

- As many as **49 million people** in the United States are at chronic risk for acute anaphylactic episodes<sup>2</sup>

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- Lifetime prevalence may be higher than **5%**<sup>3</sup>

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- Direct costs of anaphylaxis have been estimated at **\$1.2 billion** per year, with direct expenditures of \$294 million for epinephrine, and indirect costs of \$609 million<sup>4</sup>

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- **52% of patients** in a nationwide patient survey who had previously experienced anaphylaxis had never received an epinephrine auto-injector prescription<sup>3</sup>

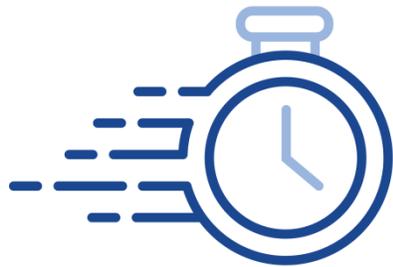
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- **60% of respondents** in same patient survey did not have an epinephrine auto-injector currently available<sup>3</sup>

**References:** 1. Turner PJ, et al. *World Allergy Org J.* 2019;12100066 2. Fromer L. *Am J Med.* 2016; doi:10.1016/j.amjmed.2016.07.018 3. Wood RA, et al. *J Allergy Clin Immunol.* 2014;133:461-467. 4. Dunn et al., (2014). Anaphylaxis: A payor's Perspective on Epinephrine/ American Journal of Medicine. DOI: <https://doi.org/10.1016/j.amjmed.2013.09.013>

# AQST-109: Potential to Solve These Issues

**First and only orally delivered epinephrine product candidate for the treatment of allergic reactions (type 1), including anaphylaxis, that would allow patients and their providers to:**



**Quickly deliver epinephrine to control emerging symptoms and prevent progression**



**Alleviate the fears associated with auto-injectors and self-injection, including needle phobia<sup>1</sup>**



**Prevent improper administration or suboptimal dosing, including associated adverse events such as injection site necrosis and/or infections<sup>2</sup>**



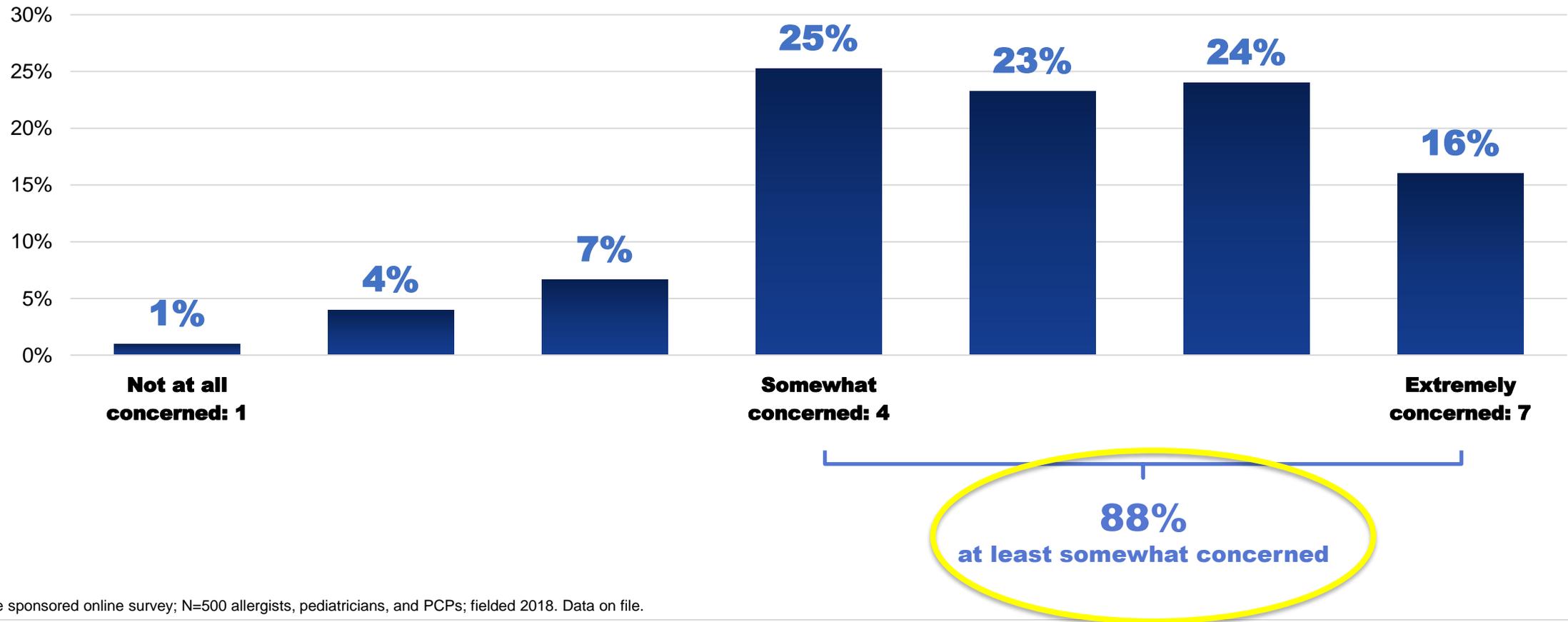
**Reduce the likelihood of noncompliance or delayed dosing because the sublingual film is small, portable, and can be administered quickly and easily<sup>3</sup>**

