



# Investor Presentation – H.C. Wainwright 25th Annual Global Investment Conference

**September 11, 2023**

Advancing medicines.  
Solving problems.  
Improving lives.

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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 Anaphylm, Libervant and our other drug candidates; risk of failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm; risk of delays in FDA approval of Anaphylm and our other drug candidates or failure to receive approval at all; risk of the failure to receive FDA approval for U.S. market access for Libervant, including by establishing a major contribution to patient care within the meaning of FDA regulations, 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 market exclusivity granted by the FDA for a nasal spray product of another company, and there can be no assurance that the Company will be successful in such endeavors; risk of delays in FDA approval of Libervant for patients aged between 2 and 5 years of age or failure to receive approval at all or for U.S. market access; risk relating to the unpredictability of the FDA’s decisions regarding orphan drug exclusivity; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product should the FDA approve Libervant for U.S. market access for any age group of epilepsy patients; risk in obtaining market access for Libervant for other reasons; risk of our ability to out-license our proprietary products in the U.S. and abroad and risks that such product candidates will receive regulatory approval in those licensed territories and risk of the rate and degree of market acceptance of our product and product candidates in those territories; risk to growing our manufacturing revenues and generate cash and capabilities to support demand for current and future licensed products; risk of eroding market share for Suboxone® and risk of a sunset product, which accounts for the substantial part of our current operating revenue; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); the success of any competing products, including generics; 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, tort claims, and antitrust litigation matters and associated costs; changes in government laws and regulations; risk of product recalls and withdrawals; risk regarding the Company’s future financial and operating results and financial position; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company’s short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed or at all; risk of failure to satisfy all financial and other debt covenants and of any default under debt financings; risk of our ability to refinance our current debt on terms and conditions satisfactory to the Company, or not at all, and there can be no assurance that the Company will be successful in such endeavors; uncertainties related to general economic, political, business, industry, regulatory, financial and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in the Company’s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission. 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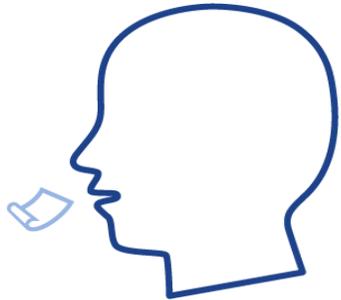
# Corporate Overview

Advancing medicines.  
Solving problems.  
Improving lives.

# Aquestive Is a Growth Story With Multiple Assets

## Revenue-Generating Base of Existing Collaborations

- 5 FDA-approved products
- 8 collaborations
- 10+ years of product sales on 6 continents
- Multiple product launches since 2022
- 150+ patents worldwide



## Potential for 2 Commercialization Events in or Prior to 2027

- Lead pipeline product candidate is Anaphylm™ (epinephrine) sublingual film
  - *First and only non-device based, oral product candidate for the emergency treatment of severe allergic reactions, including anaphylaxis*
  - *Anticipate filing for FDA approval in 2024*
- Received FDA tentative approval of Libervant™ (diazepam) buccal film for the treatment of seizure clusters in patients aged 12 and older with epilepsy
  - *Anticipate launch in 2027 (based on scheduled expiration of orphan drug block), or sooner if approved by FDA*

## Pipeline Renewal Will Come From In-house Technology

- Epinephrine prodrug platform has the potential for multiple future pipeline iterations and indications

