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): September 12, 2022

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 (the "Investor Presentation"). 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 and replaces in its entirety all prior investor presentations filed by the Company.

A copy of the Company's H.C. Wainwright presentation is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. This presentation, along with the Company's 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 and Exhibit 99.2) 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 8.01 Other Events.

On September 12, 2022, the Company issued a press release announcing the composition of its expert allergy scientific advisory board which consists of eight industry experts. A copy of the Company’s press release is attached hereto as Exhibit 99.3 and incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor Presentation dated September 2022.
99.2	H.C. Wainwright presentation dated September 2022.
99.3	Press Release dated September 12, 2022 announcing the composition of the Company's expert allergy scientific advisory board which consists of eight industry experts.

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: September 12, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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


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Corporate Presentatio
September 2022
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Forward-Looking Statement

This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "
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 advancer
Libervant™, AQST-109, and other product candidates through the regulatory and development pipeline; and business strategies, market opportunities, and other statements that are not historical facts. These fo
looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequ
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 d
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 for
skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those describec
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
product development activities and clinical trials and plans for AQST-109 and our other drug candidates; risk of delays in FDA approval of our drug candidate Libervant, AQST-109, and our other drug candidates or
to receive approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of loss of our' orphan drug ap
and failure to obtain resulting drug exclusivity for our products; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of Libervant relative to FDA-approved dia
rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pa
or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and the
be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA ap
and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technolog
financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent lit
challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy al
short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default thereof; short-term an
term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial
our current operating revenues; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and p
candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements
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 legislati
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
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; ch
in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; an
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 o
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 subs
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-
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.

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.

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

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Strategic Priorities

Proven track record of success

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

Near-term pipeline catalysts

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

Multiple cash-generating opportunities

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

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

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

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Our Team

Daniel Barber
President, CEO and Director

Peter Boyd
SVP, Business Process & Information Technology

Lori J. Braender
General Counsel and Chief Compliance Officer

Cassie Jung
Vice President, Operations and Product Management

Ken Marshall
Chief Commercial Officer

Mark Schobel
Chief Innovation & Technology Officer

Ernie Toth
Chief Financial Officer

Ken Truitt
Chief Medical Officer

Steve Wargacki
Vice President, Resea and Development

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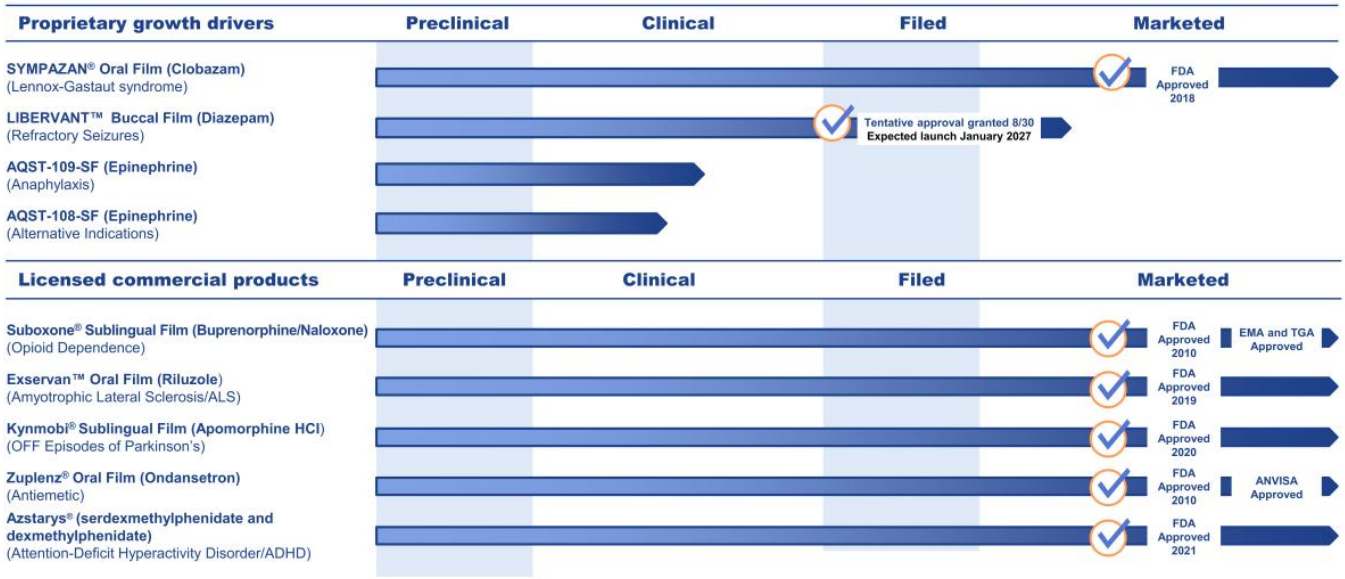
Product Portfolio



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AQST-109: Reimagining How to Treat Anaphylaxis

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

- As many as **49 million people** in the United States are at chronic risk for acute anaphylactic episodes[2]
- Lifetime prevalence may be higher than **5%**[3]
- Direct costs of anaphylaxis have been estimated at **$1.2 billion** per year, with direct expenditures of $294 million for epinephrine, and indirect costs of $609 million[4]
- **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]

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

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Epinephrine Auto-injectors, The Current Standard of Care, Are Challenging

- Patients and caregivers using epinephrine auto-injectors often experience **fear, anxiety**, and **needle phobia**[1,2]
  - Needle fear has been reported in 68% of children aged 6 to 8 years and 65% in children aged 9 to 12 years[3]
  - Fear acquired in childhood appears to persist into adulthood[4]
  - Additionally, some patients (or their caregivers) may be unable to properly inject the medication[5]

- Severe outcomes and fatalities have been correlated with **delayed administration** of epinephrine[6,7]

- **Late administration** of epinephrine has been linked to greater risk of a **biphasic reaction**, which is a recurrence of anaphylaxis following treatment for the condition[8]

References: 1. Chad L, et al. *Eur J Allergy Clin Immunol*. 2013;68:1605-1609. **2.** Orenius T, et al. *SAGE Open Nursing*. 2018;4:1-8. doi:10.1177/2377960818759442 **3.** Taddio A, et al. Vaccine. 2012;30:4807-4812. doi:10.1016/j.vaccine.2012.05.011 **4.** Baxter AL, et al. *J Allergy Clin Immunol*. 2017;139(2)(suppl AB147):469. doi:10.1016/j.jaci.2016.12.482. **5.** Prince BT, et al. *J Asthma Allergy*. 2018;11:143-151. **6.** Song TT, et al. *Cu Opin Allergy Clin Immunol*. 2015;15:323-328. doi:10.1097/ACI.0000000000000185 **7.** Dudley LS, et al. *West J Emerg Med*. 2015;16(3):385-387. doi:10.5811/westjem.2015.25337 **8.** Cardona V, et al. *World Allergy Org J* 2020;13:13100472.