**References:** 1. Mcleon & Rogers M. J Adv Nurs. 2019;75(1):30-42. 2. Cardona V, et al. World Allergy Org J. 2020;13:13100472. 3. Rachid et al., (2020): Pharmaceutics. 2018;10(1):24



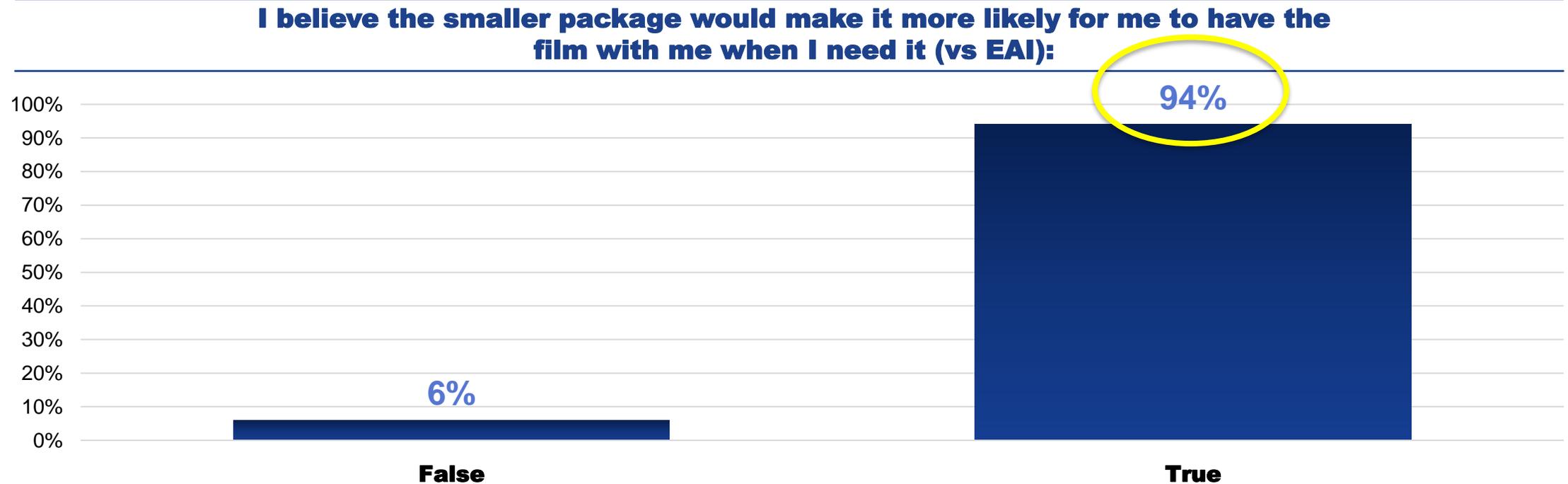
# Physician Research: Concerns About Patients Having EAI With Them at All Times

**How concerned are you with patients and/or their caregivers consistently having their auto-injector(s) with them when they leave home?**



\*Aquestive sponsored online survey; N=500 allergists, pediatricians, and PCPs; fielded 2018. Data on file.

