

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): August 3, 2022

Aquestive Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

001-38599
(Commission File Number)

82-3827296
(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 investor presentations, 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 presentations are attached hereto as Exhibits 99.1 and 99.2, respectively, 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. The investor presentations 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 and 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 9.01 Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Aquestive Therapeutics Corporate Presentation dated August 2022
99.2	Aquestive Therapeutics Q2 2022 Earnings Supplemental Materials dated August 2022

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: August 3, 2022

Aquestive Therapeutics, Inc.

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



Aquestive Therapeutic Corporate Presentation

August 2022

Advancing medicine
Solving problems
Improving lives



Our Path

Proven track record of success

- Technology-based pharmaceutical company
- 5 FDA-approved products
- 10+ years of product sales
- 200+ patents worldwide



Near-term pipeline catalysts

- AQST-109 Epinephrine Sublingual Film
 - First and only orally delivered epinephrine product candidate
 - Median time to peak concentration (T_{max}) of 12 minutes at target 4-minute hold time*, compared to 50 minutes for 0.3mg Intramuscular Injection (IM)
 - Expect End-of-Phase 2 meeting with FDA to occur in 4Q22 and to commence pivotal PK study shortly thereafter
- Libervant™ Buccal Film (diazepam) †
 - PDUFA date of December 23, 2021
 - Ready to launch if granted US market access

Multiple cash-generating opportunities

- Continuous quarterly growth in commercial sales of Sympazan® Oral Film (clobazam)
- Cash flow positive manufacturing business
- Business performance and capital options support commercial operations, potential Libervant launch, and pipeline development



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

†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. Aquestiv has received conditional acceptance of the use of this trade name, which is subject to final FDA review and acceptance.

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



Our Team



Daniel Barber
President, CEO and
Director



Peter Boyd
SVP, Business Process &
Information Technology



Lori J. Braender
General Counsel and
Chief Compliance Officer



Ken Marshall
Chief Commercial Officer



Mark Schobel
Chief Innovation &
Technology Officer



Gary H. Slatko, MD
Chief Medical Officer

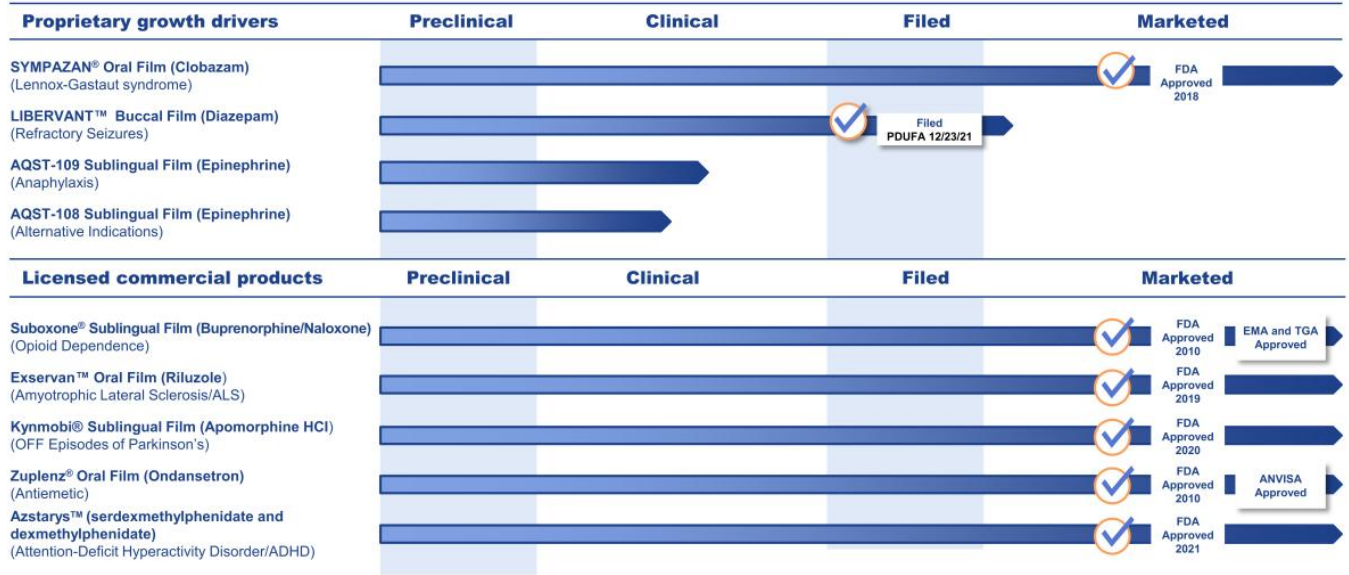


Ernie Toth
Chief Financial Officer



Theresa Wood
SVP, Human Resources

Our Products



AQST-109: Reimagining How to Treat Anaphylaxis

Advancing medicine
Solving problems
Improving lives

Anaphylaxis: A Serious Systemic Hypersensitivity Reaction That is Usually Rapid in Onset And May Be Fatal¹

