**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): March 7, 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 Exhibits 99.1 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference and replaces in its entirety all prior investor presentations filed by the Company other than 4Q Supplemental Materials filed by the Company on March 7, 2023, which along with this investor presentation are 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 Exhibits 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Aquestive Therapeutics Corporate Presentation dated March 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: March 7, 2023

Aquestive Therapeutics, Inc.

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


Aquestive
Corporate Presentation
March 2023
Advancing medicine
Solving problem
Improving live

## Disclaimer

This presentation contains "forward-looking" statements that are based on the beliefs and assumptions and on information currently available to management of Aquestive Therapeutics, Inc. (together with its consolidated subsidiary, the "Company", "we" or "our"). All statements other than statements of historical fact contained in this presentation are forward-looking statements. Forward-looking statements include information regarding our estimated financial position for the quarter and year ended December 31, 2022; the anticipated impact of our End-of-Phase 2 (EOP2) meeting with the FDA; the advancement and related timing of AQST-109 through the regulatory and development pipeline; clinical trial timing and plans for AQST-109, including the ability to address the FDA's concerns provided in the EOP2 meeting including through labeling and providing sufficient additional supporting data; the potential benefits AQST-109 could bring to patients; the ability to license AQST-109 outside the United States; the ability to fund our business operations, including through licensing and other transactions of our products and product candidates; and business strategies, market opportunities and other statements that are not historical facts. These forward-looking statements are also 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 ingredients 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, we are unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic. 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.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors 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 its product development activities and clinical trials for AQST-109; risk of the Company's failure to generate sufficient data in its PK/PD comparability submission for FDA approval of AQST-109; risk of the Company's failure to address the concerns identified in the FDA End-of-Phase 2 meeting for AQST-109; risk of delays in or the failure to receive FDA approval of AQST-109; 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; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company described under "Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2021, quarterly reports on Form 10-Q, current reports on Form 8-K and our other filings with the Securities and Exchange Commission. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this presentation. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this presentation, or to conform any of the forward-looking statements to actual results or to changes in its expectations.

This presentation also contains estimates, projections and other information concerning the Company's business and the markets for the Company's 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.

Financial information contained in this presentation relating to the three and twelve months ended December 31, 2022 are preliminary and unaudited and remain subject to change. As such the Company's independent auditors have not audited, studied, reviewed or performed any procedures with respect to such preliminary information and, accordingly, they did not express an opinion or provide any other form of assurance with respect thereto for the purpose of this presentation. Our financial closing procedures for the quarter and year ended December 31, 2022 have not been completed, and as such there can be no assurance that such preliminary results are indicative of the future performance of the Company and actual results may differ materially.

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® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

# Our Quest

- Advancing medicines to solve therapeutic problems
- Delivering clinical and therapeutic advances
- Improving patients lives

# Our Strategic Priorities

## Proven track record of success

- Technology-based pharmaceutical company
- 5 FDA-approved products
- 10+ years of product sales on 6 continents
- 200+ patents worldwide
  - *23 filed patents covering AQST-109 (epinephrine) sublingual film*
  - *19 patents covering Libervant™* (diazepam) buccal film*

## Potential for 2 major product launches between 2025 - 2027

- Lead pipeline asset is AQST-109
  - *First and only oral product for the emergency treatment of severe allergies, including anaphylaxis*
  - *Anticipate launch in 2025 or sooner, if approved*
- Received tentative approval of Libervant*
  - *Anticipate launch in 2027 (based on orphan drug block), or sooner if approved by FDA*
  - *Currently exploring out-licensing opportunities*

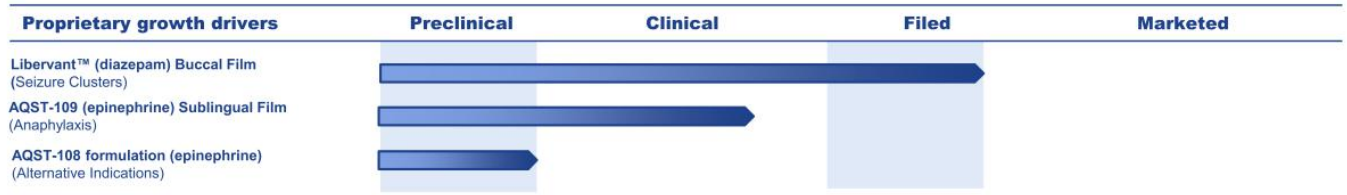
## Focused on completing financial turnaround in 2023