# Patient Survey: Impact, Epinephrine On Hand



\*Aquestive sponsored online; N=75 EAI patients, 75 caregivers; fielded February 2021. Data on file

# AQST-109: Commercial Opportunity

PharmFilm® delivers market share  
within existing market



## Features/benefits customers are looking for in a new epinephrine delivery:

- Portability
- Usability
- Needle free
- Temperature tolerability\*
- Waterproof/resistant\*

**Patient  
convenience**



**Medical  
advance**

Aquestive allergy  
franchise  
delivers market expansion

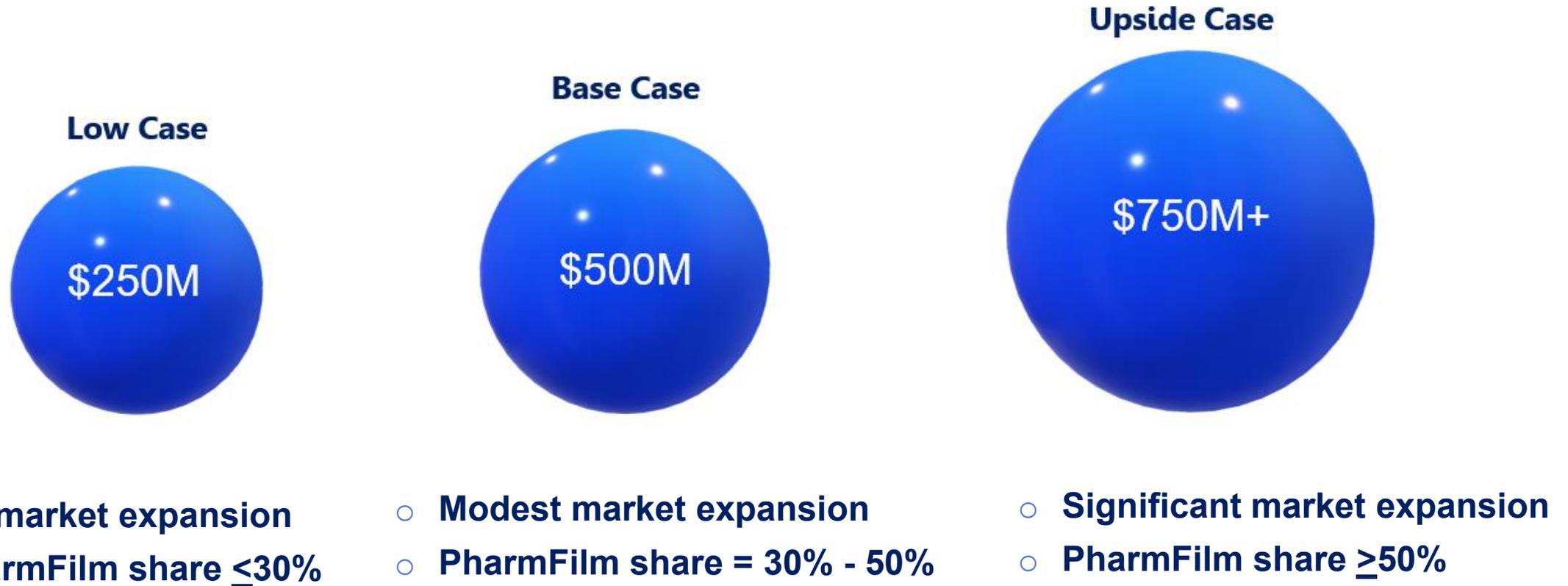


## Expected opportunities to increase the customer base:

- Previously reluctant (e.g., needle-phobic or size-resistant) patients more readily adopt PharmFilm dosing
- Increased carry rates due to size, in turn, increase engagement with the brand and annual refill rates
- Given current lack of promotion in the market, Aquestive launch plans to re-engage HCPs, patients, and advocacy groups

