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): June 29, 2023

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. A copy of the Company's investor presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The investor presentation is available on the Company's website located at www.aquestive.com, although the Company reserves the right to discontinue that availability at any time.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Exchange Act, nor shall it be deemed to be incorporated by reference in any filing under the 33 Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events

On June 29, 2023, the Company issued a press release announcing the submission of its New Drug Application (NDA) for its drug candidate Libervant™ (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients between two and five years of age. The Company received tentative approval for Libervant for the treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients 12 years of age and older in August 2022, but Libervant is currently under an orphan drug exclusivity block for U.S. market access until January 2027 for a competing FDA approved product. The Company expects to hear from the FDA on the acceptance of its NDA for this pediatric age group of the epilepsy patient population, and the timing of the related target action date on this NDA, within approximately two months.

The Company also announced the appointment of Carl N. Kraus, M.D., as Chief Medical Officer of the Company, effective June 26, 2023.

A copy of the Company's press release is attached hereto as Exhibit 99.2 and incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Aquestive Therapeutics Corporate Presentation dated June 29, 2023.
99.2	Aquestive Therapeutics, Inc. Press Release dated June 29, 2023.

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: June 29, 2023

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Exhibit 99.1


Aquestive
Corporate Presentation
June 2023
Advancing medicines.
Solving problems.
Improving lives.
1

Disclaimer

This presentation and the accompanying oral commentary has been prepared by Aquestive Therapeutics, Inc. (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 of Libervant™, Anaphylm™ ("AQST-109"), and other product candidates through the regulatory and development pipeline and ability to bring those products to market and achieve market acceptance of those products; the potential benefits our products could bring to patients; the outlicensing of our products in the U.S. and abroad; our growth and future financial and operating results and financial position, including regarding the profitability of the Company's manufacturing operations and the current and future financial outlook of the Company; ability to refinance the Company's current debt; and business strategies, market opportunities (including total addressable market size), and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of global business or macroeconomic conditions, including as a result of inflation, rising interest rates, instability in the global banking system, and geopolitical conflicts, including the war in Ukraine, 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 global business or macroeconomic conditions discussed above.

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 Anaphylm 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 our ability to out-license our proprietary products in the U.S. or 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 sunsetting 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 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; risk of failure to satisfy all financial and other debt covenants and of any default under debt financings; uncertainties related to general economic, political, business, industry, regulatory, financial and market conditions and other unusual items; uncertainties related to general economic, financial, 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.

This presentation also contains estimates, projections and other information concerning the Company's business and the markets for the Company's products and product candidates, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and actual events, or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, the Company obtained this industry, business, market and other data from reports, research surveys, clinical trials studies and similar data prepared by market research firms and other third parties, from industry, medical and general publications, from other publicly available information, and from government data and similar sources.

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

PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. The trade name for AQST-109 "Anaphylm" 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.

I. Corporate Overview

Advancing medicines.
Solving problems.
Improving lives.

Our Quest

- Advancing medicines, solving therapeutic problems, and improving lives
- Our pipeline of product candidates aims to overcome barriers that patients face with existing treatment options and provide new paradigms for treating critical and complex conditions

Aquestive Is a Growth Story With Multiple Assets

Revenue-Generating Base of Existing Collaborations

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

Potential for 2 Commercialization Events 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

We Have a Strong Vision for Building the Company

In the next five years, we aim to:

- Grow the existing and ex-U.S. collaboration revenue
- Secure FDA approval for Anaphylm in the U.S.
- Launch Libervant in the U.S. in 2027[1]
- Utilize our epinephrine prodrug platform for future product launches after Anaphylm and Libervant, if approved by the FDA

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

Our Core Technology is Branded as PharmFilm®

Where You Need It, When You Need It™

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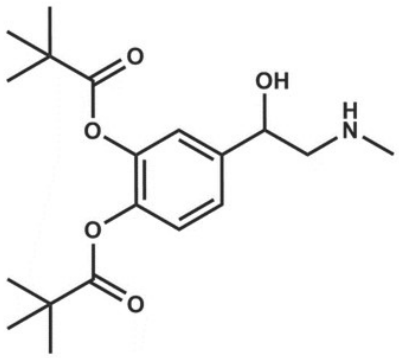
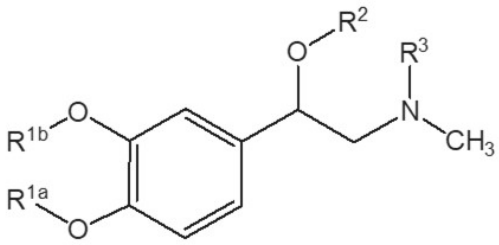
Advancing medicines.
Solving problems.
Improving lives.

And Our Future Technology Is Already In-house

AQST-108



Anaphylm (AQST-109)



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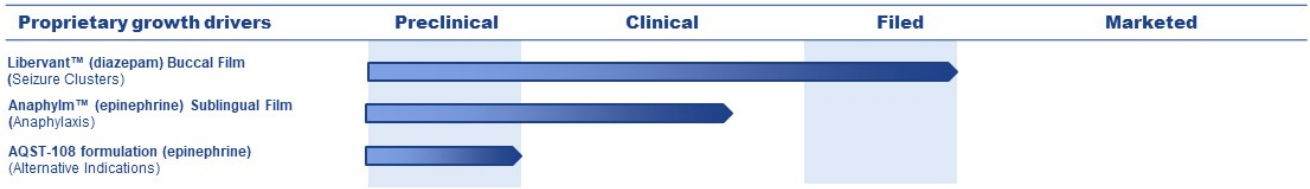
Product Portfolio – Significant Licensing Opportunities in 2023



Licensing Opportunities

Libervant™ (diazepam) buccal film

United States
Asia
South America

Anaphylm™ (epinephrine) sublingual film

Ex-U.S. Rights

Regional Licensing Agreements

Hypera – Brazil
Ondif® ondansetrona

Zambon - EU
emylif®

Haisco - China
(riluzole) oral film (development stage)

Mitsubishi Tanabe – U.S.
Exservan® (riluzole) oral film

Global Licensing Agreements

Assertio Therapeutics
Sympazan® (clobazam) oral film C
5 mg • 10 mg • 20 mg

Indivior
Suboxone® Sublingual Film (buprenorphine and naloxone) C

Pharmanovia
Libervant™ (diazepam) buccal film

IP Licenses (Royalty-Only)

Kempharm
azstarys® C
serdexmethylphenidate and dexmethylphenidate

KYNMOBI® (apomorphine HCl) sublingual film
10 mg • 15 mg • 20 mg • 25 mg • 30 mg

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Potential for Two Transformative Launches

Anaphylm™ (epinephrine) Sublingual Film

- Potential indication of treatment of severe allergic reactions, including anaphylaxis
- Anticipate submitting New Drug Application (NDA) by the end of 2024
- Estimated Total Addressable Market of ~ $1B[1]

Libervant™ (diazepam) Buccal Film

- Indicated for the treatment of seizure clusters in patients aged 12 and older with epilepsy
- Tentatively approved by FDA
- Expected Launch 2027[2]

1. Estimated total addressable market is an Aquestive Therapeutic's calculations based on (i) WAC Price for generic EipPen as of March 2020 and (ii) epinephrine market TRx volume as of December 2022. 2. Estimate is based on an orphan drug market exclusivity block until January of 2027 by a competing nasal spray product.

Strong Leadership Team

Daniel Barber
President, CEO and Director

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

Gary Slatko
Chief Medical Officer

Steve Wargacki
SVP, R&D

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Executed on Key Deliverables in the Last 12 Months

Since management change in May 2022, the team has:

- Raised $47M in non-dilutive financing
- Signed 3 new licensing agreements on 3 continents
- Supported two new product launches of licensees
- Received FDA tentative approval for Libervant
- Successfully closed 4 litigation cases
- Continued to advance Anaphylm towards an NDA submission
- Reduced existing debt by 17.6%[1]

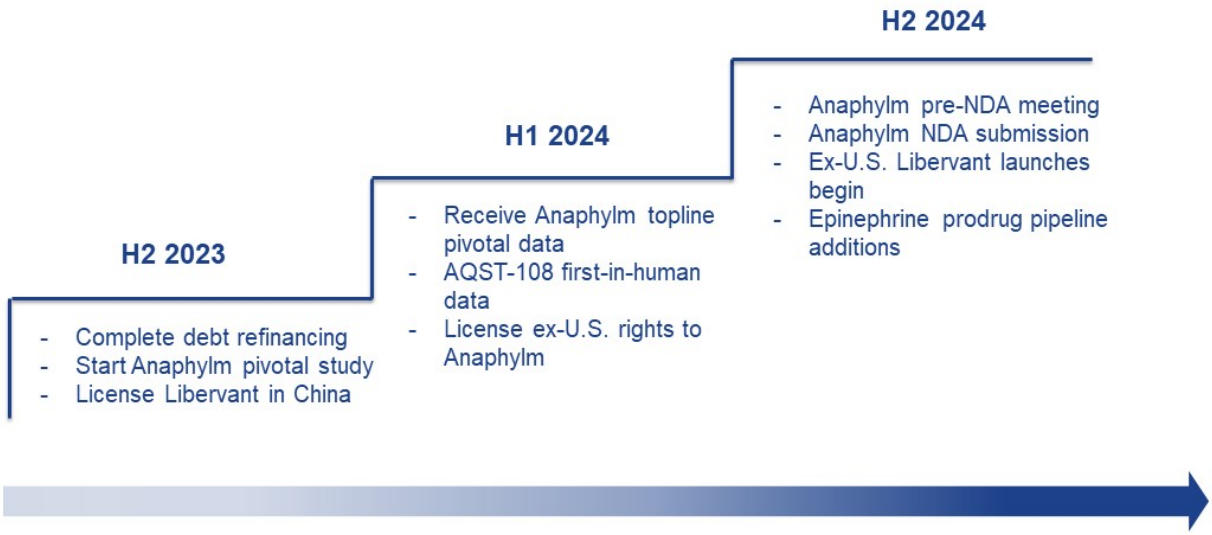
1. As of December 31, 2022, the outstanding debt was $51,500,000. As of March 31, 2023, the outstanding debt was $42,414,025, resulting in a difference of $9,085,975, or 17.6%.

