UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 15, 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. This information may be amended or updated at any time and from time to time through another Current Report on Form 8-K, a later company filing or other means. A copy of the Company's investor presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The investor presentation is available on the Company's website located at www.aquestive.com, although the Company reserves the right to discontinue that availability at any time.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the 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 June 15, 2022, the Company issued a press release providing a business update in connection with the positive topline data from the first three arms of Part 3 of the EPIPHAST study for the Company's AQST-109 epinephrine oral film product candidate in clinical development. A copy of the Company's press release is attached hereto as Exhibit 99.2 and incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor Presentation
99.2	Press Release dated June 15, 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: June 15, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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


Aquestive
Aquestive Therapeutics
Corporate Presentation
June 2022
Advancing medicines.
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 negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the advancement of Libervant™, 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 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 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 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 approval 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 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 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 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, including 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 all 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 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, 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.

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.

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 Oral Film
  - First and only orally delivered epinephrine product candidate
  - Median time to peak concentration (T_{max}) of 15 minutes
  - On track to request End-of-Phase 2 meeting in 4Q22 and commence pivotal PK study thereafter
- Libervant™ Buccal Film (diazepam)*
  - NDA filed on June 23, 2021
  - Ready to launch if granted US market access

Multiple cash-generating opportunities

- 13+ quarters of continuous 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

*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.

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

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

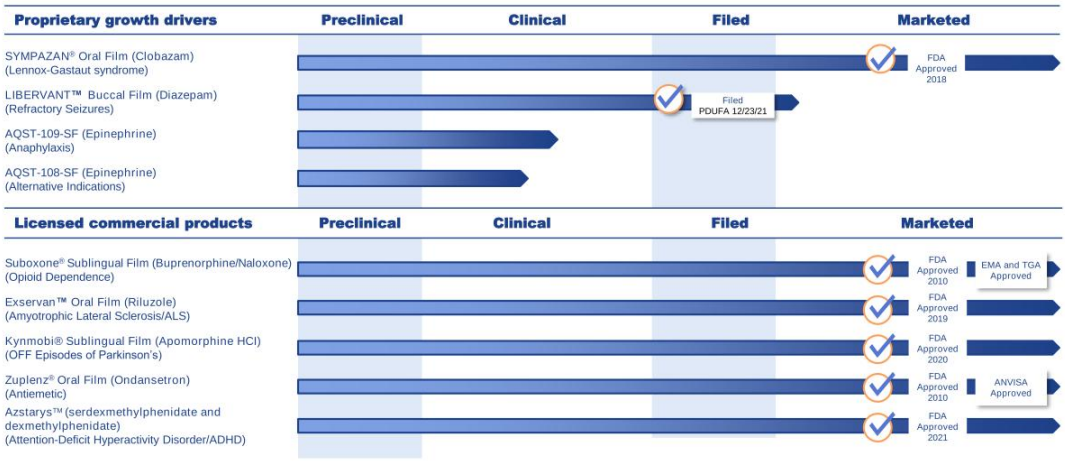
Mark Schobel
Chief Innovation & Technology Officer

Gary H. Slatko, MD
Chief Medical Officer

Ernie Toth
Chief Financial Officer

Theresa Wood
SVP, Human Resources

Our Products



Aquestive
Advancing medicines.
Solving problems.
Improving lives.

AQST-109: Reimagining How to Treat Anaphylaxis

Advancing medicines.
Solving problems.
Improving lives.

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]
- Chronic allergies cost the United States healthcare system more than $18 billion annually[2]
- **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.

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. Curr 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.

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[2,3]

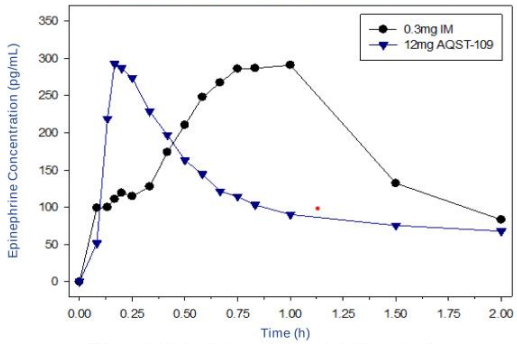
Reduce the likelihood of noncompliance or delayed dosing because the sublingual film is small, portable, and can be administered quickly and easily[3]

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

AQST-109: Pharmacokinetic 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 (Cmax) and overall variability (CV%) continued to improve versus Part 1

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



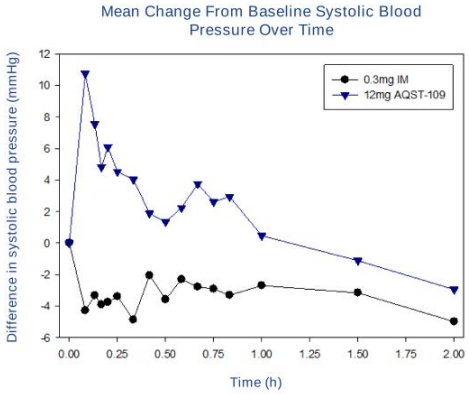
*Represents data from topline results. Figure derived from arithmetic means.

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}.