\*Target Product Profile

# AQST-109: Potential Annual Peak Net Sales\*



\*Potential revenues are internal estimates of peak year sales based on current information – peak year sales are assumed ~5 years post launch

# AQST-109: Development Pathway

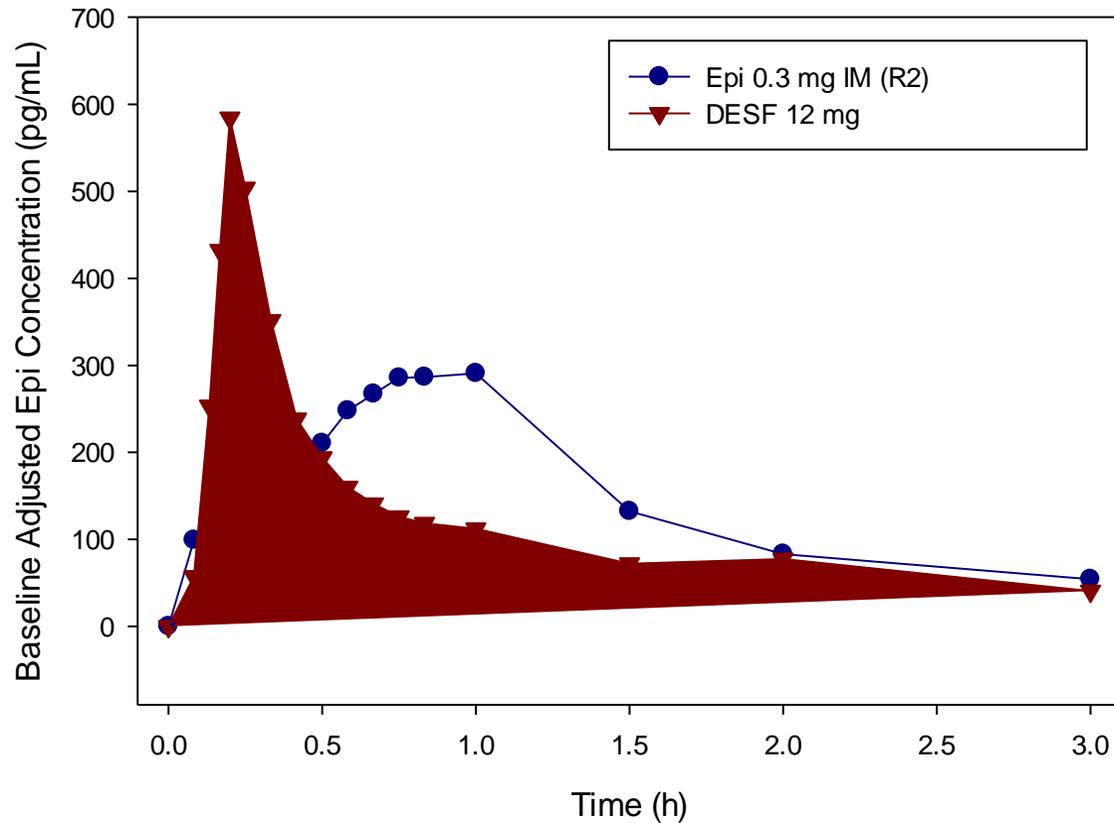
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# AQST-109: Critical Therapeutic Parameters

- **Is there sufficient drug absorption to bridge to efficacy?**
  - Maximum drug plasma concentrations (C<sub>max</sub>)
  - Systolic / diastolic blood pressure – change from baseline
  - Heart rate – change from baseline
- **Is drug absorption as fast as the standard of care in a non-clinical setting (EpiPen auto-injector)?**
  - Time to maximum drug plasma concentrations (T<sub>max</sub>)
  - Time to 100 pg/mL
  - Partial area under the curve (AUC) at identified time points
- **Is the therapeutic candidate safe?**
  - Treatment-emergent adverse events (TEAE's)
  - Serious adverse events (SAE's)
  - Administration site irritation
- **Is the therapeutic candidate effective under a variety of conditions?**
  - Administration after food
  - Administration under various pH levels
  - Potential impact of angioedema