We Are Now Focused on the Next Chapter

Over the next 90 days, the Company aims to:

- Continue to strengthen the balance sheet
- Refinance the existing debt (anticipate standard 5 yr, 3 yr i/o deal)
- Out-license Libervant in China
- Submit pivotal protocol for Anaphylm to the FDA for review

Potential Near-term Milestones Targeted



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II. Anaphylm™ (epinephrine) Sublingual Film

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Anaphylaxis Market Overview

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Anaphylaxis: A Serious Systemic Hypersensitivity Reaction That is Usually Rapid in Onset And May Be Fatal[1]

- As many as **32 million people** in the United States are at chronic risk for acute anaphylactic episodes[2]
- Direct costs of anaphylaxis have been estimated at **$1.2 billion** per year[3]
- **52% of patients** in a nationwide patient survey who had previously experienced anaphylaxis had never received an epinephrine auto-injector prescription[3]
- **60% of respondents** in same patient survey did not have an epinephrine auto-injector currently available[3]

1. Turner PJ, et al. *World Allergy Org J.* 2019;12100066. 2. FARE, 2022; https://www.foodallergy.org/resources/facts-and-statistics. 3. Fromer L. The American Journal of Medicine (2016);129, 1244-1250.

Treatment of Anaphylaxis – Epinephrine

Epinephrine is the first line of treatment for anaphylaxis[1]

- ***Epinephrine is the only*** *medication proven to stop a life-threatening allergic reaction*

Epinephrine dosage (current medication delivery systems):[2]

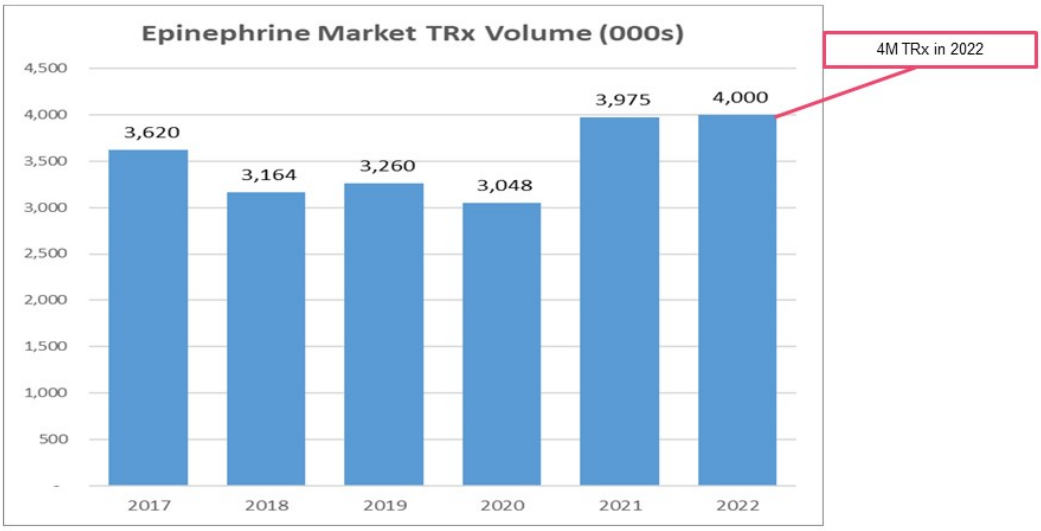
- ***0.3-0.5 mg intramuscularly (IM) or subcutaneously***
- ***Children's dosage is weight based:***
    1. 0.10 mg (for children 16.5 to 33 pounds) — AUVI-Q® brand only
    2. 0.15 mg (for children under 66 pounds)
    3. 0.3 mg (for children and adults over 66 pounds)

A second dose of epinephrine can be given as needed[2]

1. Epinephrine in the Management of Anaphylaxis. Brown JC, Simons E, Rudders SA. J Allergy Clin Immunol Pract. 2020 Apr;8(4):1186-1195. doi: 10.1016/j.jaip.2019.12.015 PMID: 32276687. 2. EpiPen® Package Insert.

Epinephrine Market

The 2022 Epinephrine market surpassed 4 million TRx and has rebounded to historical highs following a downturn due to generics and the Covid-19 pandemic. TRx counts have exceeded prior year for 9 consecutive months.[1]



1. *Symphony Health* Data April 2023.

Generic Market With High Levels of Dissatisfaction and Unmet Need

Current Standard of Care = Large, Needle Based Injectors[1]

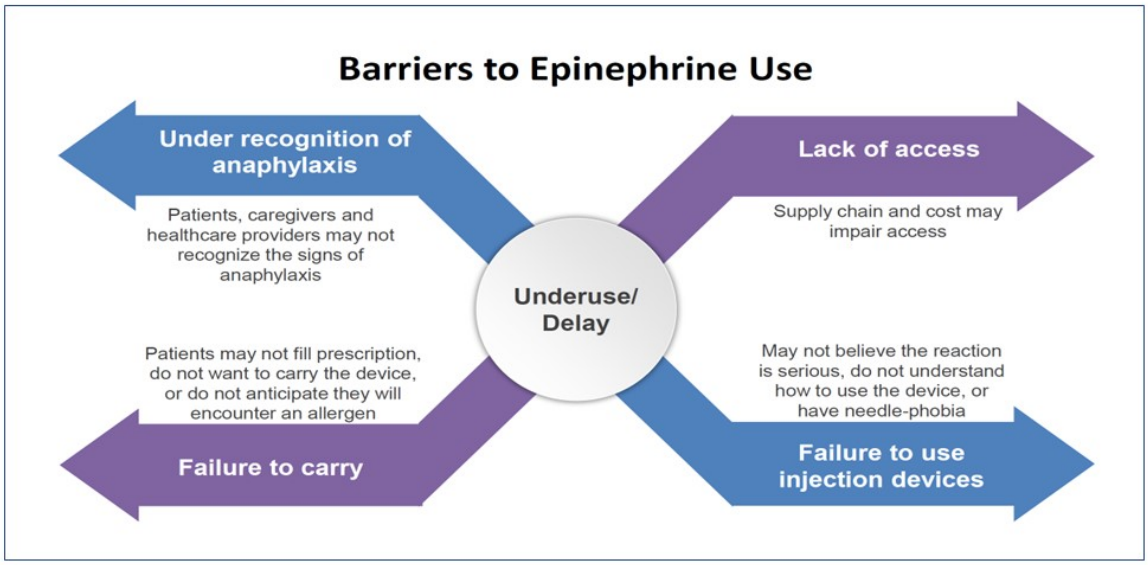
- Oversized devices
  - *Hard to carry*
  - *Medical guidelines recommend always having 2 doses on hand*
- Needle based
  - *High prevalence of needle phobia (especially in children)*
- Not always intuitive to use
  - *Even trained health care providers have been shown to incorrectly inject*

Numerous Studies and Patient Surveys Articulate Significant Dissatisfaction with Current Offerings

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

Recent FDA Public Document Highlighted the Barriers to Epinephrine Use[1]



1. https://www.fda.gov/media/168054/download/Slide 14.

AnaphyIm™ (epinephrine) Sublingual Film

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

Portability

+

Non-device administration

+

Fast absorption into the bloodstream

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PharmFilm® Platform Projecting Robust Stability

Chemical Stability

- ≥ 2 years room temperature
- ≥ 6 months accelerated conditions
- Successful Scale Up Executed

Environmental Stability

- Light resistant
- Water resistant
- Withstands extreme cold conditions
- High temperature excursions while maintaining shelf-life

Patents/Patent Applications Extending into 2042

Title	Patent Status
ENHANCED DELIVERY EPINEPHRINE COMPOSITIONS	• Granted U.S. Patent 11,191,737 (5/4/2037) • 8 Foreign applications • **Priority date:** May 5, 2016 • Possible patent term to 2037
ENHANCED DELIVERY EPINEPHRINE AND PRODRUG COMPOSITIONS	• 2 U.S. applications • 8 Foreign applications • **Priority date:** May 4, 2017 • Possible patent term to 2037
PRODRUG COMPOSITIONS AND METHODS OF TREATMENT	• 2 U.S. applications • 1 Foreign application • **Priority date:** late 2019 • Possible patent term to 2041
PHARMACEUTICAL COMPOSITIONS WITH ENHANCED STABILITY PROFILES	• 1 U.S. application • **Priority date:** October 2021 • Possible patent term to 2042

Competitive Product Summary[1]

	ORAL	AUTO INJECTOR				INTRA NASAL		
Company	Aquestive[2]	VIATRIS[3] teva	IMPAX	kaléo	US WorldMeds	ARS PHARMA[2]	Bryn[2, 4]	AMPHASTAR PHARMACEUTICALS[2]
Brand	Anaphylm	EpiPen/Generic	Adrenaclick®	Auvi-Q®	Symjepi®	neffy®	Utuly™	N/A
Administration	Sublingual	Auto-Injector	Auto-Injector	Auto-Injector	Syringe Device	Nasal Spray	Nasal Spray	Nasal Spray
Dosing (Adult/Jr)	TBD	0.3 / 0.15 mg	0.3 / 0.15 mg	0.3 / 0.15 / 0.10 mg	0.3 / 0.15 mg	2 mg	6.6 mg	Not Reported
Market Position	1st & Only Oral	90%+ Share	Negligible	<10%	Negligible	1 Dose per Device	2 Doses per Device	Potentially 3rd Nasal to Market
Regulatory Status (FDA)	Expected NDA Filing 2024	Approved/Marketed				Filed Fall '22	Expected Filing 1H '23	Expected NDA Filing 2023

1. The data presented on this slide are based on cross-study comparisons and are not based on any heat-to-head trials as a result, comparability may be limited/inaccurate. Cross-study comparisons are inherently limited and may suggest misleading similarities or difference. 2. Pending FDA Review. 3. VIATRIS: Formerly Mylan. 4. US WorldMeds markets for Adamis.