- Continue to focus on strong dealmaking capabilities
- Prioritize potential reducing/refinancing existing debt
- Refresh next-gen pipeline opportunities

*Libervant was granted tentative approval by U.S. Food & Drug Administration (FDA) in August 2022 for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. Due to an existing FDA regulatory grant of orphan drug market exclusivity for a competitive product sold by another company, Libervant is not yet eligible for marketing in the United States. As a result, the FDA cannot give final approval for Libervant until the expiration or inapplicability of the orphan drug market exclusivity, including, for example, by a reversal of the FDA's decision and determination that Libervant is "clinically superior" to the other FDA approved product.

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

# Product Portfolio – Significant Partnering Opportunities in 2023




## Partnering Opportunities

**Libervant (diazepam) buccal film**

*United States*
*Asia*
*South America*

**AQST-109 (epinephrine) sublingual film**

*Ex-US Rights*

## Regional Licensing Agreements

**Pharmanovia – EU, MENA**
Libervant™ (diazepam) buccal film

**Hypera – Brazil**
Ondif® ondansetrona

**Zambon - EU**
emylif®

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

**Mitsubishi Tanabe -US**
Exservan® (riluzole) oral film

## Global Licensing Agreements

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

**Indivior**
Suboxone® Sublingual Film (buprenorphine and naloxone) ©

## IP Licenses (Royalty-Only)

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

**Kempharm**
azstarys© serdexmethylphenidate and dexmethylphenidate



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# Product Licenses on 6 Continents

Libervant™
(diazepam) buccal film

Suboxone® Sublingual Film
(buprenorphine and naloxone) C-III

Sympazan®
(clobazam) oral film C-IV
5 mg • 10 mg • 20 mg

Exservan®
(riluzole) oral film

Ondif®
ondansetrona

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

emylif®
Riluzole
Orodispersible Film

azstarys® C-II
serdexmethylphenidate
and dexmethylphenidate
26.1/5.2mg • 39.2/7.8mg • 52.3/10.4mg capsules



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# Potential for Two Transformative Launches


**AQST-109 (epinephrine) Sublingual Film**

- Potential indication of treatment of severe allergic reactions including, anaphylaxis
- Anticipate filing NDA in mid-2024
- 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
- Potential peak sales of ~ $200M[1]

1. Aquestive Therapeutics Data on File.

# 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 T

**Mark Schobel**
Chief Innovation & Technology Officer

**Cassie Jung**
SVP, Operations

**Gary Slatko**
Chief Medical Officer

**Steve Wargacki**
SVP, R&D

# 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[1]

- Epinephrine is the first line of treatment for anaphylaxis
  - *Epinephrine is the only medication proven to stop a life-threatening allergic reaction*

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

- A second dose of epinephrine can be given as needed


1. EpiPen® Package Insert.

# Generic Market with High Levels of Dissatisfaction & Unmet Ne

## Current Patient Choice = 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*

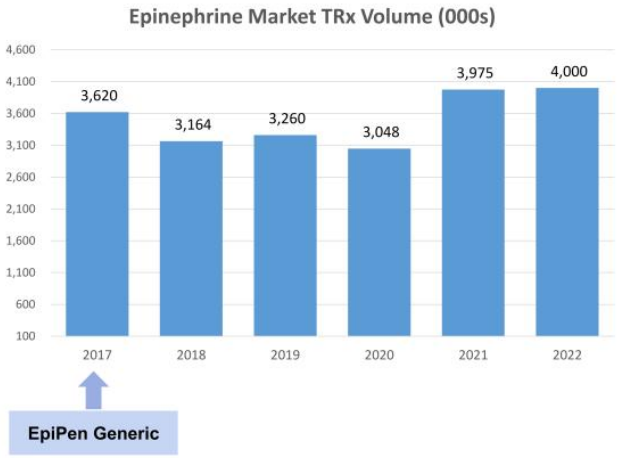
## Numerous Studies and Patient Surveys Articula Significant Dissatisfaction with Current Offerin