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AQST-109: Potential to Solve These Issues

AQST-109 is the first and only orally delivered epinephrine product candidate for the treatment of allergic reactions (type 1), including anaphylaxis, that would allow patients and their providers to:

Quickly deliver epinephrine to control emerging symptoms and prevent progression

Alleviate the fears associated with auto-injectors and self-injection, including needle phobia[1]

Prevent improper administration or suboptimal dosing, including associated adverse events such as injection site necrosis and/or infections[2]

Reduce the likelihood of noncompliance or delayed dosing because the sublingual film is small, portable, and can be administered quickly and easily[3]

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

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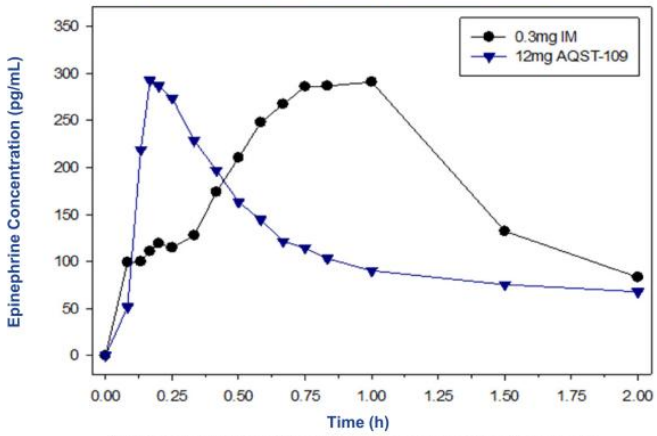
AQST-109: Pharmacokinetic (PK) Values Comparable to Existin Epinephrine Auto-injectors in Part 2 of EPIPHAST Trial

- Favorable time to maximum concentration (T_{max})
- Partial area under the curve (AUC) out to 30 minutes
- Maximum plasma concentration (Cmax) and overall variability (CV%) continued to improve versus Part 1 of EPIPHAST Trial

Mean Baseline Adjusted Epinephrine Concentration Over Time by Treatment, 0-2 hours*



*Represents data from topline results. Figure derived from arithmetic means.

Description†	AQST-109 12 mg, Part 2	Epinephrine IM 0.3 mg, Part 2
No. Subjects/No. of doses	24/48	24/48
C_{max} (pg/mL) (ISCCV%)	274 (96%)	350 (48%)
AUC 0-t (hr•pg/mL)	362	538
AUC 0-30 min (hr*pg/mL)	56.7	47.5
T_{max} (min)	15	50
T_{max} range (min)	8-120	12-120

†Represent data from topline results. Geometric means presented for C_{max} and AUC 0-t, median T_{max}.

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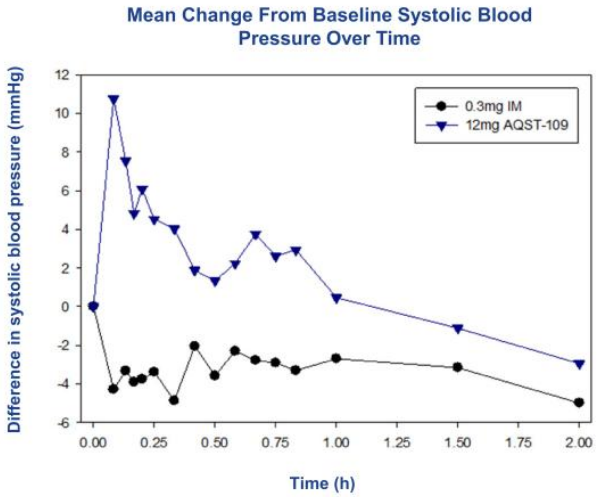
AQST-109: Pharmacodynamic (PD) Values Compared Favorably to Epinephrine Auto-injectors in Part 2 of EPIPHAST Trial

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



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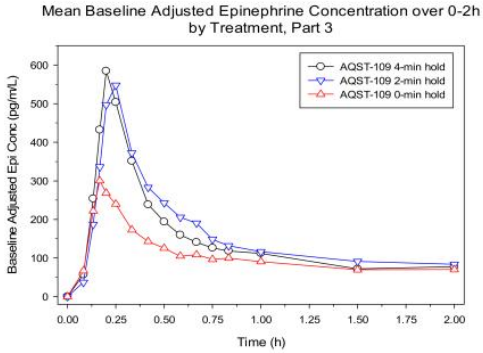
AQST-109: Rapid Absorption With Favorable PK Per Initial Data From Part 3 of EPIPHAST Trial

- Tmax of 12 minutes at target 4-minute hold time, compared to 50 minutes for 0.3mg Intramuscular Injection (IM)
- 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

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)	Epinephr IM Injecti 0.3 mg (from Par (N=48 dos
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

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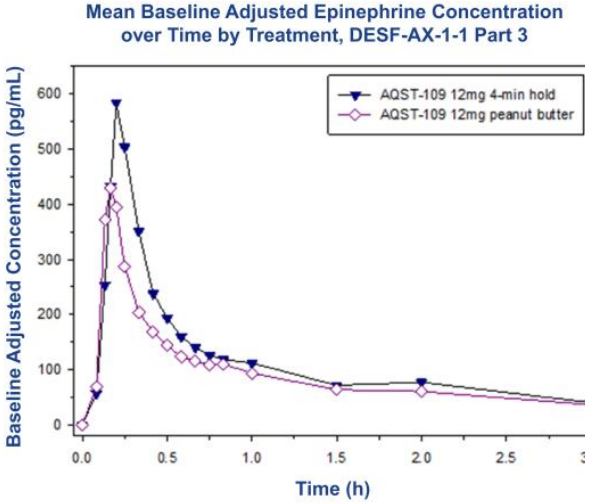
AQST-109: Rapid Absorption With Comparable PK After Consuming Peanut Butter From Part 3 of EPIPHAST Trial

- Study results for the sublingual administration of AQST-109 epinephrine sublingual film after consuming a peanut butter sandwich demonstrate consistent performance
  - Consistent Tmax of 12 minutes
  - Comparable Cmax
  - Consistent partial AUC's



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AQST-109: De-Risking Potential Administration Errors From Part 3 of EPIPHAST Trial Findings

- Even if film is swallowed immediately with water, substantial epinephrine absorption and exposure still occurs
  - Comparable Cmax and overall AUC
  - Tmax of 25 minutes compares favorably to 50 minutes for 0.3 mg IM
- This finding has the potential of lowering the risks associated with patient non-compliance to administration instructions in a real-world setting

Parameter	4-minute hold (N=22)	Swallowed Film (N=20)
Geometric C_{max}(pg/mL)	350	313
$AUC_{0\text{-}10min}$(hr*pg/mL)	12.8	2.4
$AUC_{0\text{-}20min}$(hr*pg/mL)	51.2	28.1
$AUC_{0\text{-}30min}$(hr*pg/mL)	79.1	73.2
$AUC_{0\text{-}t}$(hr*pg/mL)	411.5	481.0
T_{max}(minutes)	12	25