AnaphylM:
Product Development

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Scientific Advisory Board

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

University of Medicine and Dentistry of NJ - Rutgers

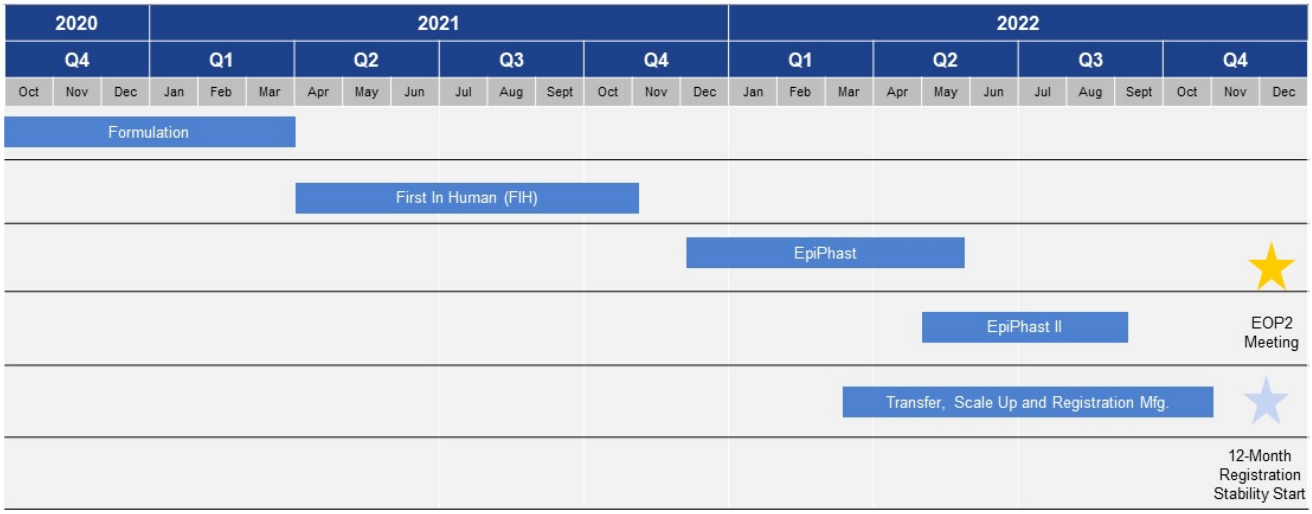
Anaphylm Clinical Trials to Date

Study	Description	Study Status	N
210010	First-in-Human (FIH), Single Ascending Dose (SAD) study to evaluate safety and tolerability, as well as pharmacokinetic (PK) performance and pharmacodynamic (PD) effect, of DESF (Anaphylm)	Complete	44
EPIPHAST Part 1	• Evaluate multiple formulations and strengths of DESF (Anaphylm) • Benchmark against epinephrine 0.5mg manual intramuscular (IM) injection	Complete	35
Part 2	• Confirm benchmarking vs. epinephrine 0.3mg manual IM injection • Evaluate intrasubject variability and adequacy of washout period	Complete	24
Part 3	• Characterize conditions of use and effect of use errors (different saliva hold times and directly swallowing film) • Film performance after ingestion of sticky substance (peanut butter)	Complete	24
EPIPHAST II	Characterize: • repeat dose performance of DESF (Anaphylm) • performance against EpiPen	Complete	24
AQ109102	Evaluate: • differences in PK and PD results based on changes to administration instructions • additional repeat dose data on DESF (Anaphylm) • performance of various approved auto-injectors	Complete	30
AQ109106	Evaluate differences in PK and PD results based on changes to administration instructions	Complete	35
AQ109103	Further characterization of PK performance and PD effect of DESF (Anaphylm) to inform pivotal study design	Ongoing	24

Agency Interactions on Anaphylm Program to Date

Interaction	Key Takeaways
Pre-IND Meeting *(December 1, 2021)*	• 505(b)(2) NDA regulatory approval pathway acceptable (no efficacy trials required) • Bracket PK to 0.3mg IM and safety to 0.5mg IM • Evaluate potential for extrinsic factors to impact DESF (ANAPHYLM) absorption
Stability Excursion Protocol Review *(July 29, 2022)*	• Design and planned analysis of the proposed excursions are reasonable and can be expected to provide data to support product and patient labeling
End Of Phase 2 (EOP2) Meeting-CMC Meeting Feedback *(October 4, 2022)*	• Proposed Chemistry Manufacturing and Controls (CMC) package for both active pharmaceutical ingredients (API) and DESF (Anaphylm) considered sufficient and reasonable for future NDA filing
Nonclinical Study Plans *(October 11, 2022)*	• Aligned with FDA on NDA, enabling nonclinical toxicology package
EOP2 Meeting *(November 15, 2022)*	• Reaffirmed 505(B)(2) regulatory approval pathway acceptable (no efficacy trials required) • Modified bracketing strategy to compare PK performance to IM and autoinjectors • Use during conditions of anaphylaxis to be considered in overall risk/benefit profile
FDA Response to General Correspondence *(March 1, 2023)*	• FDA agreed to review pivotal protocol • FDA agreed to separate meeting to align on risk/benefit characterization after pivotal study alignment

AnaphyIm Timeline To Date



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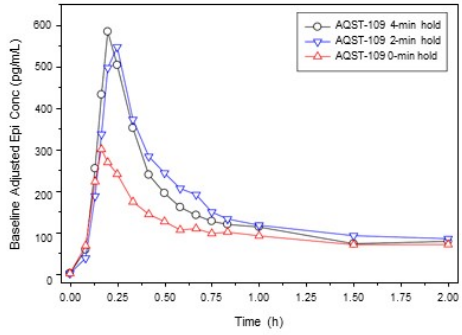
EPIPHAST I Part 3: Favorable Pharmacokinetic (PK) Per Initial Data

- Median time to peak concentration (Tmax) of 12 minutes at target 4 minute hold time*, compared to 50 minutes for 0.3mg Intramuscular Injection (IM)
- Partial area under the curve (AUC) within clinically relevant periods of 10, 20 & 30 minutes at target 4 minute hold time compared to 0.3mg IM
- Median time to reach 100 pg/mL (suggested as threshold for onset of hemodynamic effects) was 8 minutes at target 4 minute hold time and 10 minutes for 0.3mg IM

Mean Baseline Adjusted Epinephrine Concentration over 0-2h by Treatment, Part 3



Study Results	AQST-109 12mg 4-minute hold time (Target) (N=22 doses)	AQST-109 12mg 2-minute hold time (N=23 doses)	AQST-109 12mg 0-minute hold time (N=21 doses)	AQST-109 12 mg (from Part 2) (N=48 doses)	Epinephrine IM Injection 0.3 mg (from Part 2) (N=48 doses)
Geometric Cmax (pg/mL)	350.4	303.9	211.2	274.3	350.6
AUC 0-10 minutes (hr*pg/mL)	12.8	9.5	9.4	7.9	9.4
AUC 0-20 minutes (hr*pg/mL)	51.2	45.7	30.9	33.1	23.0
AUC 0-30 minutes (hr*pg/mL)	79.1	75.1	49.8	56.7	47.5
Median Tmax (minutes)	12	15	15	15	50

*Hold time is holding the film under the tongue and limiting swallowing for different periods of time.

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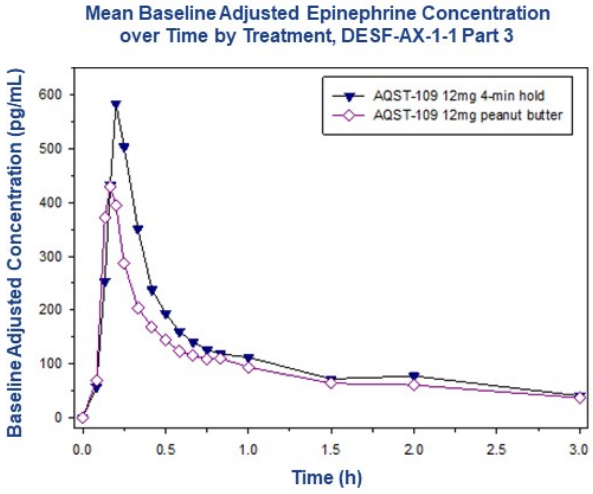
EPIPHAST I Part 3: Rapid Absorption With Comparable PK After Consuming Peanut Butter From Part 3 of EPIPHAST Trial

- Study results for the sublingual administration of Anaphylm sublingual film after consuming a peanut butter sandwich demonstrate consistent performance
  - Consistent Tmax of 12 minutes
  - Comparable Cmax
  - Consistent partial AUCs



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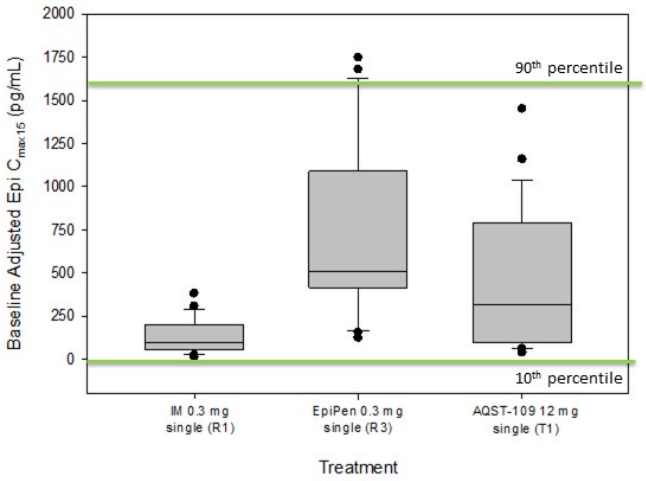
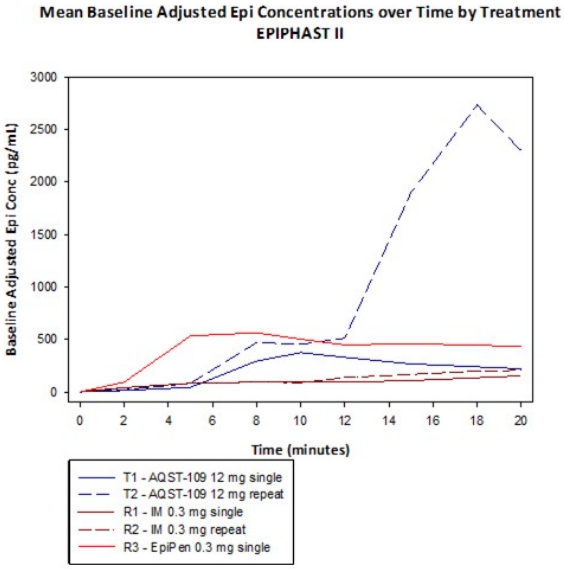
EPIPHAST II: Topline Results

Anaphylm Cmax values within the timeframe critical to abate the cascade of anaphylaxis is comparable to and well bracketed by the 0.3mg IM and the EpiPen®



Geometric means presented for Cmax.