- Right place, right time
  - *<50% of patients carry their EpiPen® – often due to hassle factor*
- Refusal of treatment [2,3,4]
  - *25-50% 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[5]
  - *23-35% of patients and caregivers fail to dose correctly*

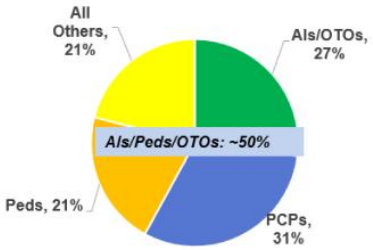
1. KOL feedback; Aquestive Market Research. 2. Warren et al. Ann Allergy Asthma Immunol (2018). 3. Brooks et al. Ann Allergy Asthma Immunol (2017). 4. Asthma and Allergy Foundation of America Patient Survey Report (2019).
5. El Turki et al. EmergMed J (2017).

# Significant & Addressable Market Opportunity

## Epinephrine Auto-Injector Market: 2015-2021[1]




## Allergists, Pediatricians, and Otolaryngologists (OTO) prescribe roughly 1/2 of all EAI Rx's[2]




- Large portion of annual Rx's are written by a target audience addressable by Aquestive (i.e., high-decile Allergists, OTOs and Pediatricians)
- Further, many of the Rx's written by PCP's/Others, are "downstrean refill prescriptions, for patients that were originally seen and prescrit an epinephrine product by an Allergist, OTO or Pediatrician

1. Symphony Health.
2. Aquestive Therapeuticscs Data on File.



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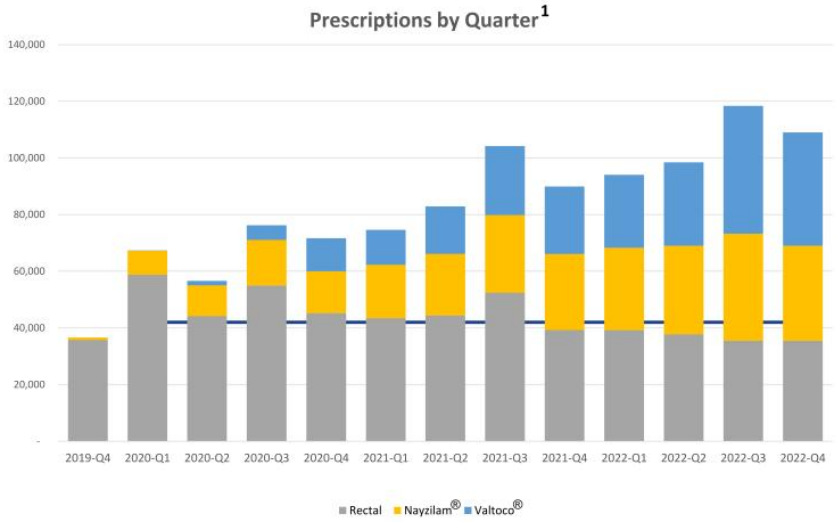
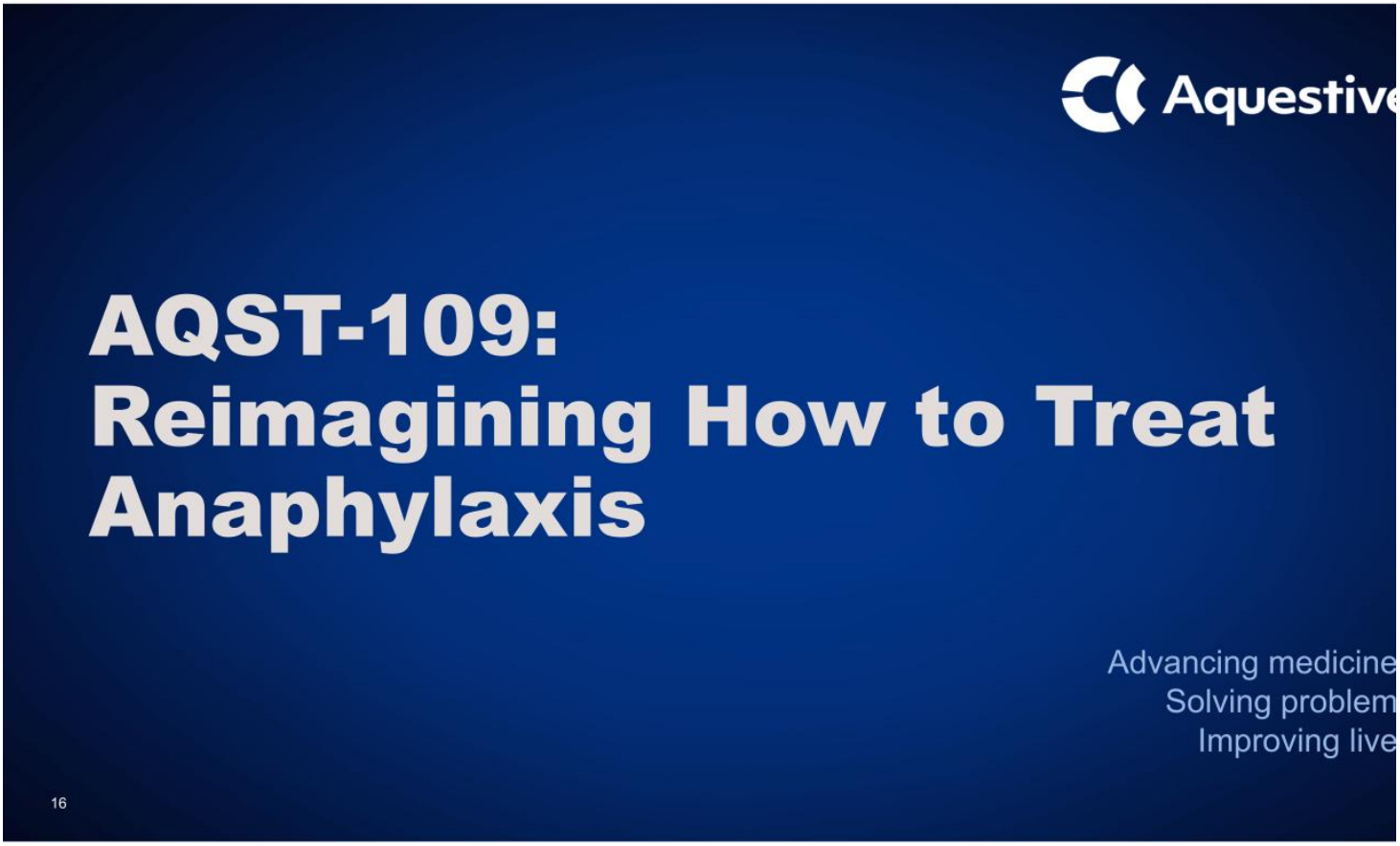
# Potential Analog: Seizure Cluster Acute Rescue Market