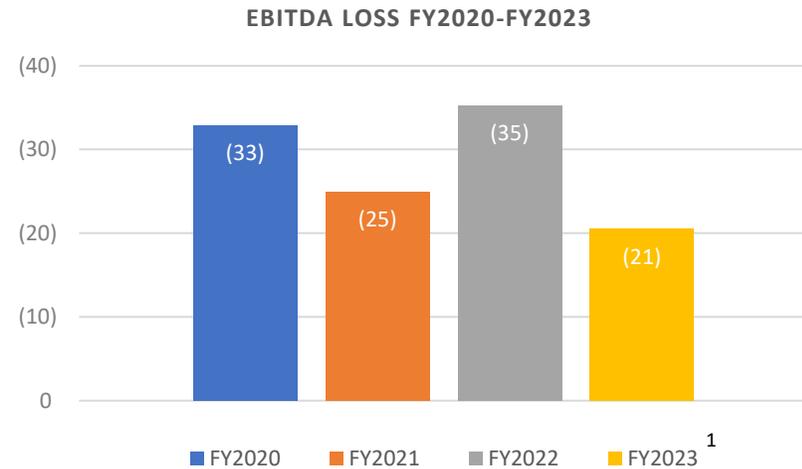
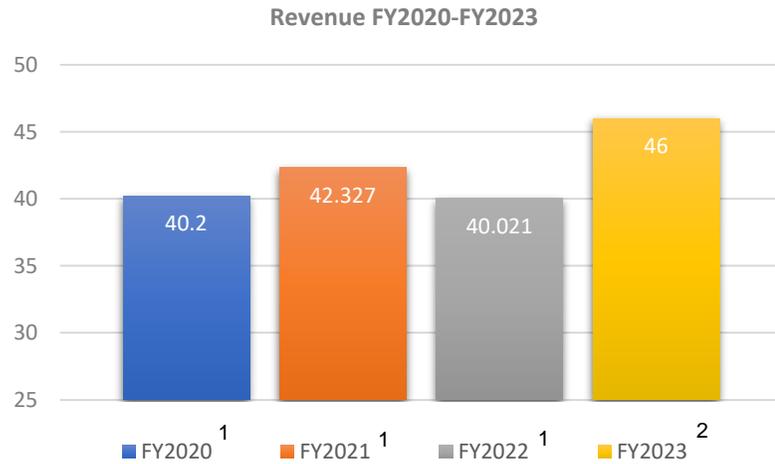
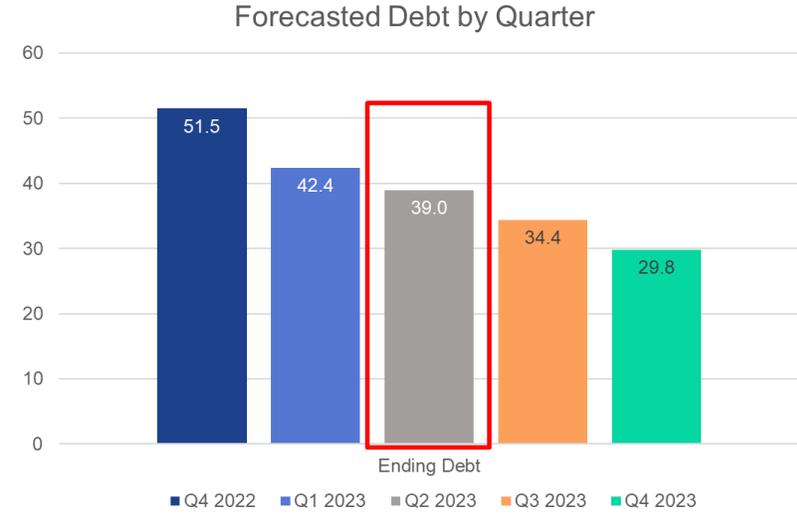
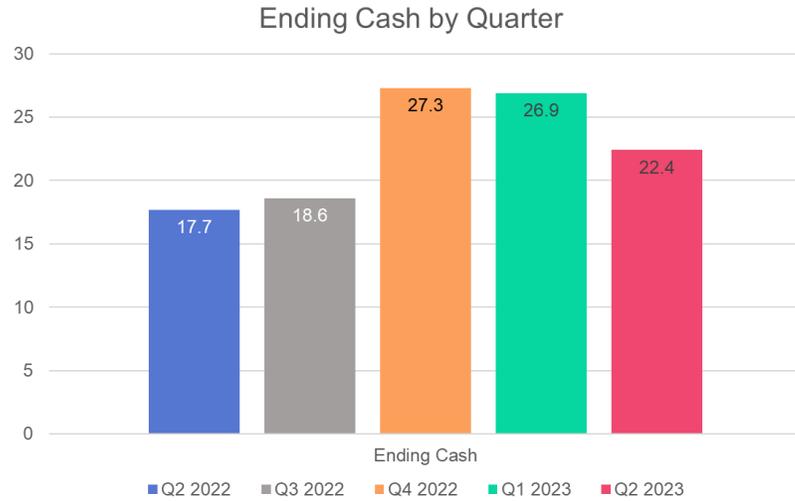


# Our Core Technology is Branded as PharmFilm®

*Where You Need It, When You Need It™*



# Key Financial Metrics (in millions)



1. Excludes proprietary sales from Sympazan®  
 2. Estimate is guidance range mid-point of \$44-48 mil. provided by Aquestive in Aug. 2023.