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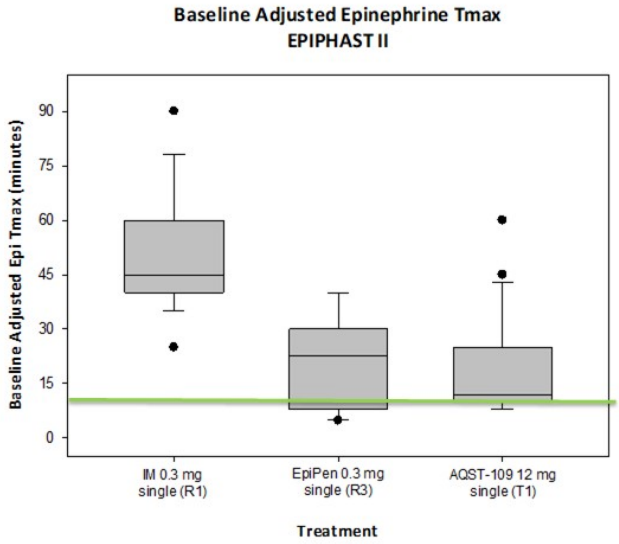
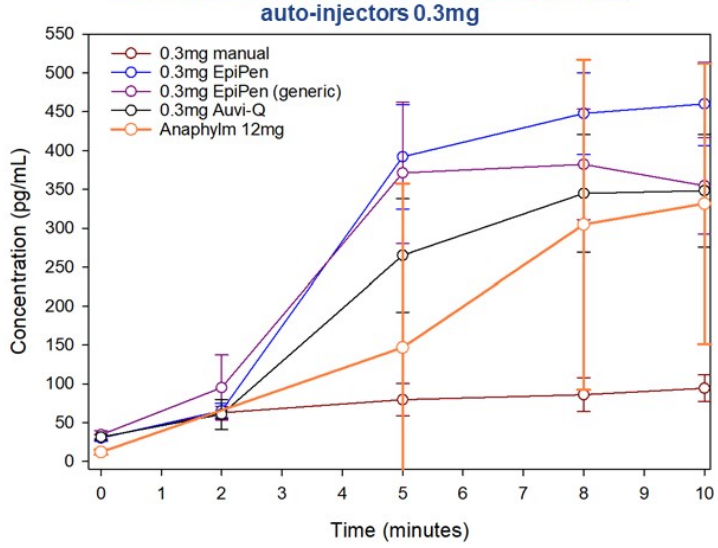
EPIPHAST II: Time to Maximum Concentration (Tmax)



- Anaphylm showed a shorter median Tmax than both 0.3mg IM and the 0.3mg EpiPen
- Range of Tmax values across the study is consistent with EpiPen
- Both EpiPen and Anaphylm provide faster Tmax values than the 0.3mg IM

Anaphylm: Similar Exposure to Auto-injectors During the First 10 Minutes Following Dosing[1]

Comparison of epinephrine plasma concentrations over time of Anaphylm 12mg to various approved auto-injectors 0.3mg



Comparison of epinephrine exposure at 10 minutes of Anaphylm 12mg to various approved auto-injectors 0.3mg

Parameter	0.3mg Manual (N=27)	Auvi-Q (N=29)	Anaphylm (n=12)	EpiPen (generic) (N=29)	EpiPen (N=27)
$AUC_{0\text{-}10min}$ (hr*pg/mL)	5.3	26.7	**28.3**	37.7	43.7

1. Cross-study comparison from AQ109102 and AQ109106.

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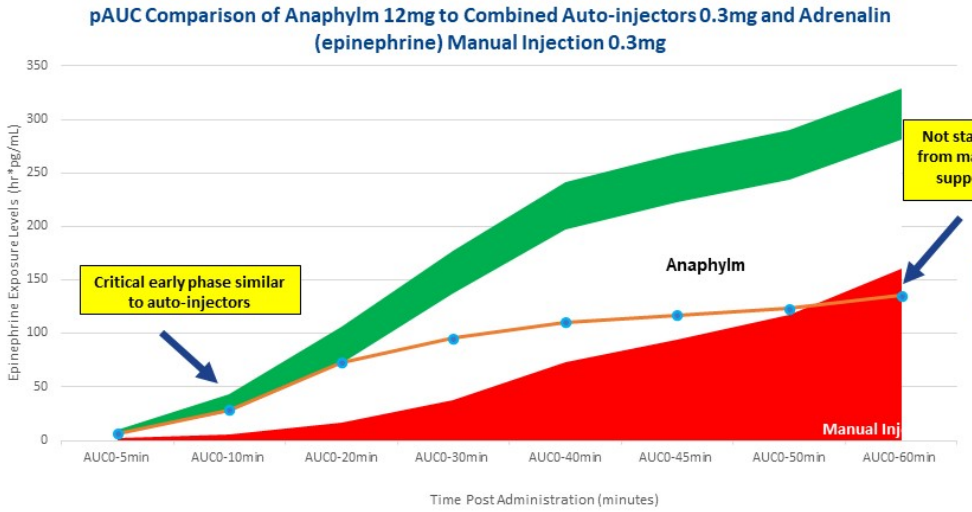
Anaphylm Data Brackets Existing Products to 45 Minutes[1]

FDA recommended bracketing between the exposures produced by auto-injectors and manual injection across a range of relevant time points characterized as pAUC.



Partial AUC (%CV)	Manual Injection	Anaphylm
AUC0-45min	94.4 (75.6%)	117.0 (93.6%)
AUC0-50min	117.2 (72.3%)	123.3 (92.4%)
AUC0-60min	160.4 (66.2%)	135.1 (90.1%)

1. Bracketing end points subject to alignment with FDA. Cross-study comparison from AQ109102 and AQ109106.

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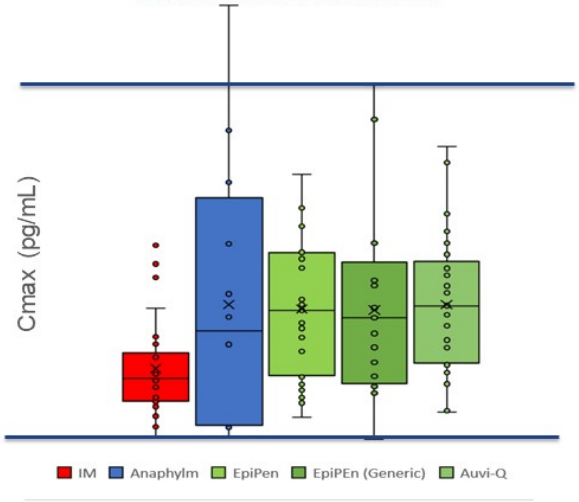
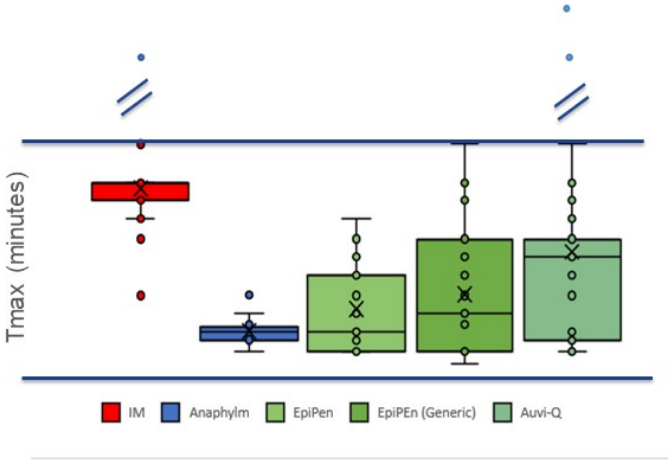
Key PK Parameters Compare Favorably to Existing Treatments[1]

Anaphylm 12mg provides a consistently fast Tmax with median and mean Cmax levels bracketed by the current FDA approved products.

Median and Mean Cmax



Median Tmax



Bars above show highest and lowest 75% quartile ranges of approved products.

1. Cross-study comparison of AQ109102 and AQ109106.

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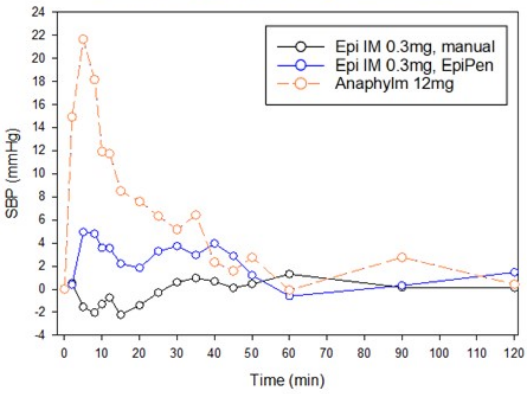
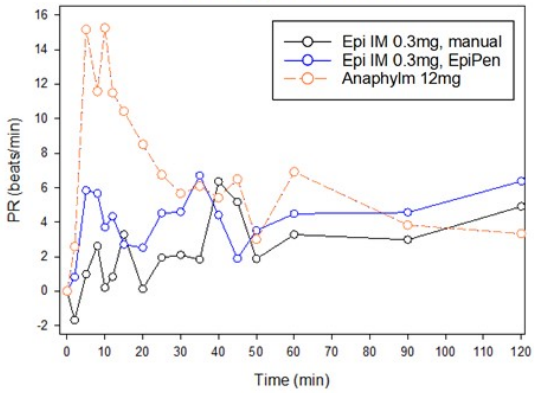
Clinically Favorable PD from Anaphylm[1]

Anaphylm demonstrates a rapid increase in systolic blood pressure (SBP), pulse and diastolic blood pressure (DBP) within 2 minutes. Injected epinephrine produces moderate increases in SBP and pulse with no measurable effect on DBP.