- As many as **49 million people** in the United States are at chronic risk for acute anaphylactic episodes²

- Lifetime prevalence may be higher than **5%**³

- Chronic allergies cost the United States healthcare system more than **\$18 billion** annually²

- **52% of patients** in a nationwide patient survey who had previously experienced anaphylaxis had never received an epinephrine auto-injector prescription³

- **60% of respondents** in same patient survey did not have an epinephrine auto-injector currently available³

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.

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 years³
 - Fear acquired in childhood appears to persist into adulthood⁴
 - Additionally, some patients (or their caregivers) may be unable to properly inject the medication⁵

- ▶ 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 condition⁸

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.000000000000185 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.

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 phobia¹



Prevent improper administration or suboptimal dosing, including associated adverse events such as injection site necrosis and/or infections²

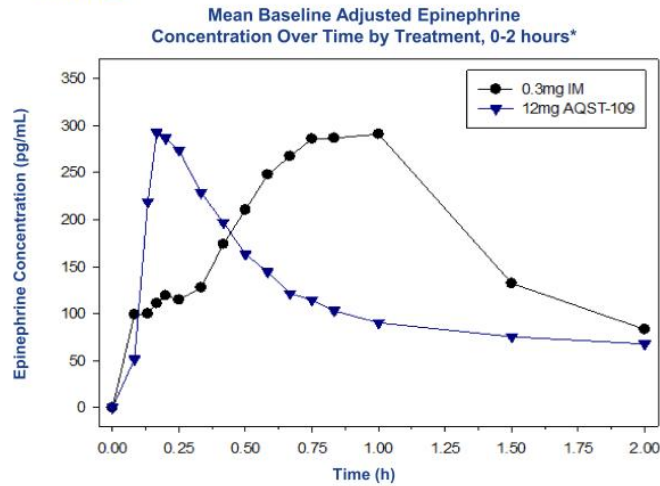


Reduce the likelihood of noncompliance or delayed dosing because the sublingual film is small, portable, and can be administered quickly and easily³

References: 1. Mcleon & Rogers M. *J Adv Nurs*. 2019;75(1):30-42. 2. Libermann P. *Ann Allergy Asthma Immunol*. 2005 Sep;95(3):217-26 3. Fast Track Designation Request. Aquestive Therapeutics, Inc. 2021.

AQST-109: Pharmacokinetic (PK) Values Comparable to Existing 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 (C_{max}) and overall variability (CV%) continued to improve versus Part 1 of EPIPHAST Trial



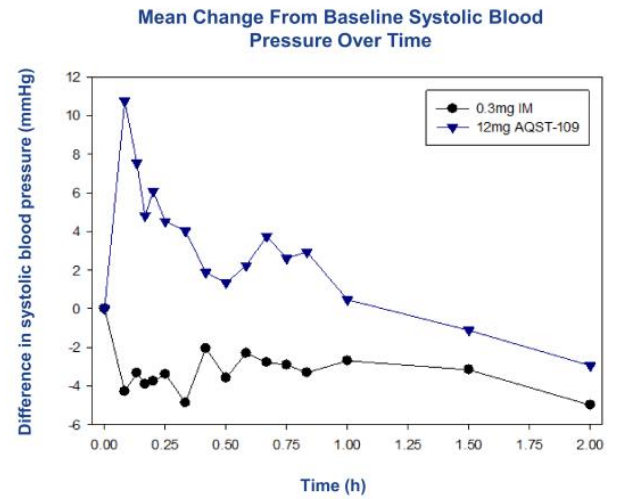
*Represents data from topline results. Figure derived from arithmetic means.

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} .