1. Estimate is guidance range mid-range of \$19-22 mil. provided by Aquestive in Aug. 2023

# Strong Vision for Building the Company

**In the next five years, the team aims to:**

- Grow the existing and ex-U.S. collaboration revenue
- Secure FDA approval for Anaphylm™ (epinephrine) Sublingual Film in the U.S.
- Launch Libervant™ (diazepam) Buccal Film in the U.S. in 2027 or sooner<sup>1</sup>
- Utilize epinephrine prodrug platform to develop future product candidates after Anaphylm and Libervant, if approved by the FDA for U.S. market access

1. Estimate is based on an orphan drug market exclusivity block until January of 2027 by a competing nasal spray product.

# Strong Leadership Team

## Strong Operations & Partnering Team



**Lori J. Braender**  
SVP, General Counsel



**Ken Marshall**  
Chief Commercial Officer



**Peter Boyd**  
SVP, IT, HR, &  
Communications



**Ernie Toth**  
Chief Financial Officer

## Experienced Science/IP/Development Team



**Mark Schobel**  
Chief Innovation &  
Technology Officer



**Cassie Jung**  
SVP, Operations



**Carl Kraus**  
Chief Medical Officer



**Steve Wargacki**  
SVP, R&D



**Daniel Barber**  
President, CEO and  
Director



# Executed on Key Deliverables in the Last 15 Months

Since the leadership change in May 2022, the team has:

- Raised \$47 million in non-dilutive financing
- Signed three new licensing agreements on three continents
- Supported two new product launches of licensees
- Received FDA tentative approval for Libervant
- Successfully closed four litigation cases
- Continued to advance Anaphylm towards an NDA submission
- Reduced existing debt by approximately 25%

# Lead Asset: Anaphylm Development Timeline

	2023												2024											
	Q1			Q2			Q3			Q4			Q1			Q2			Q3			Q4		
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
<b>Pilot Studies</b>	[Blue bar spanning Jan-Mar 2023]																							
<b>Pivotal Study</b>													[Blue bar spanning Feb-Mar 2024]											
<b>Pediatric Study</b>																[Blue bar spanning Feb-Mar 2024]								
<b>Pre-NDA Meeting</b>																			[Blue bar spanning Jul-Sep 2024]					
<b>NDA Submission</b>																						[Blue bar spanning Oct-Dec 2024]		

# Anaphylm Commercial Overview

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We believe that Anaphylm, if approved by FDA, has the potential to achieve significant market share in the presence of auto injectors and nasal sprays.

# Drug Device Products Create Significant Barriers to Use

## Current Standard of Care = Large, Needle Based Injectors<sup>1</sup>



- Oversized devices
  - *Hard to carry*
  - *Medical guidelines recommend always having 2 doses on hand*
- Needle based
  - *High prevalence of needle phobia (especially in children)*
- Not always intuitive to use
  - *Even trained health care providers have been shown to incorrectly inject*

## Numerous Studies and Patient Surveys Articulate Significant Dissatisfaction with Current Offerings

- Right place, right time<sup>2</sup>
  - *<50% of patients carry their EpiPen® – often due to hassle factor*
- Refusal of treatment<sup>3,4,5</sup>
  - *25-50% of patients refuse treatment with EpiPen® – often due to needle reluctance*
- Time to treat post exposure<sup>1</sup>
  - *60% of patients/caregivers delay treatment – often due to needle reluctance*
- Failed administration in the field<sup>6</sup>
  - *23-35% of patients and caregivers fail to dose correctly*

1. KOL feedback; Aquestive Market Research. 2. Fromer L. The American Journal of Medicine (2016);129, 1244-1250. 3. Warren et al. Ann Allergy Asthma Immunol (2018). 4. Brooks et al. Ann Allergy Asthma Immunol (2017). 5. Asthma and Allergy Foundation of America Patient Survey Report (2019). 6. El Turki et al. EmergMed J (2017).