Mean Baseline Adjusted Changes in Systolic Blood Pressure Following Administration



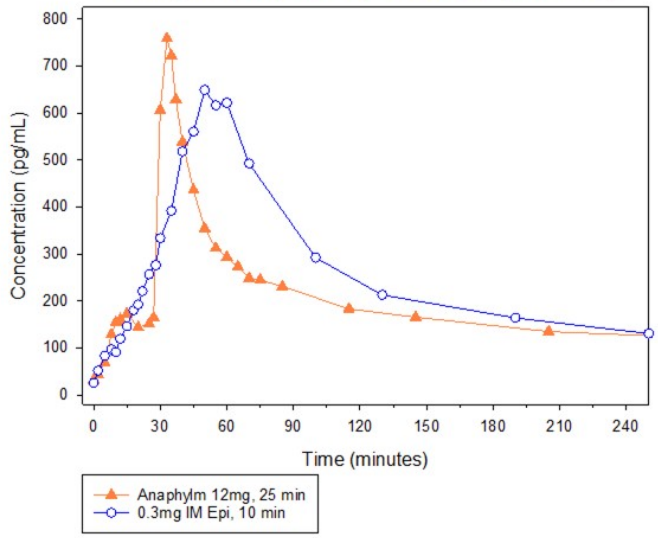
Mean Baseline Adjusted Changes in Pulse Following Administration



1. Cross-study comparison of AQ109102 and AQ109106.

Repeat Dose – 25 Minutes[1]

Comparison of Anaphylm 12mg repeat dose data (25 minutes) to 0.3mg manual injection repeat dose data (10 minutes)



Description	0.3mg Manual Injection Repeat Dose (10 min)	Anaphylm Repeat Dose (25 min)
# Subjects	23	27
C_{max} (pg/mL)	755	882
AUC_{0-t} (hr*pg/mL)	1300	776
AUC_{0-45} (hr*pg/mL)	181	207
Tmax (minutes)	50	33
Tmax Range (minutes)	30 - 70	10 - 70

- Geometric Means presented for Cmax, AUC0-t, AUC0-45. Median Tmax.
- Data presented from cross-study analysis of AQ109201 (0.3mg manual injection repeat dose at 10 min) and AQ109102 (Anaphylm repeat dose at 25 minutes - top-line results).

1. Cross-study comparison from AQ109201 (EpiPhast II) and AQ109102.

Summary and Next Steps

- **AQ109102 compared Anaphylm to multiple epinephrine auto-injectors**
  - Confirmation of target range between existing reference listed drug (RLD) epinephrine injections
- **AQ109106 focused on administration instructions**
  - Confirmation of Anaphylm Cmax comparability
  - Confirmation that Anaphylm early pAUC parameters are bracketed by other RLDs
- **Next Steps**
  - Refine administration instructions in ongoing pilot study (AQ109103)
  - Finalize pivotal study protocol – expect to submit for FDA review/alignment in Q3 2023
  - Expect to begin execution of pivotal study in Q4 2023

Regulatory Path Potentially De-risked by Recent Epinephrine Nasal Spray FDA Advisory Committee Meeting

VOTING QUESTION [1]

VOTE: Do the PK/PD results support a favorable benefit-risk assessment for ARS-1 in adults for the emergency treatment of allergic reactions (Type 1) and anaphylaxis?

a. If not, what additional data are needed?

VOTING RESULTS 16:6

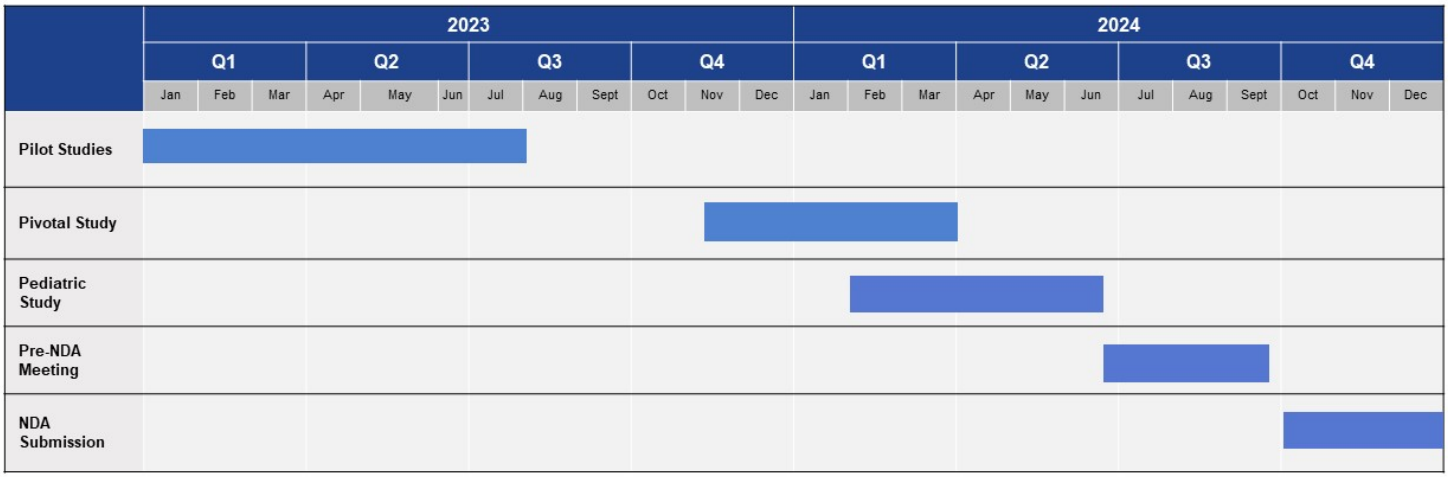
VOTE: Do the PK/PD results support a favorable benefit-risk assessment for ARS-1 in children (<18 years of age) ≥ 30 kg for the emergency treatment of allergic reactions (Type 1) and anaphylaxis?

a. If not, what additional data are needed?

VOTING RESULTS 17:5

1. https://www.fda.gov/media/168054/download.

Anaphylm 2023-2024 Critical Path



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III. Libervant™ (diazepam) Buccal Film

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The Unmet Need in Refractory Seizures…

~1M Epilepsy patients[1]

Suffer from uncontrolled, **refractory seizures**

~85%

of patients with refractory seizures will not interact with the historically available Treatment[2,3,4,5]

Seizures Account for **1M**

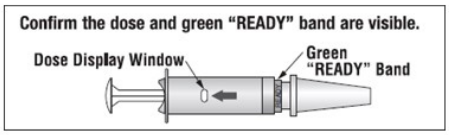
EMERGENCY DEPARTMENT

visits annually[6]

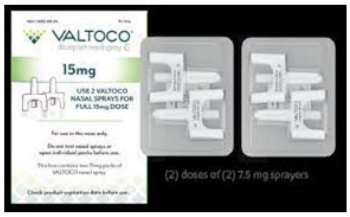
1. Laxer, Ketal, The consequences of Refractory Epilepsy and its treatment; Epilepsy & Behavior, Vol 37, Aug 2014, Pgs 59 –70; https://doi.org/10.1016/j.yebeh.2014.05.031, 2. Triangle Insights Group (2017). Synthesis of Epilepsy (ARS) Primary Research. Internal Aquestive report: unpublished, 3. Epilepsy Data and Statistics | CDC - 1.2% of the US population had active epilepsy (95% CI* = 1.1-1.4). This is about 3.4 million people with epilepsy nationwide: **3 million adults** and **470,000 children**. 4. Breakthrough Seizures: Causes, Treatment, and Prevention (healthline.com) - About 1 in 3 people with epilepsy experience breakthrough seizures. 5. 2022 Symphony Data shows 420,000 labeled rescue rxs, if a patient fills 2.5 times a year that's 168,000 patients. 6. Seizure visits to ED: ht t p s:// /www.ncbi.nlm.nih.gov/pmc/articles/PMC2657249/.

Current Treatments are Either Rectal or Intra Nasal Options

Diastat® AcuDial™ (diazepam rectal gel) 5 mg/mL



VALTOCO® (diazepam nasal spray)



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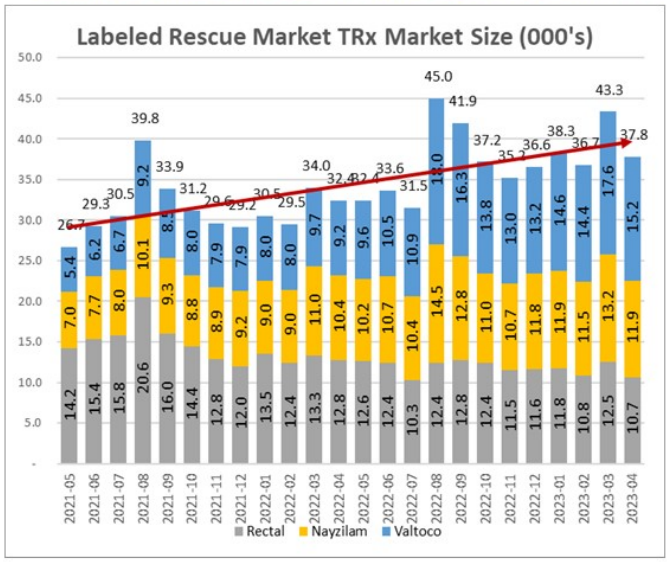
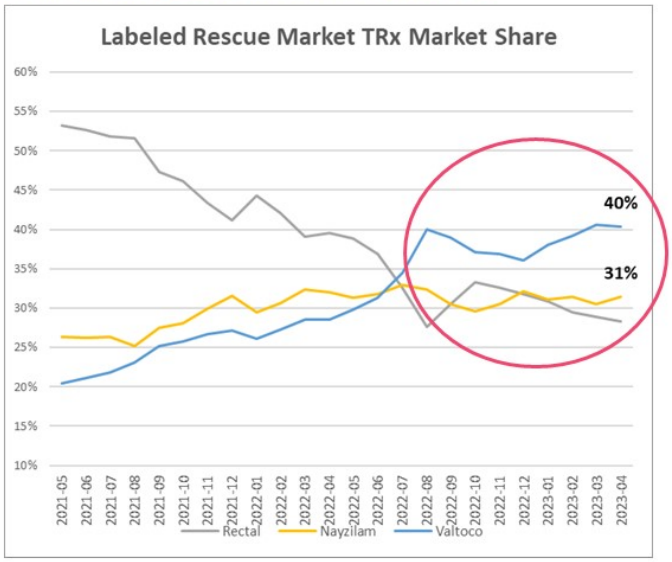
Seizure Rescue Market

The seizure rescue market continues to grow with new products being promoted. Based upon publicly available data, Valtoco® has flat to growing market share in all age groups in which it competes.[1]





1. *Symphony Health* Data April 2023.