# AQST-109: Part 3 of EPIPHAST Trial Demonstrates Rapid Absorption

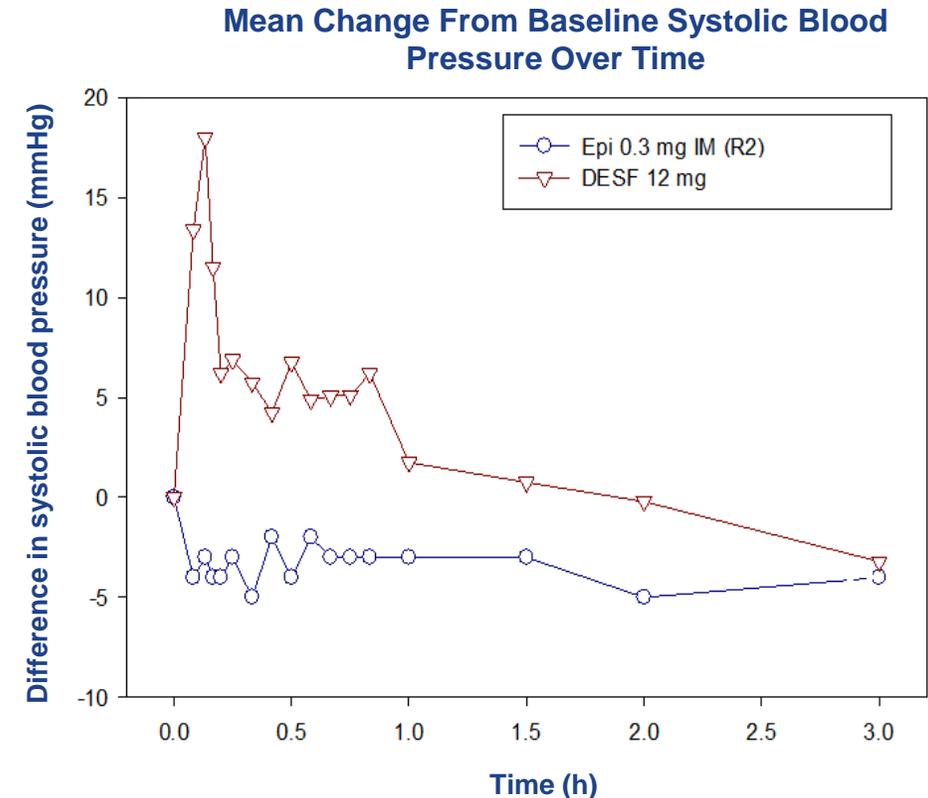
Mean Baseline Adjusted Epinephrine Concentration over 3 hours



- Tmax of 12 minutes vs. 50 minutes for IM
- Higher AUC within clinically relevant periods of 10, 20 & 30 minutes compared to IM
- Median time to reach 100 pg/mL (suggested as threshold for onset of hemodynamic effects) was 8 minutes vs. 10 minutes for IM