Why don't patients carry their epinephrine rescue medication (TRx in place)?



Reasons	Solutions
Inconvenient to carry <sup>1</sup> <ul style="list-style-type: none"><li>➤ Size</li><li>➤ Environmental Limits</li></ul>	Commercialize a product designed to fit daily life
Won't use invasive device <sup>1</sup>	
Forgot to carry – intermittent use <sup>1</sup>	

1. KOL feedback; Aquestive Market Research Data on File.

# Do People Remember to Carry Their Mobile Phones?

97% of Americans own a cellphone<sup>1</sup>

The average American checks their smartphone  
96 times a day, or once every 10 minutes...<sup>2</sup>

1. <https://www.pewresearch.org/internet/fact-sheet/mobile/> 2. [Americans Check Their Phones 96 Times a Day - Asurion](#)

# Anaphylm is Extremely Durable in Real Life Situations

Unlike drug devices, Anaphylm in its primary package can handle:

- **Temperature Excursions** - *Excursion testing currently in process*
- **Exposure to Light** - *Foil primary package protects the product from direct sunlight*
- **Exposure to Liquids** - *Primary package is water resistant*



Why don't patients use their epinephrine  
rescue medication?



Reasons	Solution
Needle Phobia <sup>1</sup>	Portable, orally delivered product provides lower barrier to use; less incentive for ineffective antihistamines
Complicated Delivery <sup>1</sup>	
Substitute Use of Antihistamines <sup>2</sup>	

1. KOL feedback; Aquestive Market Research Data on File. 2. Stanley M. Fineman (2014) Optimal Treatment of Anaphylaxis: Antihistamines Versus Epinephrine, Postgraduate Medicine, 126:4,73-81.

# OTC Antihistamines: A Potentially Deadly Misperception

## Goal is clear:

- Early treatment is critical to prevent a potentially fatal outcome

## Preferred delivery is clear:

- Data indicate that antihistamines are more commonly used to treat patients with anaphylaxis – *ease of carry and use versus EAls is noted*<sup>1</sup>

## Right medicine at the right time falls short:

- In a study of pediatric anaphylaxis-related hospital admissions, administration of antihistamine was associated with a >7 times increased odds of delay in seeking care<sup>2</sup>
  - The study authors concluded that a delay in seeking care for anaphylaxis can subsequently delay epinephrine administration and increase mortality

1. Fineman S; Optimal treatment of anaphylaxis: antihistamines versus epinephrine 2. Wiley E, et al; The Association of Antihistamine Administration and Delayed Presentation for Care in Pediatric Patients Admitted with Anaphylaxis