Availability of therapeutic candidates addressing the new routes of administration over the past three years was expected to nearly double the labele rescue market[2]

1. Symphony Health, Metys®, Jan 2021 –Dec 2022.
2. Aquestive Therapeutics Data on File.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AQST-109:
Reimagining How to Treat
Anaphylaxis
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# AQST-109 (epinephrine) Sublingual Film

***First and only orally delivered epinephrine product candidate***

**Portability**

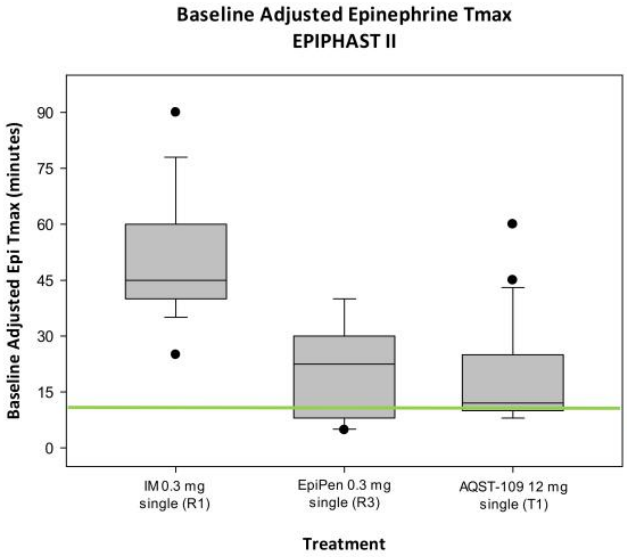
+

**Non-device administration**

+

**Fast absorption into the bloodstream**

# Strong Clinical Data Presented




Fastest Median Tmax

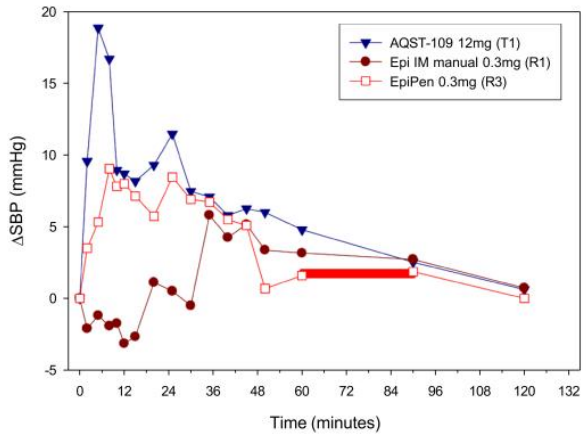
- AQST-109 showed a shorter median time to maximum concentration (Tmax) than both 0.3 mg intramuscular (IM) and 0.3 mg EpiPen[1]
- Range of Tmax values across study is consistent with EpiPen
- Both EpiPen and AQST-109 provide faster median Tmax values than 0.3 mg IM

1. Data presented at American College of Allergy Asthma and Immunology (ACAAI) Annual Scientific Meeting in November 2022

# EPIPHAST II: Pharmacodynamic (PD) Results

- AQST-109 demonstrates a pharmacodynamic response for Systolic Blood Pressure (SBP) and Pulse consistent with that of EpiPen
- Pronounced early peak in PD implies rapid and robust onset of therapeutic benefits

Mean Baseline Adjusted SBP over 130 minutes by Treatment
EPIPHAST II, Single Administration Treatments




Mean Baseline Adjusted Pulse over 130 minutes by Treatment
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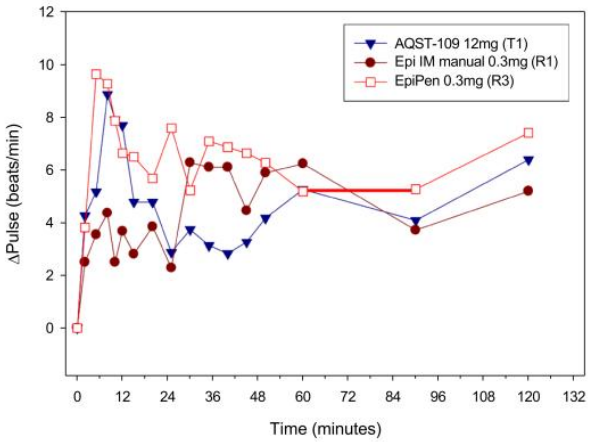