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AQST-109: Development Steps

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

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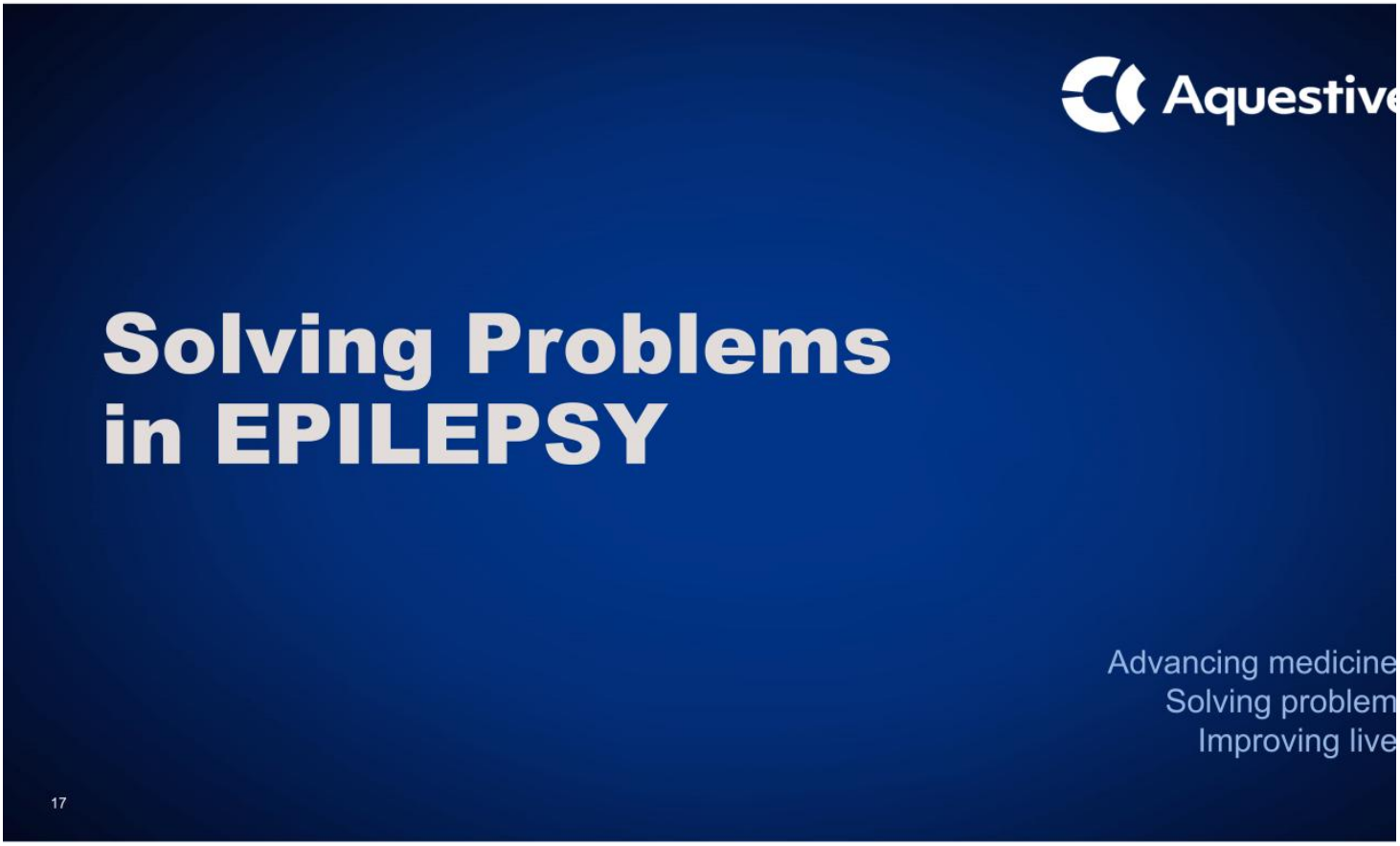
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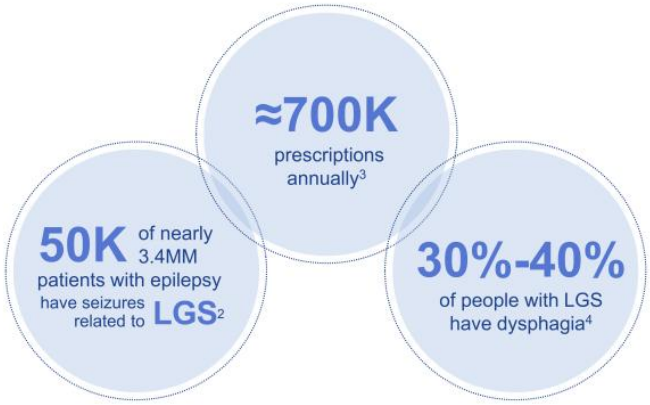
Solving Problems in EPILEPSY:

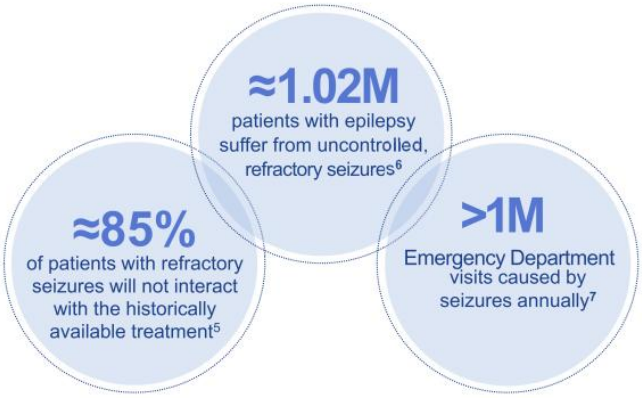
SYMPAZAN® Oral Film (clobazam)

- Commercialized for Lennox-Gastaut syndrome (LGS), a rare, severe form of epilepsy characterized by multiple manifestations of cognitive impairment and developmental delays[1]



LIBERVANT™ Buccal Film (diazepam)

- Under FDA review for management of refractory patients with epilepsy on stable regimens of AEDs who experience seizure clusters



References: **1**. van Rijckevorsel. Treatment of Lennox-Gastaut syndrome: overview and recent findings *Neuropsychiatr Dis Treat*. 2008;4(6):1001-1019; **2**. Kwan and Brodie. Early Identification of Refractory Epilepsy *N Engl J Med*. 2000;342(5):314-319. **3.** Symphony Health 2020 data on file. **4.** Ogawa K, Kanemoto K, Ishii Y, Koyama M, Sirasaka Y, Kawasaki J, Yamasaki. Long-term follow-up study of Lennox–Gastaut syndrome in patients with severe motor and intellectual disabilities: with special reference to the problem of dysphagia. Seizure. 2001; 10:197-202. **5.** Triangle Insights Group. Synthesis of Epilepsy (ARS) Primary Research. 2017. Internal Aquestive report: unpublished. **6**. 2017. Centers for Disease Control and Prevention, https://www.cdc.gov/media/releases/2017/p0810-epilepsy-prevalence.html. **7.** Pallin DJ, Goldstein JN, Moussally JS, Pelletier AJ, Green AR, Camargo CA Jr. Seizure visits in US emergency departments: epidemiology and potential disparities in care. *Int J Emerg Med*. 2008;1(2):97-105.