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

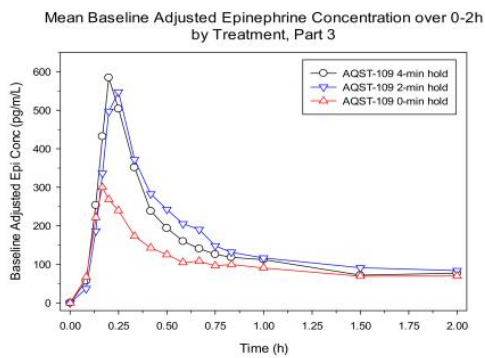
- Administration of epinephrine is known to cause an increase in systolic blood pressure over time
- Quantifying the increase in systolic blood pressure after administration of epinephrine is an important measure in assessing the effectiveness of a delivery system
- AQST-109 demonstrated strong and predictable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



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

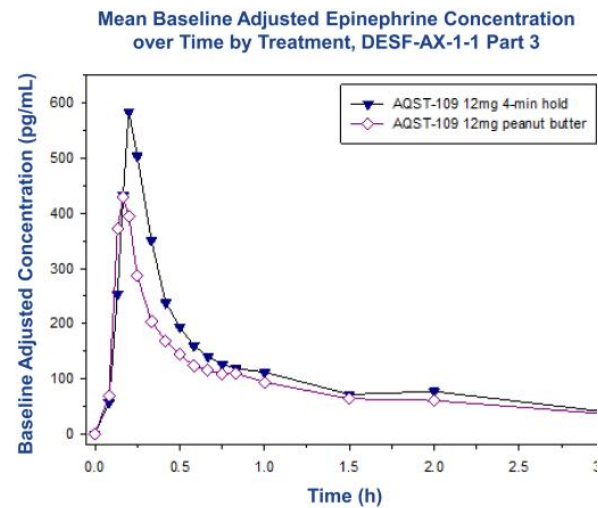
- Median time to reach 100 pg/mL (suggested as threshold for onset of hemodynamic effects) was 8 minutes at target 4-minute hold time and 10 minutes for 0.3mg IM



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 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

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



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 C_{max} and overall AUC
 - T_{max} 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 _{0-10min} (hr*pg/mL)	12.8	2.4
AUC _{0-20min} (hr*pg/mL)	51.2	28.1
AUC _{0-30min} (hr*pg/mL)	79.1	73.2
AUC _{0-t} (hr*pg/mL)	411.5	481.0
T _{max} (minutes)	12	25

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)** for AQST-109 after receiving FDA clearance in February 2022

- Aquestive received **Fast Track Designation for AQST-109** in March 2022

- Three-part **EPIPHAST** study of AQST-109 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

- **Repeat dosing comparative study** of AQST-109 and 0.3 mg epinephrine auto injector **ongoing, to be completed during Q3 2022**

- Expect an **End-of-Phase 2 meeting** with the FDA to occur **in the fourth quarter of 2022** and **commencing the pivotal PK study of AQST-109 shortly thereafter**

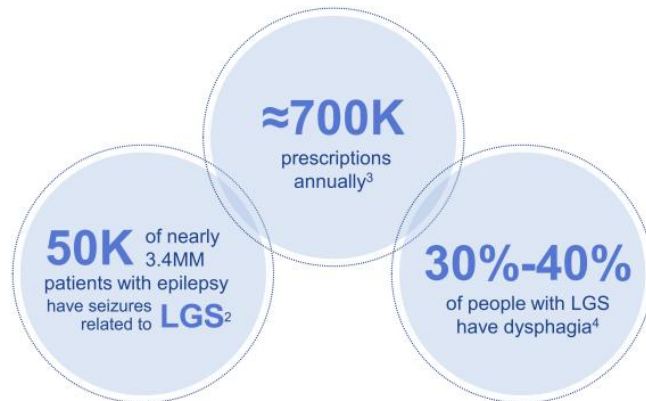
Solving Problems in EPILEPSY

Advancing medicine
Solving problems
Improving lives

Solving Problems in EPILEPSY:

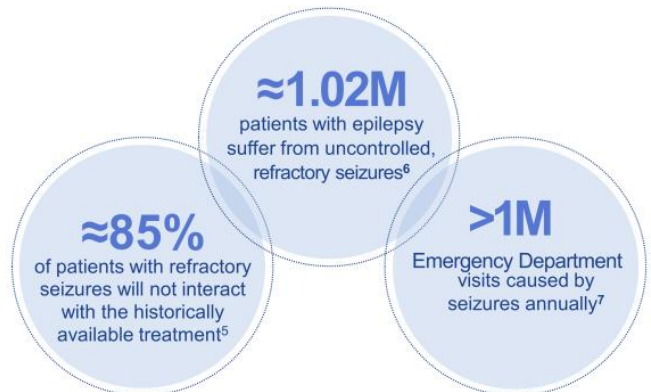
SYMPAZAN® Oral Film (clobazam)