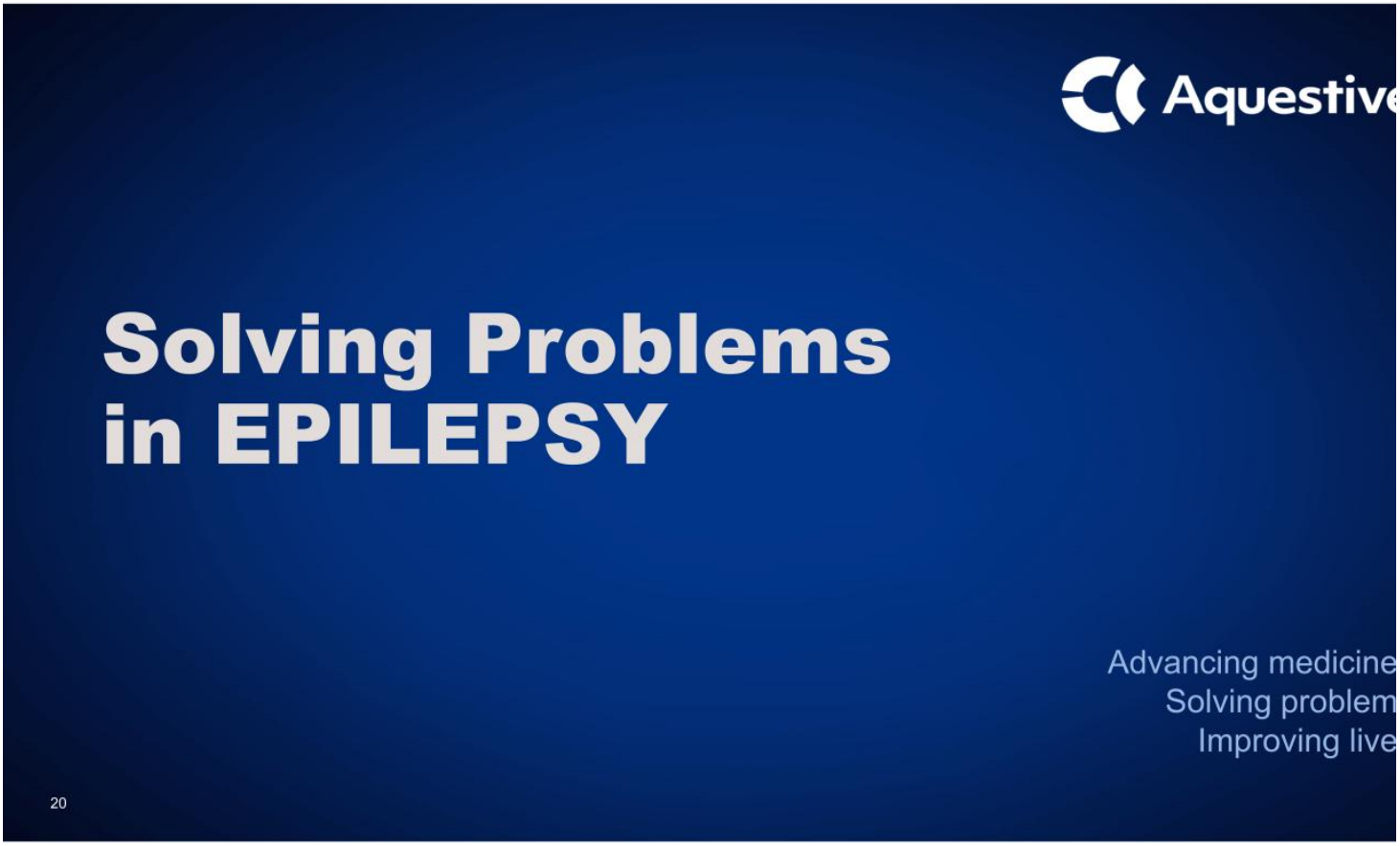
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# The Unmet Need in Refractory Seizures…

**≈1M** **Epilepsy patients**[1]

Suffer from uncontrolled, **refractory seizures**

**~92%**

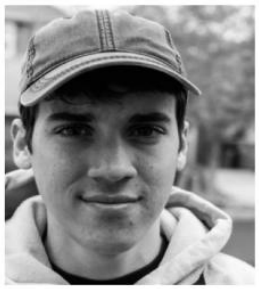
of patients with Refractory seizures will not interact with the historically available treatment[2]

**1M** **Seizures**

**account for**

**EMERGENCY DEPARTMENT**

visits annually[3]



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. Seizure visits to ED: https:// /www.ncbi.nlm.nih.gov/pmc/articles/PMC2657249/.

# Libervant™ (diazepam) Buccal Film Path to Launch

**PDUFA Date**
- December 23, 2021

**Tentative Approval Received**
- August 30, 2022

**Libervant LAUNCH**
- Currently anticipating January 2027


**Potential Path Forward**

*H1 2023 Await FDA comments on study design*

*H2 2023 Conduct study*

# 2023 Outlook

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# Financial Summary (NASDAQ: AQST)

## Full Year 2023 Guidance (as of March 7, 2023)

- Total revenues of approximately $37 to $41 million
- Non-GAAP adjusted EBITDA loss of approximately $31 to $36 million