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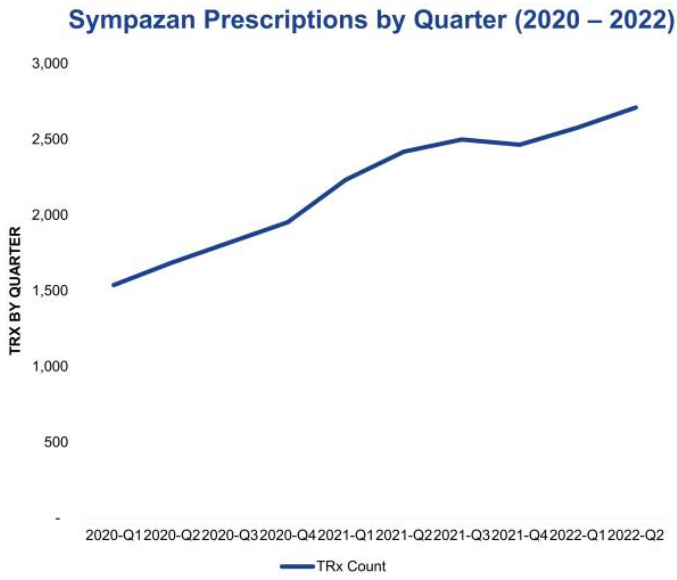
Continued Expansion of Epilepsy Franchise

- Sympazan Trxs and the number of prescribers continue to grow
- These prescribers manage a significant portion of refractory patients in the market and are the highest volume prescribers of rescue medicines
- Exposing more prescribers to the PharmFilm® technology platform via Sympazan may accelerate the uptake of Libervant, if approved by the FDA for U.S. market access



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Libervant Path to Launch

PDUFA Date
- December 23, 2021

Tentative Approval Received
- August 30, 2022

Libervant LAUNCH
- Currently anticipating January 2027

Potential Path Forward

H2 2022 *Engage with FDA on study design*
Conduct head-to-head study
H1 2023 *Submit study to FDA for review*

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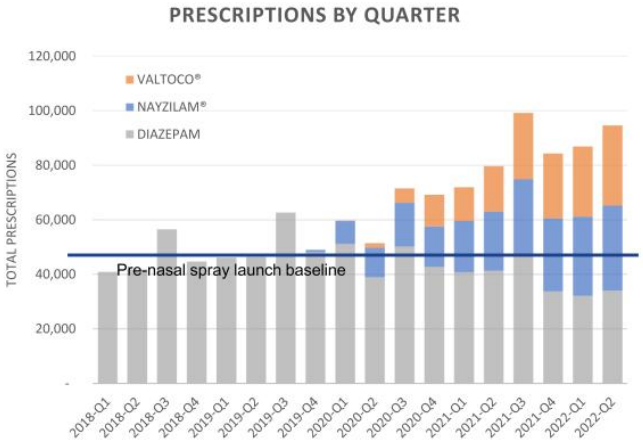
Seizure Cluster Acute Rescue Market



A significant unmet need exists for additional delivery options, especially given the ongoing shortage of diazepam rectal gel, which represents a majority of the diazepam rescue market.[1]

References: 1. Symphony Health, Metys®, Jan 2021–Dec 2021.

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Financial Summary (NASDAQ: AQST)

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

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

Capital

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

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Going Forward

Continued leverage of expertise and technology

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

Advance our novel epinephrine delivery platform

AQST-109

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

AQST-108

- Identify additional product opportunities

Identifying cash-generati opportunities

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

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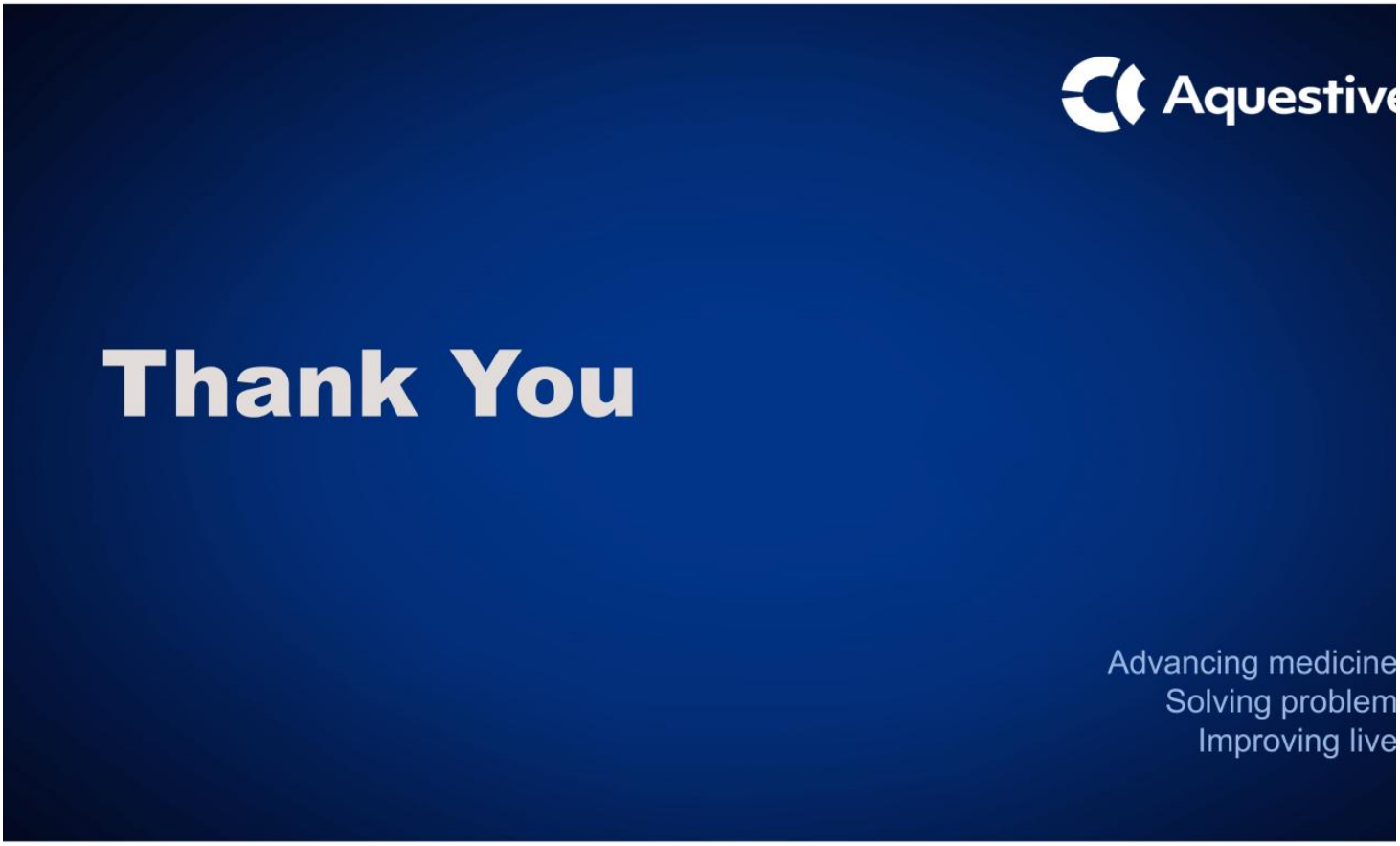
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Aquestive