- Commercialized for Lennox-Gastaut syndrome (LGS), a rare, severe form of epilepsy characterized by multiple manifestations of cognitive impairment and developmental delays¹



LIBERVANT™ Buccal Film (diazepam)

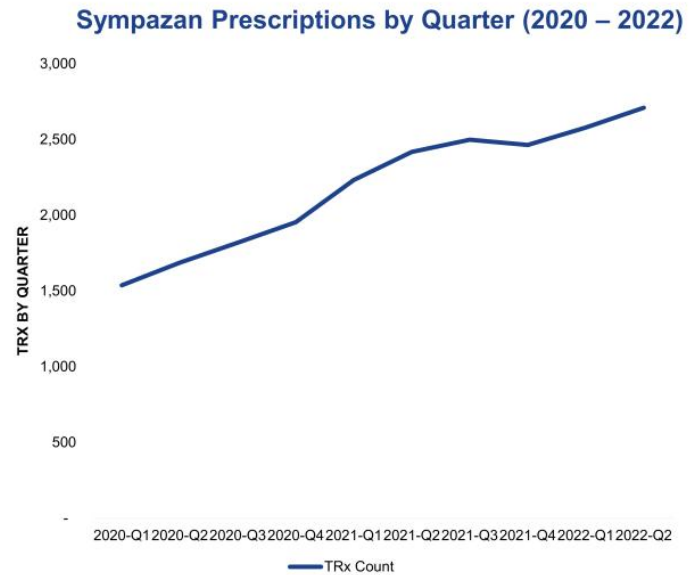
- Under FDA review for management of refractory patients with epilepsy on stable regimens of AEDs who experience seizure clusters



References: 1. van Rijkevoorsel. 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. 6. Internal Aquestiv report: unpublished. 7. 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.

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



LIBERVANT: NDA Resubmission



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.

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

- \$8M registered direct offering closed on June 8, 2022
- Available shelf registration, ATM and Common Stock Purchase Agreement

2022 Inflection Points

Continue the expansion of our epilepsy franchise

- Launch of **LIBERVANT** if approved by the FDA for U.S. market access
- Continue to grow **SYMPAZAN** prescriptions

Advance our novel epinephrine delivery platform

- **AQST-109**
 - **Q2:** Completed EPIPHAST study; initiated EPIPHAST II trial of repeat dosing comparative study AQST-109 & 0.3 mg EpiPen®
 - **Q3:** Expect to complete EPIPHAST II trial
 - **Q4:** Expect an End-of-Phase 2 meeting with FDA to occur and commence pivotal PK study shortly thereafter
- **AQST-108**
 - Identify additional product opportunities

Continue to strengthen the capital position of the Company

- Continue strong business performance to generate cash
- Appropriate use of ATM facility and Common Stock Purchase Agreement
- Utilize shelf registration under favorable conditions

Thank You

Advancing medicine
Solving problems
Improving lives



Aquestive Therapeutics Q2 2022 Earnings Supplemental Materials

August 2022

Advancing medicine
Solving problems
Improving lives



Forward-Looking Statement

This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the use of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the advancement of Libervant™, AQST-109 and other product candidates through the regulatory and development pipeline; and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of 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 and clinical trials and plans for AQST-109 and our other drug candidates; risk of delays in FDA approval of our drug candidate Libervant, AQST-109, and our other drug candidates or failure to receive approval; ability to address concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of loss of our orphan drug approval and failure to obtain resulting drug exclusivity products; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtain 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 can in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, in access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy financial and other debt covenants and of any default thereof; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the 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 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 and 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 safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters and associated costs; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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.

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 approval.