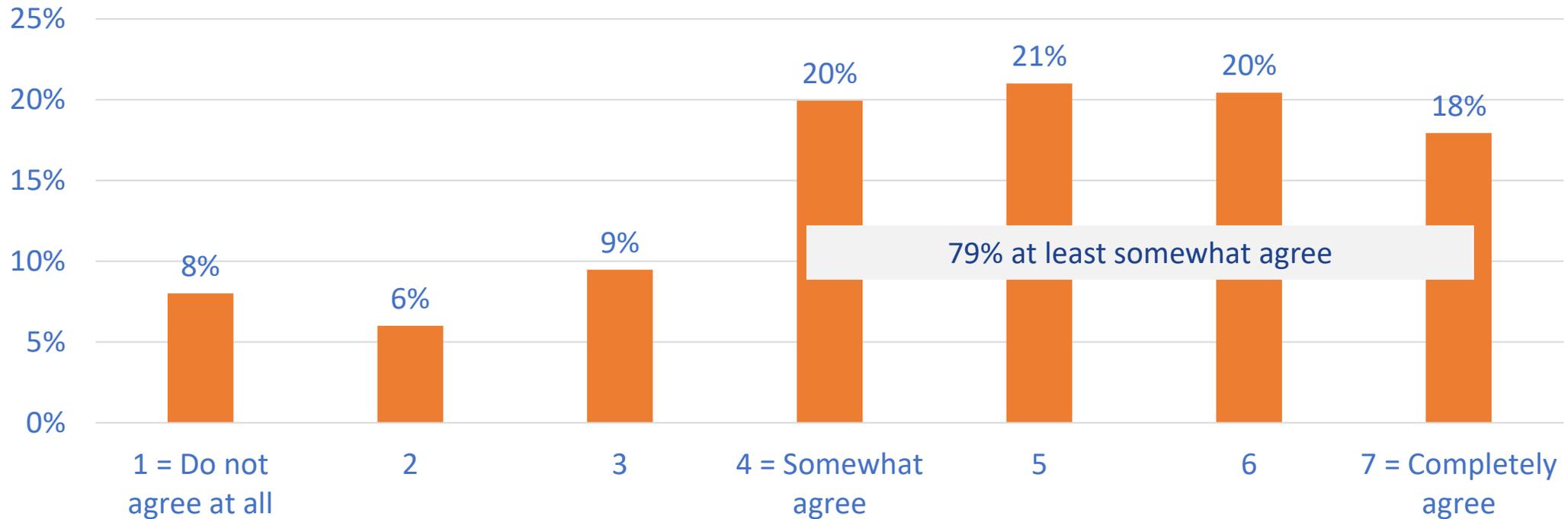


What concerns  
(besides patients not carrying rescue medication)  
do physicians have?



# Per Epinephrine Rx'ing Physicians: General Concern that Patients Too Often “Substitute-Carry” Antihistamines (vs. EAI)<sup>1</sup>

Patients with at least some risk for anaphylaxis too often carry oral antihistamines instead of an epinephrine auto-injector



1. Aquestive Therapeutics, Quantitative Physician Survey; N-501, (Allergists; Pediatricians; PCPs); 2019 Data on File



# What do patients say?

# As a Potential Replacement for Their EAI, Anaphylm Performed Exceptionally Well in a Large Patient Preference Study (N=200)<sup>1</sup>

Versus Patient's Current EAI	Total	Patients	Caregivers
"I would prefer a film medicine over my current auto-injector"	86%	87%	84%
"I am interested in having the film medicine available as an option to replace my current EAI"	99%	100%	98%
"I would proactively ask my doctor about the film medicine if it were available"	98%	100%	97%

1. Aquestive Quantitative Market Research Study; Oct. 2022 Data on File

# Given an Option Between a Nasal and Film Medicine, Anaphylm Also Performed Exceptionally Well (N=200)<sup>1</sup>

Statement	Total	Patients	Caregivers
“As a replacement for my/my child’s EAI, I would prefer a film medicine over a nasal medicine”	77%	79%	74%
“Knowing that I/my child should always have two doses at immediate disposal, I would prefer the [film / nasal] medicine”	[83% / 17%]	[83% / 17%]	[83% / 17%]

1. Aquestive Quantitative Market Research Study; Oct. 2022 Data on File

# Potential Product Positioning for Anaphylm

- First and only orally delivered epinephrine product indicated for the treatment of anaphylaxis
- Only non-drug/non-device delivery
- Durability to withstand many of the norms of daily life

# Snapshot of Market Potential (Estimated for 2028)<sup>1</sup>

- Use today's net price of \$300/TRx
- Assume awareness/engagement increases TRx size to 8 million from ~5 million in 2023
- Assume auto injectors retain 30% of the market

## Base Case

Downside Case

Category	Market Share %	Net Sales \$m
Auto injectors	33%	792
Nasal sprays	50%	1,200
Oral film	17%	408

Category	Market Share %	Net Sales \$m
Auto injectors	33%	792
Nasal sprays	33%	792
Oral film	33%	792

Upside Case

Category	Market Share %	Net Sales \$m
Auto injectors	33%	792
Nasal sprays	17%	408
Oral film	50%	1,200

1. Aquestive market projections for 2028 based on Symphony data for 2023; Data on File

# Thank You

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