Aquestive Therapeutics
H.C. Wainwright

September 2022

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Forward-Looking Statement

This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "
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 advancer
Libervant™, AQST-109, and other product candidates through the regulatory and development pipeline; and business strategies, market opportunities, and other statements that are not historical facts. These fo
looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequ
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 d
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 for
skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those describec
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
product development activities and clinical trials and plans for AQST-109 and our other drug candidates; risk of delays in FDA approval of our drug candidate Libervant, AQST-109, and our other drug candidates or
to receive approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of loss of our' orphan drug ap
and failure to obtain resulting drug exclusivity for our products; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of Libervant relative to FDA-approved dia
rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pa
or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and the
be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA ap
and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technolog
financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent lit
challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy al
short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default thereof; short-term an
term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial
our current operating revenues; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and p
candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements
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 legislati
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
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; ch
in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; an
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 o
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 subs
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-
statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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

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Strategic Priorities

Proven track record of success

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

Near-term pipeline catalysts

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

Multiple cash-generating opportunities

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

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

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

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Experienced Team

Daniel Barber
President, CEO and Director

Peter Boyd
SVP, Business Process & Information Technology

Lori J. Braender
General Counsel and Chief Compliance Officer

Cassie Jung
Vice President, Operations and Product Management

Ken Marshall
Chief Commercial Officer

Mark Schobel
Chief Innovation & Technology Officer

Ernie Toth
Chief Financial Officer

Ken Truitt
Chief Medical Officer

Steve Wargacki
Vice President, Resea and Development

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Scientific Advisory Board with Allergy Expertise

David Bernstein, MD
University of Cincinnati

Carlos Camargo, MD
Harvard Medical School

David M. Fleischer, MD
Children's Hospital Colorado

David Golden, MD
Sinai Hospital, Baltimore

Matthew Greenhawt, MD
Children's Hospital Colorado

Ruchi Gupta, MD, MPH
Northwestern

Jay Lieberman, MD
University of Tennessee

John Oppenheimer, MD
UMDNJ - Rutgers

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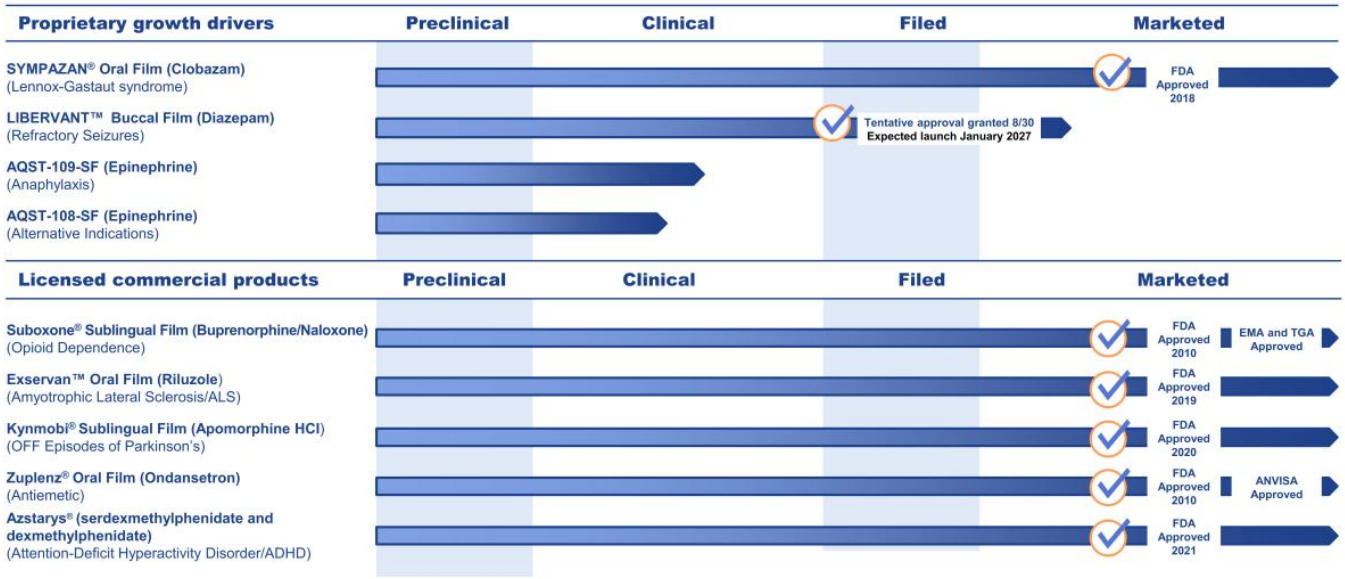
Product Portfolio



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AQST-109: Commercial Opportunity

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

- As many as **49 million people** in the United States are at chronic risk for acute anaphylactic episodes[2]
- Lifetime prevalence may be higher than **5%**[3]
- Direct costs of anaphylaxis have been estimated at **$1.2 billion** per year, with direct expenditures of $294 million for epinephrine, and indirect costs of $609 million[4]
- **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]

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

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AQST-109: Potential to Solve These Issues

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

Quickly deliver epinephrine to control emerging symptoms and prevent progression

Alleviate the fears associated with auto-injectors and self-injection, including needle phobia[1]

Prevent improper administration or suboptimal dosing, including associated adverse events such as injection site necrosis and/or infections[2]

Reduce the likelihood of noncompliance or delayed dosing because the sublingual film is small, portable, and can be administered quickly and easily[3]

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

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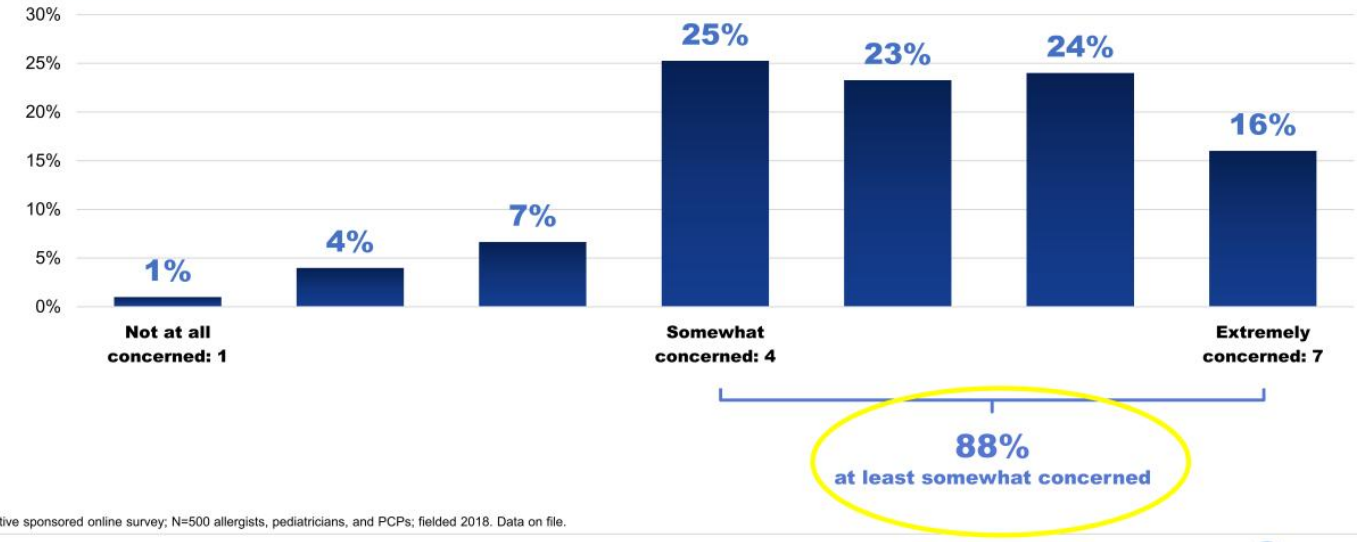
Physician Research: Concerns About Patients Having EAI With Them at All Times