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

Q2 2022 Earnings: Key Messages

Epinephrine Sublingual Film

- ❖ Completed EPIPHAST trial that demonstrated ability to provide rapid and significant epinephrine exposure under a variety of real-world conditions
- ❖ Initiated EPIPHAST II trial, comparing AQST-109 to epinephrine 0.3mg IM injection (repeat dose) and AQST-109 to EpiPen® 0.3mg (single dose)
- ❖ Expect End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to occur in fourth quarter 2022 and commence definitive pivotal pharmacokinetic (PK) studies shortly thereafter

LIBERVANT™ (diazepam) buccal film

- ❖ Continued to engage with FDA on the progress and timing of the orphan drug review of the Libervant[™] (diazepam buccal film) New Drug Application (NDA)

2022 Outlook

- ❖ Improves full-year revenue and earnings guidance

AQST 109: Epinephrine Sublingual Film

Advancing medicine
Solving problems
Improving lives

AQST-109: Epinephrine Sublingual Film

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 phobia¹



Prevent improper administration or suboptimal dosing, including associated adverse events such as injection site necrosis and/or infections²

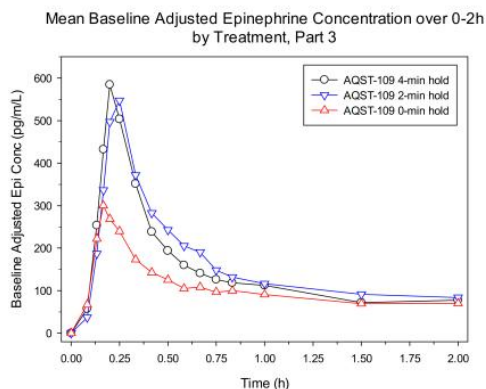


Reduce the likelihood of noncompliance or delayed dosing because the sublingual film is small, portable, and can be administered quickly and easily³

References: 1. Mcleon & Rogers M. *J Adv Nurs*. 2019;75(1):30-42. 2. Libermann P. *Ann Allergy Asthma Immunol*. 2005 Sep;95(3):217-26 3. Fast Track Designation Request. Aquestiv Therapeutics, Inc. 2021.

AQST-109: Rapid Absorption With Favorable Pharmacokinetic (PK) Per Initial Data From Part 3 of EIPHAST Trial

- Medium time to peak concentration (T_{max}) 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

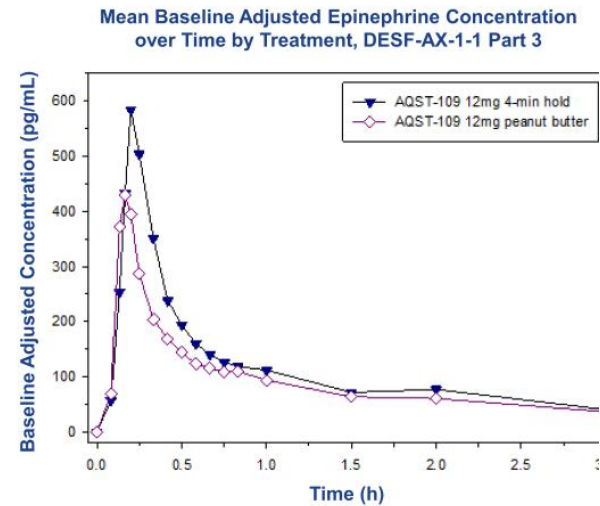


*Hold time is holding the film under the tongue and limiting swallowing for different periods of time.

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 C _{max} (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 T _{max} (minutes)	12	15	15	15	50

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



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

- Even if film is swallowed immediately with water, substantial epinephrine absorption and exposure still occurs
 - Comparable C_{max} and overall AUC
 - A T_{max} of 25min 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 _{0-10min} (hr*pg/mL)	12.8	2.4
AUC _{0-20min} (hr*pg/mL)	51.2	28.1
AUC _{0-30min} (hr*pg/mL)	79.1	73.2
AUC _{0-t} (hr*pg/mL)	411.5	481.0
Median T _{max} (minutes)	12	25

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

- **Repeat dosing comparative study** of AQST-109 and 0.3 mg epinephrine auto injector **ongoing, to be completed during Q3 2022**

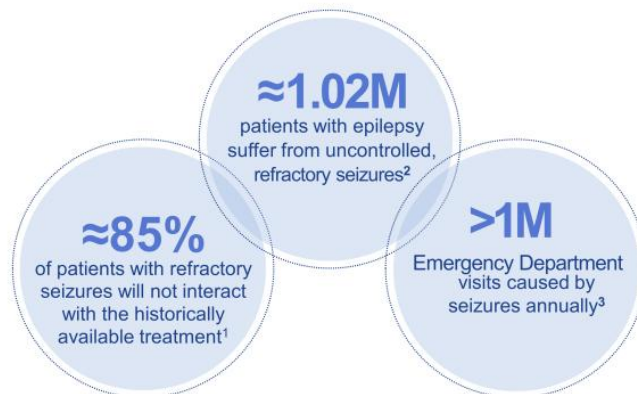
- Expect an **End-of-Phase 2 meeting** with the FDA to occur in the **fourth quarter of 2022** and **commencing the pivotal PK study shortly thereafter**