# Keys to Success in 2023

## Leverage Our Success

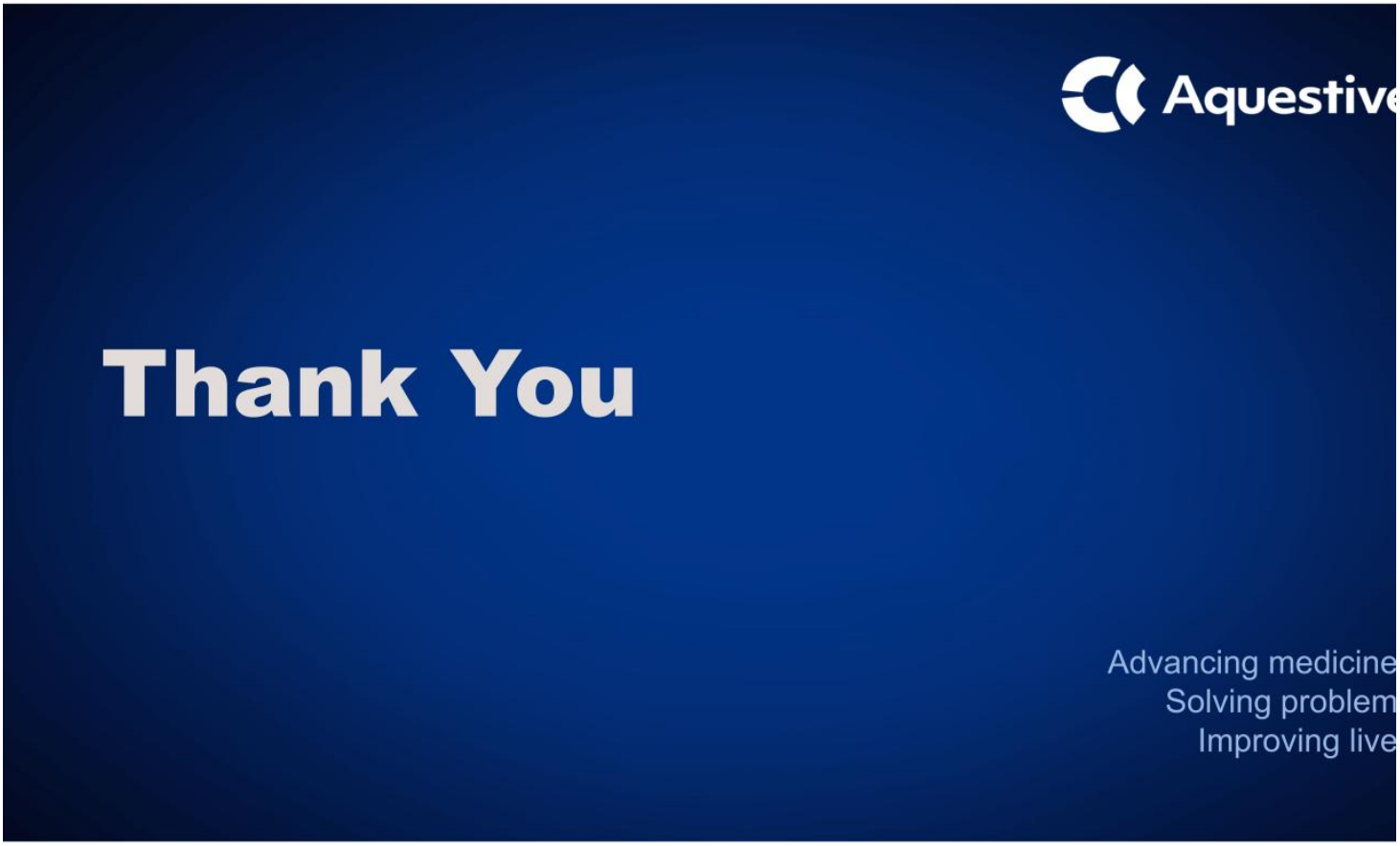
- Technology-based pharmaceutical company
- 5 FDA-approved products
- 10+ years of product sales
- 200+ patents worldwide
  - 23 filed patents covering AQST-109
  - 19 patents covering Libervant™

## Execute on Key Milestones

- AQST-109 epinephrine sublingual film
  - **First and only sublingual film using a novel prodrug of Epinephrine**
  - Completed End-of-Phase 2 meeting with FDA in 4Q22; Expecting to commence pivotal PK in Q3 2023
- Libervant™ (diazepam) Buccal Film
  - Continue to pursue early U.S. market access with FDA
  - Expected launch January 2027

## Deliver on Cash-Generatir Opportunities

- Cash flow positive manufacturing business
- Business performance and capital options support commercial operations and pipeline development
- Build potential additional license collaborations - continue potential global expansion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