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



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

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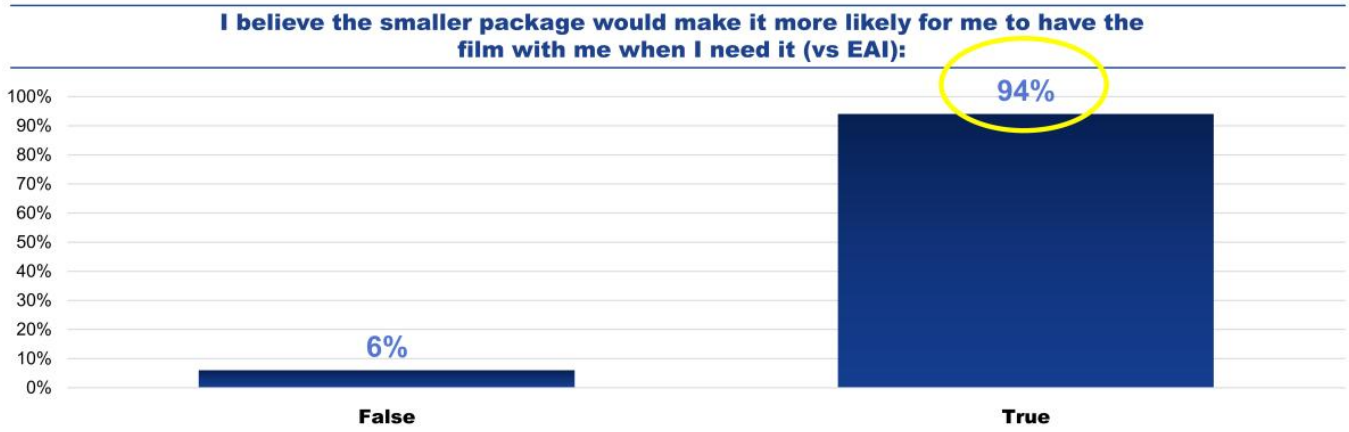
Patient Survey: Impact, Epinephrine On Hand



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

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AQST-109: Commercial Opportunity

PharmFilm® delivers market share within existing market

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

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

Patient convenience + **Medical advance**

Aquestive allergy franchise delivers market expansion

Expected opportunities to increase the customer base:

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

*Target Product Profile

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AQST-109: Potential Annual Peak Net Sales*

- **No market expansion**
- **PharmFilm share ≤30%**

- **Modest market expansion**
- **PharmFilm share = 30% - 50%**

- **Significant market expans**
- **PharmFilm share ≥50%**

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

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AQST-109: Development Pathway

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AQST-109: Critical Therapeutic Parameters

- **Is there sufficient drug absorption to bridge to efficacy?**
  - Maximum drug plasma concentrations (Cmax)
  - Systolic / diastolic blood pressure – change from baseline
  - Heart rate – change from baseline

– **Is drug absorption as fast as the standard of care in a non-clinical setting (EpiPen auto-injector)?**
  - Time to maximum drug plasma concentrations (Tmax)
  - Time to 100 pg/mL
  - Partial area under the curve (AUC) at identified time points

– **Is the therapeutic candidate safe?**
  - Treatment-emergent adverse events (TEAE's)
  - Serious adverse events (SAE's)
  - Administration site irritation

– **Is the therapeutic candidate effective under a variety of conditions?**
  - Administration after food
  - Administration under various pH levels
  - Potential impact of angioedema

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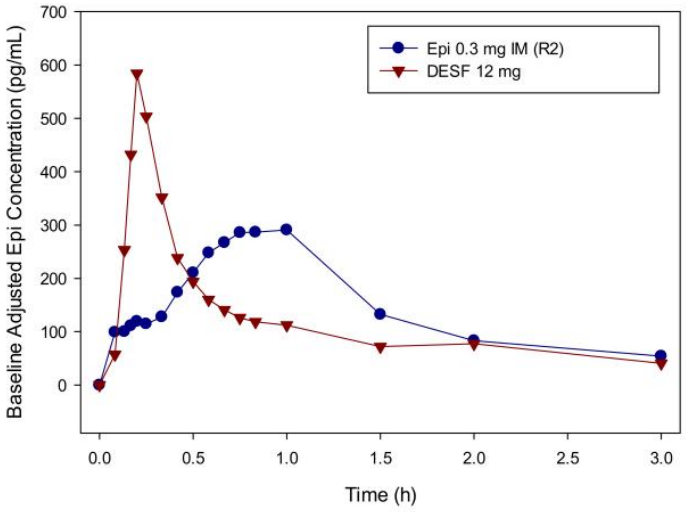
AQST-109: Part 3 of EPIPHAST Trial Demonstrates Rapid Absorptio

Mean Baseline Adjusted Epinephrine Concentration over 3 hours



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

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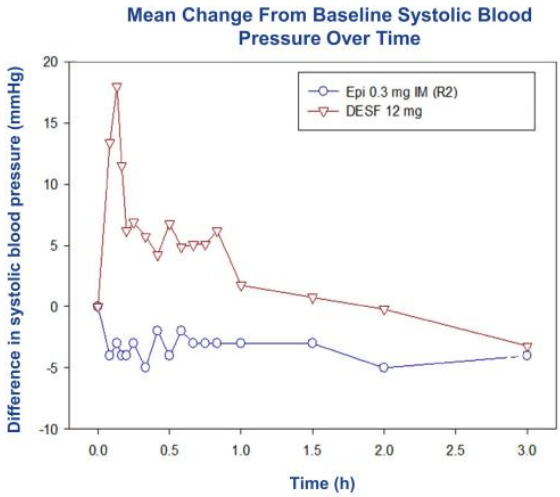
AQST-109: Pharmacodynamic (PD) Values Compared Favorably to Epinephrine Auto-injectors in EPIPHAST Trial