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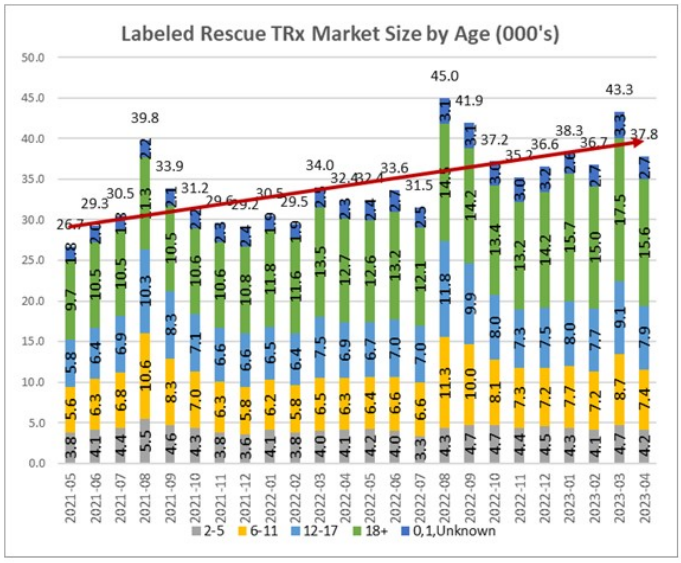
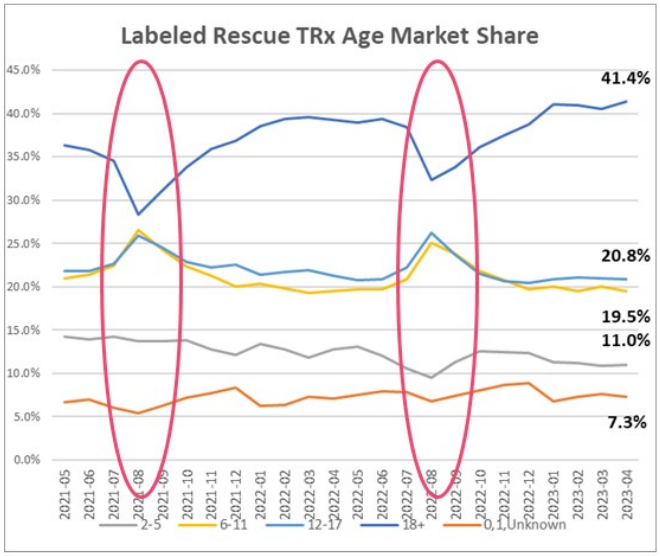
Seizure Rescue Market by Age[1]





1. *Symphony Health* Data April 2023.

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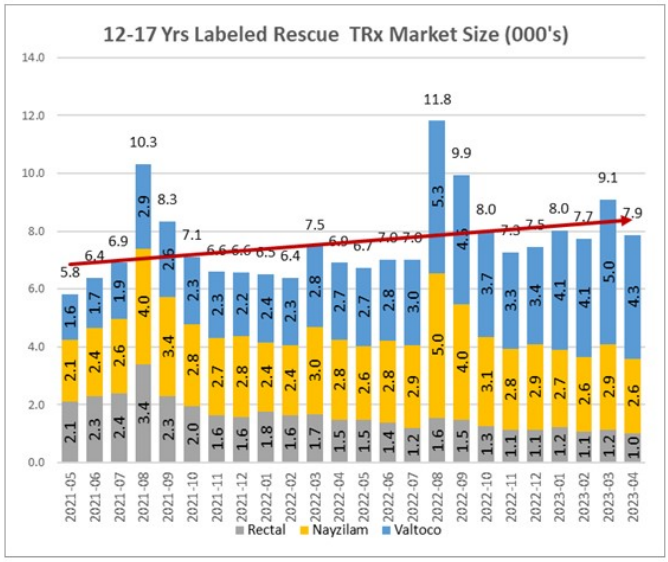
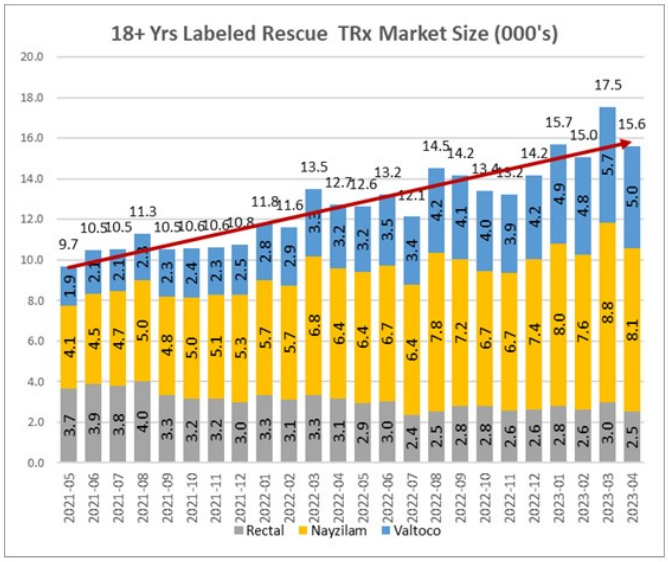
Seizure Rescue Market Size By Age 12+ Years[1]

The 18+ Age group has experienced rapid market size growth with the introduction of multiple nasal products.





1. *Symphony Health* Data April 2023.

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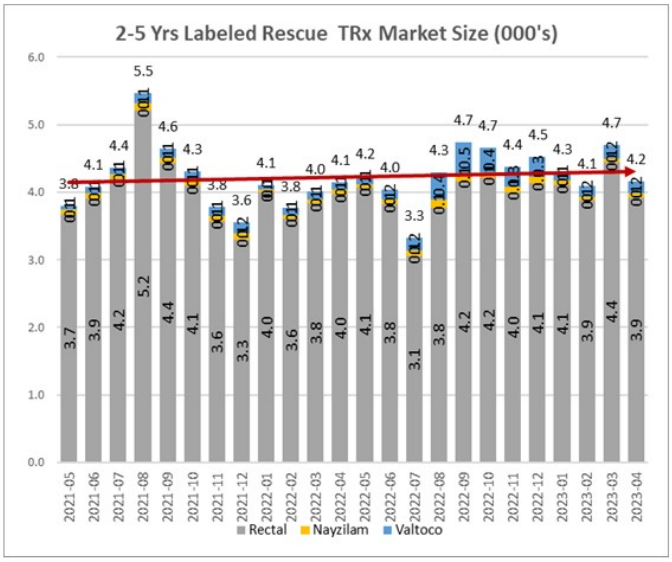
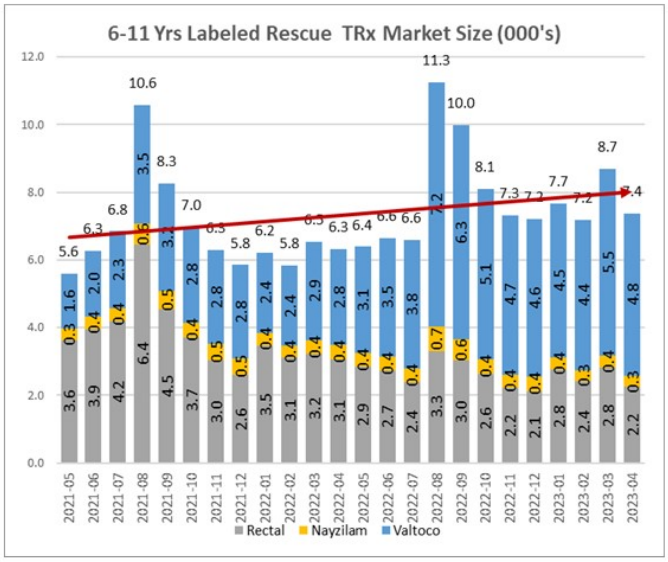
Seizure Rescue Market Size By Age 2-11 Years[1]

The 2-5 year-old age group has not experienced growth while the 6-11 year-old age group has experienced modest growth with one nasal option.





1. *Symphony Health* Data April 2023.

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Strong Patient Preference – What Patients Want [1]

% Indicating	1: Not at all Important	2	3: Somewhat Important	4	5: Highly Important	Top 2 Box
Ability to have the repetitive seizure medicine with me at all times	3%	7%	20%	26%	45%	**71%**
Ability to take the medicine as quickly as I possibly can when I need to	3%	4%	14%	28%	51%	**79%**
Ability to take the medicine in a way that is simple for me	2%	2%	13%	23%	60%	**83%**
Ability to take the medicine no matter where I am and what I am doing	3%	2%	14%	23%	58%	**81%**
Ability for me to take the medicine myself, versus someone else having to give it to me	5%	3%	22%	28%	43%	**71%**

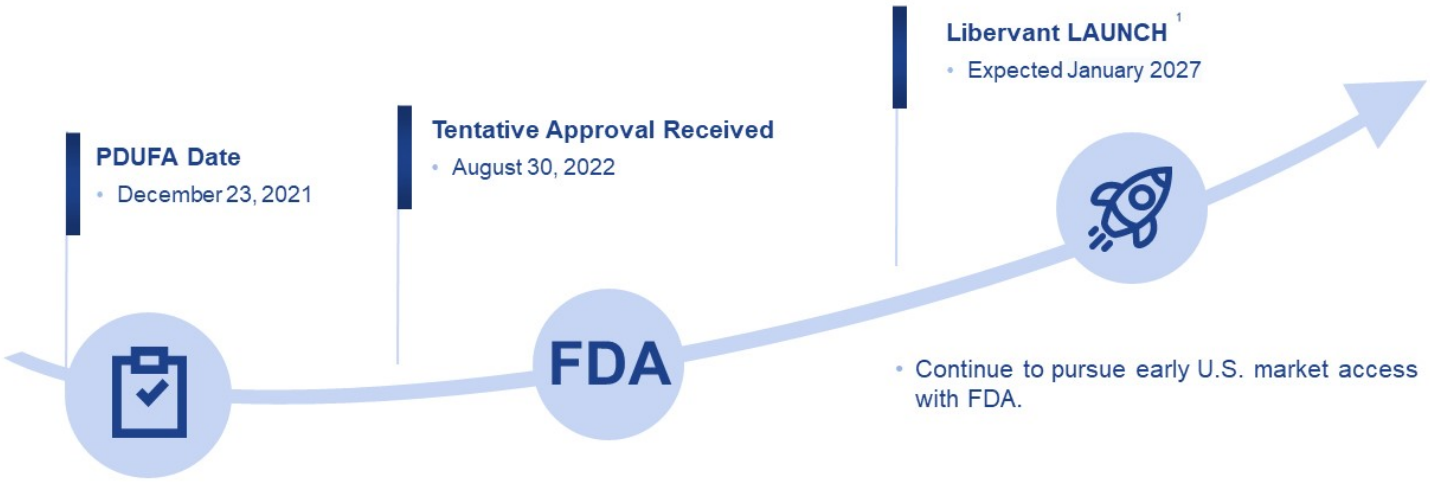
1. Aquestive Therapeutics sponsored preference study (N=101 Patients;) on file.