# AQST-109: Pharmacodynamic (PD) Values Compared Favorably to Epinephrine Auto-injectors in EPIPHAST Trial

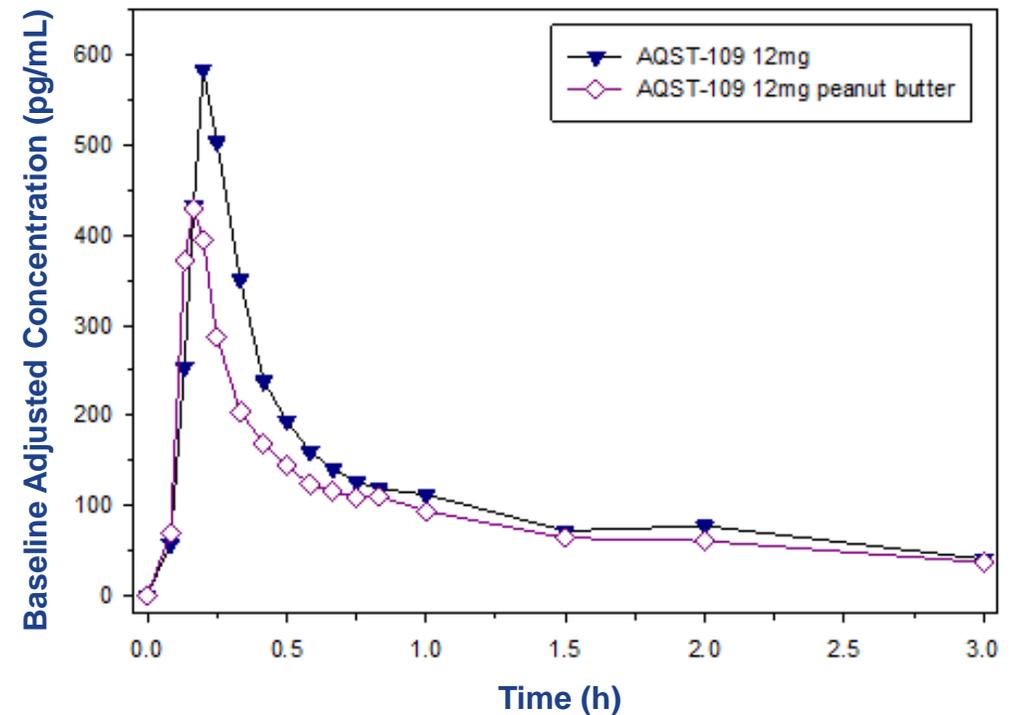
- Administration of epinephrine is known to cause an increase in systolic blood pressure over time
- Quantifying the increase in systolic blood pressure after administration of epinephrine is an important measure in assessing the effectiveness of a delivery system
- AQST-109 demonstrated strong and predictable PD values across all measured parameters (systolic and diastolic blood pressure and heart rate)



# AQST-109: Rapid Absorption With Comparable PK Under Various Administration Conditions In Part 3 of EPIPHAST Trial

- Study results for the sublingual administration of AQST-109 epinephrine sublingual film after consuming a peanut butter sandwich (right) demonstrate consistent performance
  - Consistent T<sub>max</sub> of 12 minutes
  - Comparable C<sub>max</sub>
  - Consistent partial AUC's

Mean Baseline Adjusted Epinephrine Concentration over Time by Treatment, DESF-AX-1-1 Part 3