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



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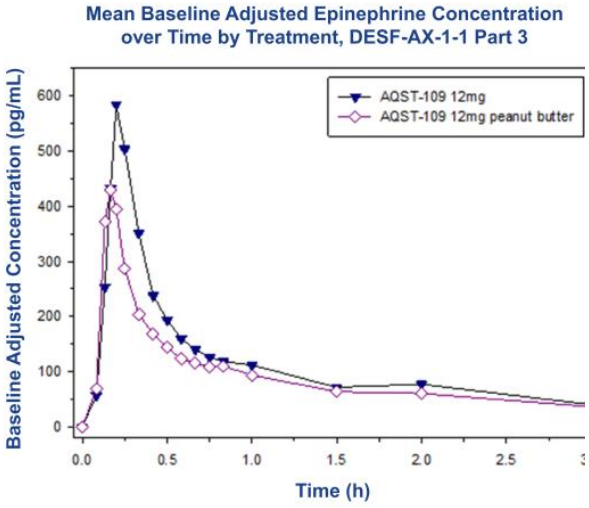
AQST-109: Rapid Absorption With Comparable PK Under Various Administration Conditions In Part 3 of EPIPHAST Trial

- Study results for the sublingual administration of AQST-109 epinephrine sublingual film after consuming a peanut butter sandwich (right) demonstrate consistent performance
  - Consistent Tmax of 12 minutes
  - Comparable Cmax
  - Consistent partial AUC's



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AQST-109: Development Steps

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

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Libervant™ (diazepam) Buccal Film Update

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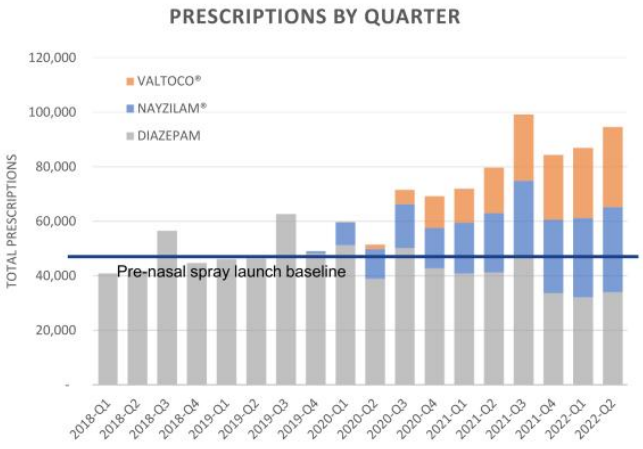
Seizure Cluster Acute Rescue Market



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

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

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

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Libervant Path to Launch

PDUFA Date
- December 23, 2021

Tentative Approval Received
- August 30, 2022

Libervant LAUNCH
- Currently anticipating January 2027

Potential Path Forward

H2 2022 *Engage with FDA on study design*
Conduct head-to-head study
H1 2023 *Submit study to FDA for review*

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Financial Summary (NASDAQ: AQST)

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

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

Capital

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

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Going Forward

Continued leverage of expertise and technology

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

Advance our novel epinephrine delivery platform

AQST-109

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

AQST-108

- Identify additional product opportunities

Identifying cash-generati opportunities

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

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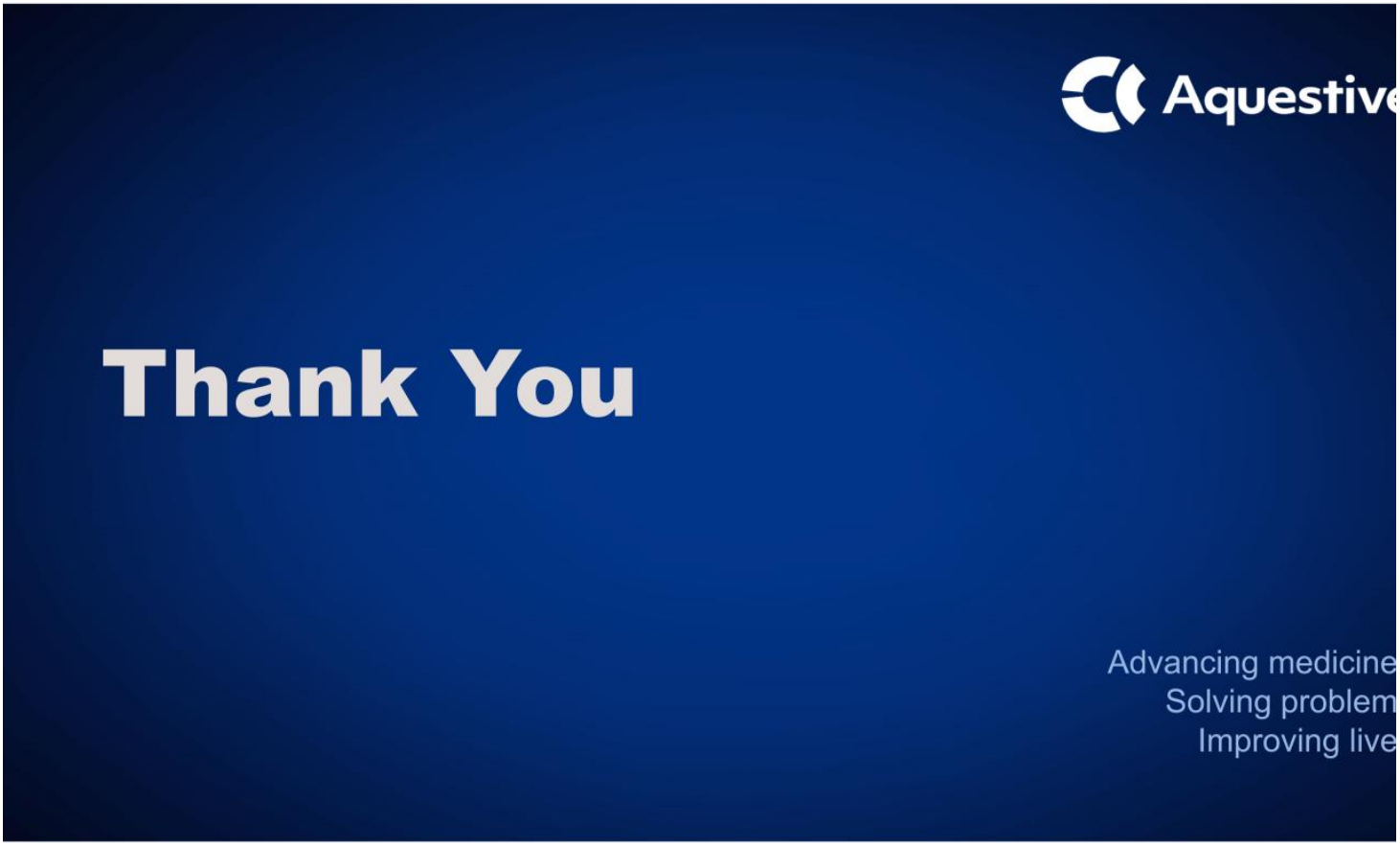
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Aquestive Therapeutics Announces Expert Allergy Scientific Advisory Board

WARREN, N.J., September 12, 2022 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, announced today the establishment of a Scientific Advisory Board comprised of eight allergy experts.

"We are very pleased to welcome these leading experts to our Scientific Advisory Board," said Dan Barber, Chief Executive Officer of Aquestive. "The accomplished individuals on our board have made significant contributions and breakthroughs in the Allergy and Immunology space, and together will bring a deep wealth of knowledge and expertise to Aquestive as we advance our AQST-109 platform and aim to make significant contributions to patients. With our planned pivotal and pediatric studies, and continued interactions with the FDA, there is no better time than now to compose an elite Scientific Advisory Board that can provide their expert insights and guidance to our program."