Strong Patient Preference – Willingness to Request[1]

% Choosing	Strongly Prefer Nasal	Prefer Nasal	No Preference	Prefer Film	Strongly Prefer Film	Film Preference
If both medicines worked just as well at stopping my repetitive seizures, I would prefer my doctor prescribe me:	6%	7%	16%	21%	50%	**71%**
Likelihood of me asking my doctor if I could switch from the current medicine I have for repetitive seizures to one of the new products:	7%	8%	20%	27%	39%	**66%**

1. Aquestive Therapeutics sponsored preference study (N=101 Patients) on file.

Libervant™ (diazepam) Buccal Film Path to Launch



- Continue to pursue early U.S. market access with FDA.

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

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IV. Existing Collaborations

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Services and Capabilities

Formulation Development

- Systematic approach applied to address permeation barriers
- Robust formulation design capabilities utilize quality- by-design principles to control risk and optimize performance

Analytical

- Systematic approach utilized to characterize complex formulations and evaluate critical quality attributes
- Specialized techniques employed to adapt to specialized dosage forms
- Constant focus on maintaining highly efficient and discriminating methodologies

Tech Transfer

- Multiple scales of analogous equipment
- Broad experience in multiple thin-film manufacturing techniques
- Process analytical technology (PAT) to continually drive innovation

Regulatory

- Experienced with the health authorities' approval process
- Leadership provided during engagements with health authorities throughout the development and approval process

Product Licenses Across the Globe

We currently have eight active worldwide licensing and manufacturing contracts; five more than just two years ago.

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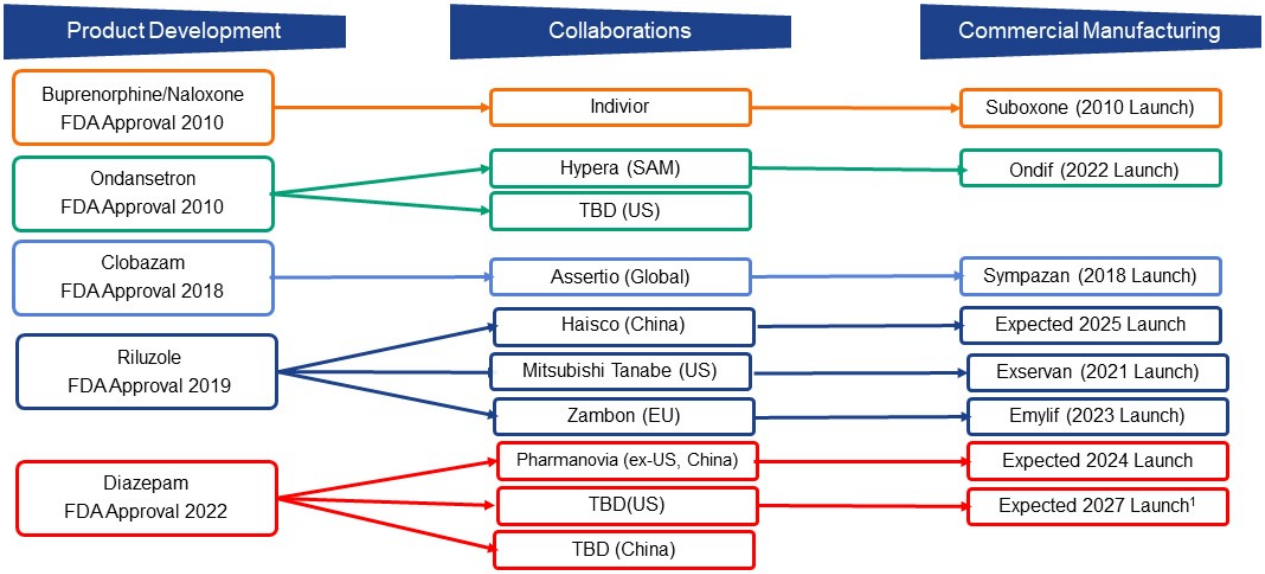
Existing Product Portfolio Has Generated Over $500M In Revenue



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

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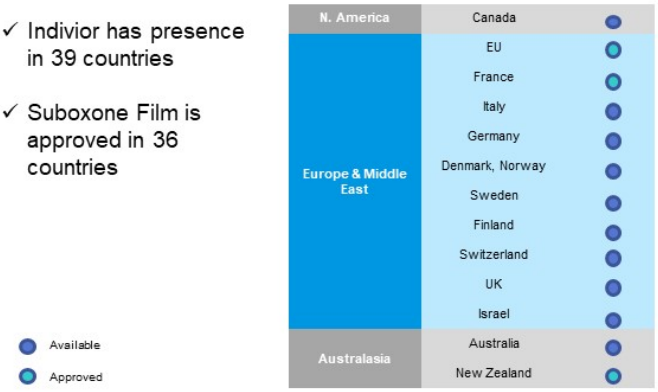
Global Diversification of Suboxone

Suboxone ROW business is expected to grow to 47% of the Suboxone Revenue by 2029[1] reducing the reliance on the Suboxone US market. Suboxone Film is currently distributed in Denmark, Finland, Germany, Italy, Norway, U.K., Sweden, Australia, Canada, Israel, and Malaysia.

SUBOXONE Film – Approved in 36 countries ex-U.S. Filings under review in Kuwait, Kingdom of Saudi Arabia and Colombia.

Suboxone ROW Market[2]

- ✓ Indivior has presence in 39 countries
- ✓ Suboxone Film is approved in 36 countries



1. Aquestive Therapeutics data on file. 2. Data from Indivior Jeffries Healthcare Conference Presentation June 7, 2023.

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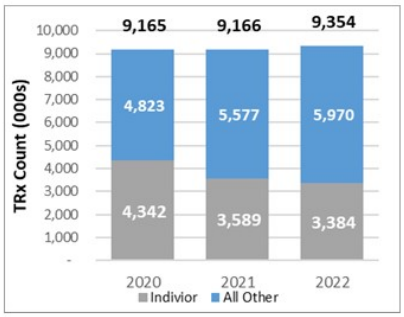
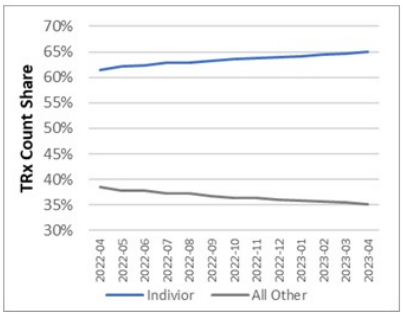
The Suboxone U.S. Market Has Been Stable for Several Years

- Suboxone U.S. market TRx is growing despite lack of promotion and alternative product forms.
- Suboxone U.S. market share is on consistent trajectory.
- Suboxone U.S. has experienced price stability for several years.

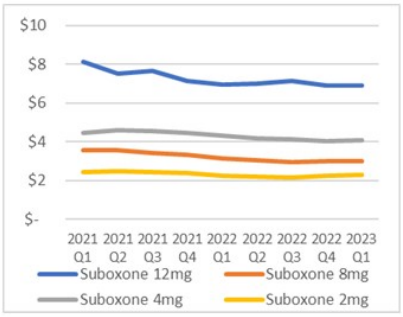
Suboxone U.S. Market[2]



Suboxone U.S. Market Share[2]



Suboxone U.S. PAC Pricing[1]



1. *Elsevier* Gold Standard Pricing Database. 2. *Symphony Health* Data April 2023. All Market Data is limited to U.S. and its territories.

Appendix

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Partial $AUC_{0\text{-}10min}$ by Study

AQST-109 12mg Sublingual Film
$AUC_{0\text{-}10min}$ by Study

Study Description	# doses	(hr*pg/mL)
Epiphast Part 2 (single dose)	48	7.9
Epiphast Part 3 (4-min hold)	22	12.8
Epiphast Part 3 (2-min hold)	23	9.5
Epiphast Part 3 (0-min hold)	21	9.4
Epiphast Part 3 (PB sandwich)	20	15.0
Epiphast II (single dose 4-min hold)	23	12.9
Epiphast II (repeat dose @ 10 min)	23	20.6
AQ109102 (single dose)	29	6.8
AQ109102 (repeat dose @ 25 min)	27	6.4
AQ109106A	12	11.3
AQ109106C	12	28.3

Geometric Means presented

Epinephrine 0.3mg Manual Injection
$AUC_{0\text{-}10min}$ by Study

Study Description	# doses	(hr*pg/mL)
Epiphast Part 2	48	6.8
Epiphast II	23	7.4
AQ1090102	27	5.3

Recent Single Administration Studies of AQST-109 12mg

Study #	# Subjects	Swallow Hold Time	Dosing Instructions	$pAUC_{0\text{-}10min}$ Endpoint > Manual IM	$pAUC_{0\text{-}20min}$ Endpoint > Manual IM	$pAUC_{0\text{-}30min}$ Endpoint > Manual IM	$pAUC_{0\text{-}45min}$ Endpoint > Manual IM	GM Cmax > Manual IM
AQST109102	29	None	Anaphylm was applied to the sublingual mucosa. No time checks or observations were conducted until after subject indicated film was dissolved.	Y	Y	Y	N	N
AQST109106A	12	None	Anaphylm was applied to the sublingual mucosa. Time checks were conducted every 30 seconds until dissolved.	Y	Y	Y	N	N
AQST109106C	12	None	Anaphylm was applied to the sublingual mucosa and held in place until dissolved with no prescribed salivary hold time.	Y	Y	Y	Y	Y