LIBERVANT™ (diazepam) buccal film

Advancing medicine
Solving problems
Improving lives

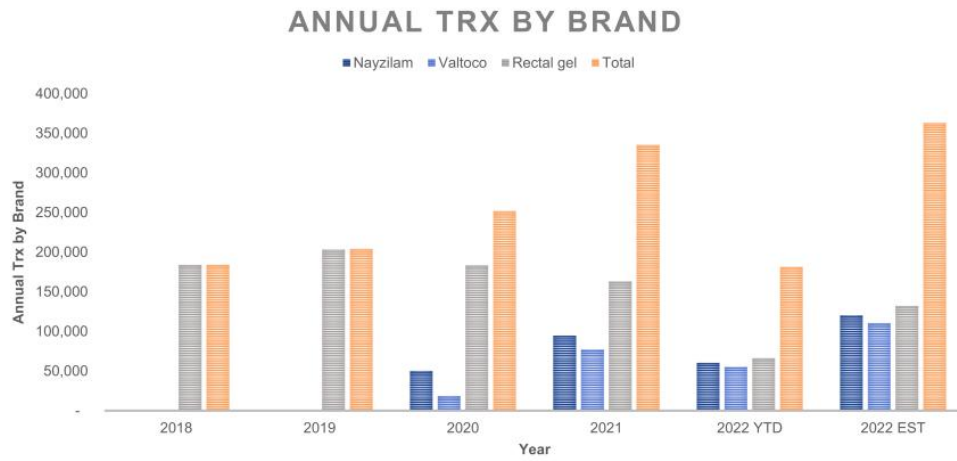
LIBERVANT™ (diazepam) Buccal Film

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



References: 1. Triangle Insights Group. Synthesis of Epilepsy (ARS) Primary Research, 2017. Internal Aquestive report: unpublished. 2. 2017. Centers for Disease Control and Prevention, <https://www.cdc.gov/media/releases/2017/p0810-epilepsy-prevalence.html>. 3. 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.

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.

LIBERVANT: NDA Resubmission



"Thank you for your message and your patience as our Office actively works through the orphan-drug exclusivity issues...we are making progress and expect to respond in a reasonable timeframe."

Quote from a communication from the Office of Orphan Products Development of the FDA -- July 2022.

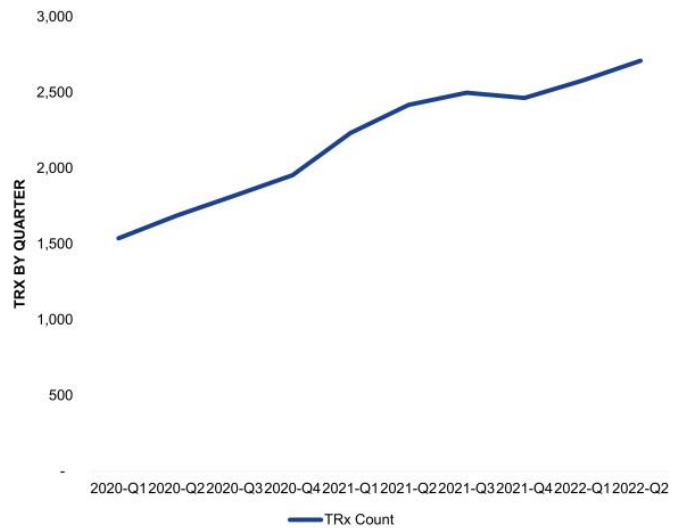
Commercial Operations

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Commercial Operations

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

Sympazan Prescriptions by Quarter (2020 – 2022)



Manufacturing Operations

- PharmFilm™ manufacturing volume increased approximately 11.5% 1H2022 compared to 1H2021
- The commercial Sympazan operations and manufacturing operations of the business continue to provide positive cash flow to the Company

PharmFilm Volume



	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022
Doses (millions)	41,520	43,203	33,629	27,890	30,916	49,182	47,509	36,413	42,182	47,125

2022 Outlook

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2022 Outlook

2022 Outlook

- 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

Thank You

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