The Scientific Advisory Board includes eight allergy experts as follows:

David Bernstein, MD, is Professor Emeritus of Medicine in the Division of Immunology and Allergy at the University of Cincinnati College of Medicine where he is co-director of the Allergy Fellowship training program. He is a former Principal Investigator of a training grant for 3 funding cycles through the National Institute of Allergy and Infectious Diseases (NIAID). Dr. Bernstein has authored or co-authored over 270 original publications. He has been engaged in the practice of Allergy and Clinical Immunology for the past 40 years. Major research interests of Dr. Bernstein include new therapies for asthma and allergic disorders, environmental causes of asthma, allergen immunotherapy and occupational asthma. Dr. Bernstein has received the Distinguished Clinician Award from the American Academy of Allergy Asthma and Immunology and this year he received the Distinguished Alumni Award from the University of Cincinnati College of Medicine.

Carlos Camargo, MD, is a Professor of Emergency Medicine, Medicine, and Epidemiology at Harvard University, and the Conn Chair in Emergency Medicine at Massachusetts General Hospital. He has over 1,200 publications, with an H-index of 149. He founded and leads the Emergency Medicine Network (EMNet), an international research collaboration with ~250 hospitals. EMNet focuses on respiratory/allergy emergencies, health services research in emergency care, and social determinants of health. Dr. Camargo also works on the role of nutrition in respiratory/allergy disorders, both in large cohort studies and in randomized controlled trials. He is past president of the American College of Epidemiology, and has worked on several U.S. guidelines, including those on diet, asthma, and food allergy.

David Fleischer, MD, is currently the Section Head of Allergy & Immunology at Children's Hospital Colorado (CHCO) and a Professor of Pediatrics at CHCO and the University of Colorado Denver School of Medicine. He is the Director of the Allergy and Immunology Center at CHCO. Dr. Fleischer's primary clinical interest is food allergy. His research has focused on the natural history of food allergy and novel treatments for food allergy, including oral, sublingual, and epicutaneous immunotherapies. Dr. Fleischer has authored many original, peer-reviewed articles, review articles, and book chapters on food allergy.

David Golden, MD, did his medical training at McGill University, and his fellowship in Allergy-Clinical Immunology at Johns Hopkins University. He is now an Associate Professor of Medicine (part-time) at Johns Hopkins, where he directed a program of research studies on insect sting allergy and anaphylaxis for 30 years. He has published numerous research articles, chapters and review articles. Dr. Golden is a co-chair of the Joint Task Force on Practice Parameters for allergy, and on the editorial boards of several major allergy journals. He established a private group practice in Baltimore that has been recognized for academic quality and superior patient care. He is also Division chief for Allergy-Immunology at Sinai Hospital of

Baltimore, and Franklin Square Hospital in Baltimore, where he developed an Allergy-Immunology curriculum and teaching program for the medical residents.

Matthew Greenhawt, MD, is a Professor in the Department of Pediatrics Section of Allergy and Immunology at Children's Hospital Colorado and the University of Colorado School of Medicine, and is the Director for the Children's Hospital Colorado Food Challenge and Research Unit in Aurora, C.O. Dr Greenhawt earned his medical degree from Tufts University School of Medicine in Boston, M.A. He then completed his residency in pediatrics at Morgan Stanley Children's Hospital of New York-Presbyterian, Columbia Presbyterian Medical Center in New York, N.Y. and his fellowship in allergy/immunology at the University of Michigan in Ann Arbor, MI. He also holds an MBA from Tufts University and a MS degree in health and healthcare policy from the University of Michigan, Rackham School of Graduate Studies. Dr Greenhawt is board certified in pediatrics and allergy/immunology.

Ruchi Gupta, MD, MPH, is a Professor of Pediatrics and Medicine at Northwestern University Feinberg School of Medicine and a Clinical Attending at Ann & Robert H. Lurie Children's Hospital of Chicago. Dr. Gupta has 17 years of experience as a board-certified pediatrician and health researcher and currently serves as the founding director of the Center for Food Allergy & Asthma Research (CFAAR). She is world-renowned for her groundbreaking research in the areas of food allergy and asthma epidemiology, most notably for her research on the prevalence of pediatric and adult food allergy in the United States. She has also significantly contributed to academic research in the areas of food allergy prevention, socioeconomic disparities in care, and the daily management of these conditions.

Jay Lieberman, MD, is currently an Associate Professor at the University of Tennessee Health Science Center and a practicing physician at LeBonheur Children's Hospital. There he serves as the acting allergy fellowship training program director and as the principal investigator for numerous clinical trials in the field of allergy focusing on food allergy. He is the current chair of the food allergy committee for the American College of Allergy, Asthma, and Immunology, is co-chair of the Joint Task Force for Practice Parameters, and serves on the executive board for the American Board of Allergy and immunology.

John Oppenheimer, MD, is the Director of Clinical Research at Pulmonary and Allergy Associates as well as Clinical Professor of Medicine at UMDNJ-Rutgers. He is board certified in Internal Medicine and Allergy and Immunology. Dr. Oppenheimer has participated in over 100 clinical studies with over 250 publications. He serves as the executive editor of the Annals of Allergy Asthma and Immunology, co-section editor of Current Reports of Allergy and Immunology, Current Opinion of Allergy and Immunology and serves as a reviewer for several journals including the Journal of Allergy and Clinical Immunology and JAMA. He is presently the liaison to the American Board of Internal Medicine for the ABAI and a member of the ABIM council. He has focused his career on guideline development and has been actively involved in measurement development in the field of allergy and immunology.

About Anaphylaxis

Anaphylaxis is a serious systemic hypersensitivity reaction with rapid onset and potentially fatal. As many as 49 million people in the United States are at chronic risk for anaphylaxis. Lifetime prevalence is at least 5%, or more than 16 million people in the United States. Direct costs of anaphylaxis have been estimated at $1.2 billion per year, with direct expenditures of $294 million for epinephrine, and indirect costs of $609 million. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years. 52% of patients, who previously experienced anaphylaxis, had never received an epinephrine autoinjector prescription, and 60% did not have an autoinjector currently available. The most common causes of anaphylaxis are foods (such as peanuts), venom from insect stings, and medications. Epinephrine injection is the current standard of treatment intended to reverse the severe manifestation of anaphylaxis, which may include skin rash, throat swelling, respiratory problems, gastrointestinal distress, and loss of consciousness.

About AQST-109
AQST-109 is a polymer matrix-based epinephrine prodrug 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 AQST-109 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.

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 on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome. Our licensees market their products 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 late-stage proprietary product pipeline focused on treating diseases of the central nervous system, or CNS, and an earlier stage pipeline 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 advancement and related timing of AQST-109 through the regulatory and development pipeline and clinical and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials for AQST-109 and our other product candidates; risk of delays in FDA approval of Libervant™ (diazepam) Buccal Film, AQST-109, and our other drug candidates or failure to receive FDA approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are

or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S., and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk in obtaining market access for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings and associated costs, including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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