Note: AQST109106B (n=11) was a repeat dose study of AQST-109 8mg

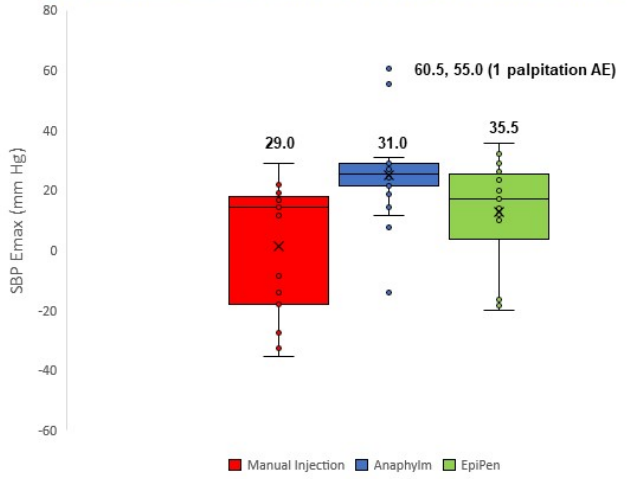
Pharmacokinetic Summary Results: Impact of Food Residue (Reference Slide #32)

Study Results	AQST-109 12mg 4-minute hold time (N=22 doses)	AQST-109 12mg PB sandwich (N=20 doses)	Epinephrine IM injection 0.3mg (Part 2) (N=48 doses)
Geometric Mean Cmax (pg/mL)	350.4	285.7	350.6
AUC 0-10 minutes (hr*pg/mL)	12.8	15.0	6.8
AUC 0-20 minutes (hr*pg/mL)	51.2	48.8	22.9
AUC 0-30 minutes (hr*pg/mL)	79.1	73.2	47.4
Median Tmax (minutes)	12	12	50

Geometric Means presented for Cmax and AUC, Median presented for Tmax

EPIPHAST II: Comparative Changes in Systolic Blood Pressure and Cardiovascular Adverse Event Profiles

Epiphast II: Maximum Change in Systolic Blood Pressure by Treatment



	EpiPen (N=22)	Manual Injection (N=23)	Anaphylm (N=23)
SBP>30mm Hg	9%	0%	13%
SBP>40mm Hg	0%	0%	9%

	EpiPen (N=22)	Manual Injection (N=23)	Anaphylm (N=23)
Cardiac Disorders	7 (31.8)	1 (4.3)	2 (8.7)
Palpitations	7 (31.8)	1 (4.3)	2 (8.7)

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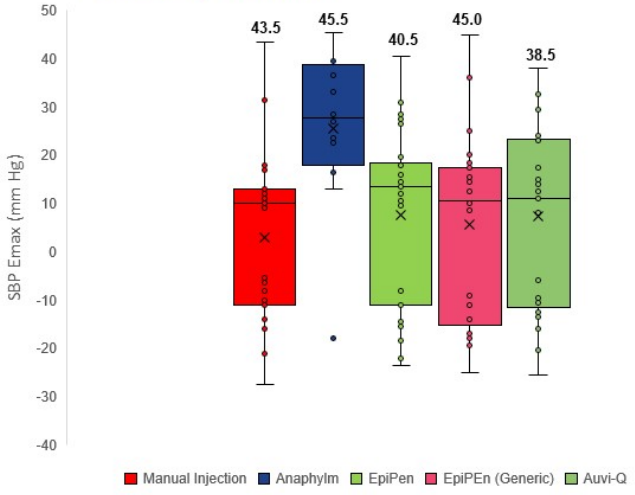
Study 102 & 106: Comparative Changes in Systolic Blood Pressure and Cardiovascular Adverse Event Profiles

Study 102/106C: Maximum Change in Systolic Blood Pressure by Treatment



	EpiPen (102, N=27)	EpiPen Generic (102, N=29)	Auvi-Q (102, N=29)	Manual Injection (102, N=27)	Anaphylm (106, N=12)
SBP>30mm Hg	7%	7%	7%	7%	42%
SBP>40mm Hg	4%	3%	0%	4%	8%

	EpiPen (102, N=27)	EpiPen Generic (102, N=29)	Auvi-Q (102, N=29)	Manual Injection (102, N=27)	Anaphylm (106, N=12)
Cardiac Disorders	2 (7.4)	2 (6.9)	0	1(3.7)	0
Palpitations	2 (7.4)	2 (6.9)	0	0	0
Atrial Tachycardia	0	0	0	1 (3.7)	0

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Exhibit 99.2

Aquestive Therapeutics Provides Business Update and Announces Chief Medical Officer Appointment

- *Submitted NDA for Libervant™ (diazepam) Buccal Film for treatment of seizure clusters in patients between two and five years of age*
- *Appointed Carl N. Kraus, M.D. as Chief Medical Officer*

WARREN, N.J., June 29, 2023 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) (the "Company" or "Aquestive"), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today provided an update on recent business developments and announced the appointment of Carl N. Kraus, M.D. as Chief Medical Officer of the Company.

NDA Filing for Libervant for Pediatric Population

Aquestive submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of Libervant™ (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) in patients between two and five years of age. The Company received tentative approval for Libervant for the treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) in patients 12 years of age and older in August 2022, but is currently under an orphan drug block to market access until January 2027. Diastat® (diazepam) Rectal Gel is the only treatment currently available to this patient population for this indication. The Company expects to hear from the FDA on the acceptance of, and issuance of a target action date on, this pediatric NDA within approximately two months.

"We are hopeful that this important subpopulation may benefit from Libervant in the near term," said Daniel Barber, Chief Executive Officer of Aquestive. "While there is inherent unpredictability in the orphan drug review process, we believe in patient choice and will continue to advocate for patient access to meaningful innovation across all age groups."

Chief Medical Officer Appointment

"I am very pleased to welcome Carl to the Aquestive team. He brings over two decades of experience in drug development, ranging from discovery through late stage development, as well as a significant medical background," said Mr. Barber. "His extensive clinical development experience will be invaluable in advancing the Anaphylm® development program as we plan to submit the pivotal study protocol to the FDA. I look forward to working with Carl as we continue to advance and expand our product development pipeline in 2023 and beyond."

Dr. Kraus commented, "I recognize the potential for Anaphylm to transform the treatment of allergic reactions. Lowering the barriers to epinephrine use via a sublingual film could help many patients with severe allergic reactions. I look forward to joining the Aquestive team as the Company continues to advance this important development program."

Aquestive named Carl N. Kraus, M.D. as Chief Medical Officer effective June 26, 2023. Dr. Kraus joins the Aquestive team from Aceragen, where he served as Chief Medical Officer from October 2021 to April 2023. Prior to that, Dr. Kraus founded and served as the Chief Executive Officer of Arrevus from January 2017 until the sale of Arrevus to Aceragen in October 2021. He previously served as Chief Medical Officer of Ology Bioservices (formerly Nanotherapeutics), which was acquired by National Resilience. Prior to joining the pharmaceutical industry, Dr. Kraus was a Medical Officer for the Center of Drug Evaluation and Research ("CDER"). Earlier in his career, he held inpatient and outpatient clinical appointments. Dr. Kraus earned his medical doctor degree from Washington University School of Medicine in St. Louis, MO, with post-graduate training in Internal Medicine (University of Chicago) and Infectious Diseases (National Institutes of Health).

About Libervant

Libervant is a buccally, or inside of the cheek, administered film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e*., seizure clusters) that are distinct from a patient's usual seizure pattern. Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products. The FDA has granted tentative approval for Libervant for treatment of these epilepsy patients 12 years of age and older, with U.S. market access for Libervant for this age group of patients subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved drug scheduled to expire in January 2027. The NDA submitted today for Libervant for epilepsy patients aged two to five is subject to FDA approval, including for U.S. market access.

About Anaphylm™

Anaphylm™ (AQST-109) is a polymer matrix-based epinephrine prodrug candidate product administered as a sublingual film that is applied under the tongue for the rapid delivery of epinephrine. The product is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a pocket, and is designed to withstand weather excursions such as exposure to rain and/or sunlight. The tradename for AQST-109 "Anaphylm" has been conditionally approved by the FDA. Final approval of the Anaphylm™ proprietary name is conditioned on FDA approval of the product candidate,

About Aquestive

Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products marketed by our licensees in the U.S. and around the world. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a proprietary product pipeline focused on treating diseases of the central nervous system and for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit Aquestive.com and follow us on LinkedIn.

Forward-Looking Statement

Certain statements in this press release include "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 approval and related timing of the NDA for Libervant by the FDA for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters) that are distinct from a patient's usual seizure pattern in patients with epilepsy aged two to five; regarding the approval for U.S. market access of Libervant for these epilepsy patients aged 12 and older and overcoming the orphan drug market exclusivity of a competing FDA approved nasal spray product extending to January 2027 for this age group of the patient population; regarding the advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA; regarding the potential benefits Libervant and Anaphylm could bring to patients, 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 the Company's business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

These forward-looking statements are based on the Company's 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 that the FDA will not approve Libervant for epilepsy patients aged two to five or grant U.S. market access for Libervant for any age group of the epilepsy patient population, including as covered under the NDA for Libervant submitted for epilepsy patients aged two to five, by overcoming the seven year orphan drug market exclusivity of an FDA approved competing product in effect until January 2027, and there can be no assurance that the Company will be successful in obtaining any such product approval or approval for U.S. market access; risk that a competing pediatric epilepsy product of Libervant will receive FDA approval prior to the Company's receipt of FDA approval of the Libervant NDA for this pediatric age group of the epilepsy patient population; 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 competing product should the FDA approve Libervant for U.S. market access for any age group of epilepsy patients; risk in obtaining market access for our product and product candidates for other reasons; risks associated with the Company's development work, including any delays or changes to the timing, cost and success of the Company's product development activities and clinical trials for Analphylm and other product candidates; risk of the Company's failure to generate sufficient data in its NDA submission for FDA approval of Analphylm; risk of the Company's failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Analphylm; risk of delays in or the failure to receive FDA approval of Analphylm, including the risk that the FDA may require additional clinical studies for FDA approval of Analphylm, and there can be no assurance that the Company will be successful in obtaining such approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of our ability to out-license our proprietary products in the U.S. or abroad and risks that such product candidates will receive regulatory approval in those licensed territories; risk of our ability to enter into other commercial transactions with third parties that will support growth of the business and execution of key initiatives; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; 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; risk of failure to satisfy all financial and other debt covenants and of any default; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk that we are unable to refinance our current corporate debt on terms and conditions satisfactory to the Company, or not at all; risk of eroding market share for Suboxone® and risk of a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of the rate and degree of market acceptance of our licensed and product candidates in the U.S. and abroad; 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; 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 its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K and our other filings with the 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 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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