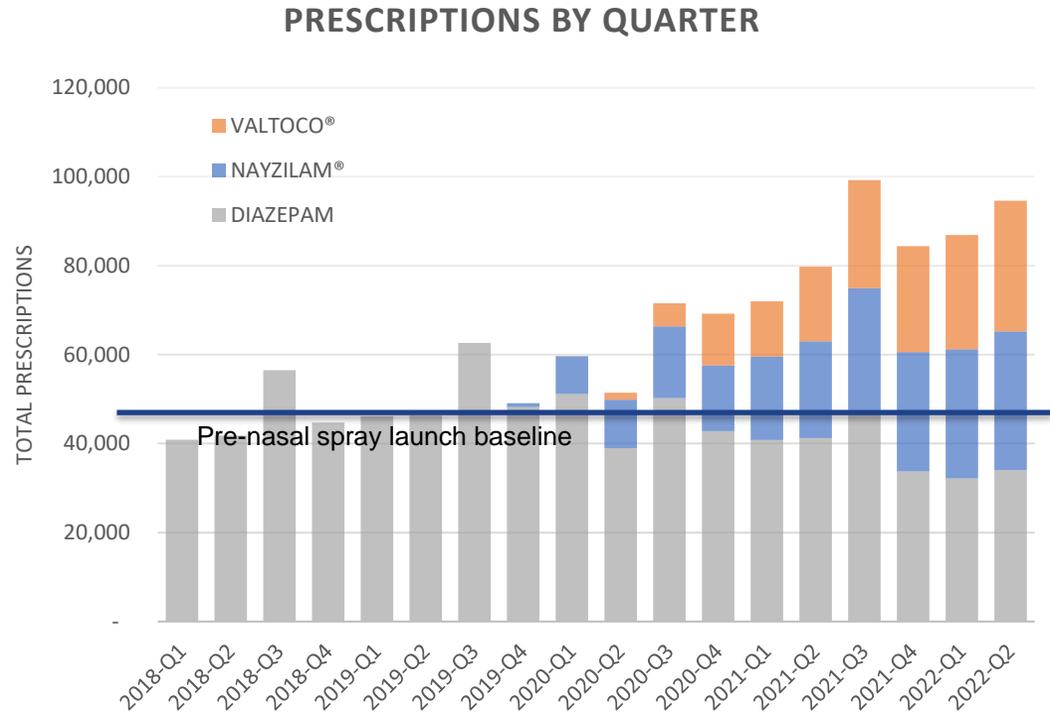
# AQST-109: Development Steps

- FDA confirmed that the **505(b)2 approval path is acceptable for AQST-109**
- **Aquestive opened its Investigational New Drug (IND)** after receiving FDA clearance in February 2022
- Aquestive received **Fast Track Designation for AQST-109** in March 2022
- Three-part **EPIPHAST** study completed in June 2022
  - Final Formulation and dose identified
  - Favorable comparison to Reference Listed Drug (RLD) in replicate design crossover study
  - Demonstrated robust performance across a variety of real-world conditions of use
- **Topline data from repeat dosing comparative study** of AQST-109 and 0.3 mg epinephrine auto injector to be announced by September 30, 2022
- **End-of-Phase 2 meeting** set with the FDA **in the fourth quarter of 2022** and **commencing the pivotal PK study shortly thereafter**

# Libervant™ (diazepam) Buccal Film Update

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# Seizure Cluster Acute Rescue Market



- Availability of therapeutics candidates addressing the new routes of administration over the past three years was expected to nearly double the labeled rescue market<sup>1</sup>
- Approaching \$230M in net revenue for 2022<sup>2</sup>
  - Potential to reach 450k Rxs this year at 1.4 units/Rx and \$365/unit (net dollars)<sup>1</sup>

A significant unmet need exists for additional delivery options, especially among adult patients

**References:** 1. Symphony Health, Metys®, July 2022. 2. Aquestive Therapeutics 2022 Data on File.

# Libervant Path to Launch



# Financial Summary (NASDAQ: AQST)

## Full Year 2022 Guidance (as of August 2, 2022)

- Total revenues of approximately \$46 to \$49 million
- Non-GAAP adjusted gross margins of approximately 70% to 75%
- Non-GAAP adjusted EBITDA loss of approximately \$37 to \$43 million

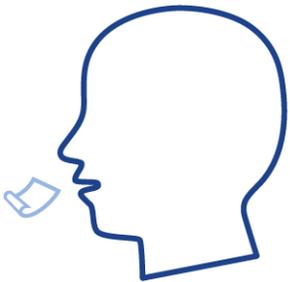
## Capital

- \$8 million registered direct offering closed on June 8, 2022
- Available shelf registration and ATM

# Going Forward

## Continued leverage of expertise and technology

- 5 FDA-approved products
- Tentative approval of **LIBERVANT** granted and anticipated launch in 2027



## Advance our novel epinephrine delivery platform

### AQST-109

- **Q2:** Completed EPIPHAST trial
- **Q3:** Completed EPHIPHAST II trial
- **Q4:** End-of-Phase 2 meeting with FDA planned in Q4 and commence pivotal PK study shortly thereafter

### AQST-108

- Identify additional product opportunities

## Identifying cash-generating opportunities

- Continue strong business performance to generate cash
- Appropriate use of ATM facility
- Utilize shelf registration under favorable conditions





# Thank You

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