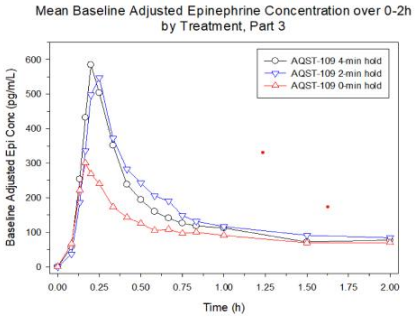
AQST-109: Pharmacodynamic (PD) Values Compared Favorably to Epinephrine Auto-injectors in Part 2 of EPIPHAST

- 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 IM
- AUC within clinically relevant periods of 10, 20 & 30 minutes at target 4-minute hold time compared to 0.3mg IM



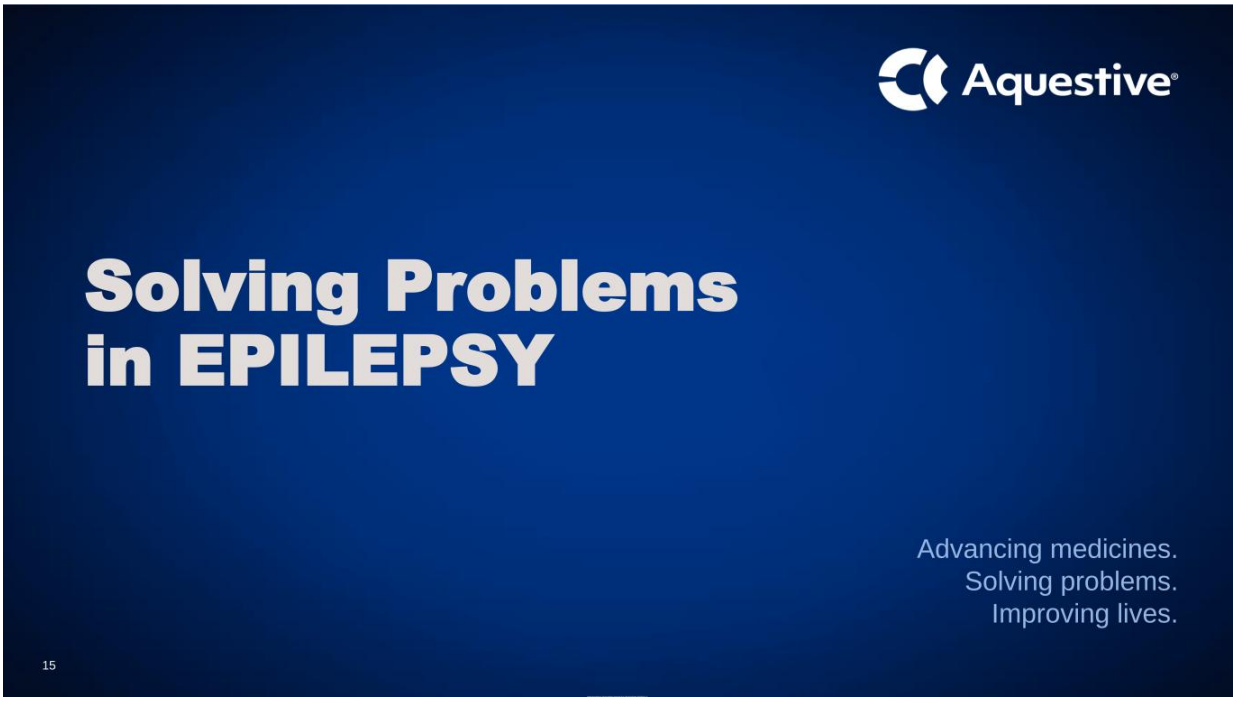
*Hold time is holding the film under the tongue and limiting swallowing for different periods of time

- 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)	Epinephrine IM Injection 0.3 mg (from Part 2) (N=48 doses)
Arithmetic Mean Cmax (pg/mL)	678.4	663.9	359.8	426.1	396.7
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: Development Steps

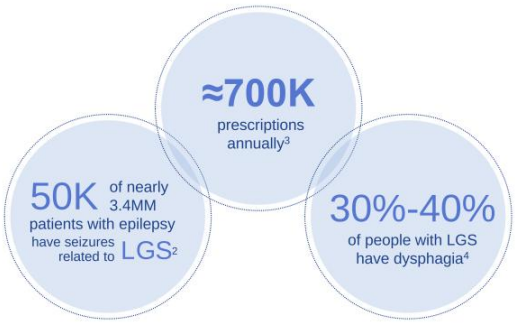
- FDA confirmed that the **505(b)2 approval path is acceptable for AQST-109**
- **Aquestive opened its Investigational New Drug** (IND) after receiving FDA clearance in February 2022
- Aquestive received **Fast Track Designation for AQST-109** in March 2022
- Part 3 of AQST-109 EPIPHAST study commenced in April 2022; **EPIPHAST study completion expected by the end of Q2 2022**
  - The purpose of Part 3 is to continue to study the administration of the film under a variety of conditions and further characterize its pharmacokinetics, pharmacodynamics, and safety
- **Repeat dosing comparative study** of AQST-109 and 0.3 mg epinephrine auto injector **to be conducted during Q3 2022**
- Anticipate conducting an **End-of-Phase 2 meeting** with the FDA and **commencing the pivotal PK study in the second half of 2022**


Aquestive
Solving Problems
in EPILEPSY
Advancing medicines.
Solving problems.
Improving lives.
15

Solving Problems in EPILEPSY:

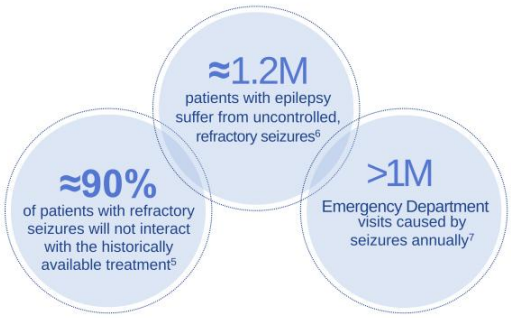
SYMPAZAN® Oral Film (clobazam)

- 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

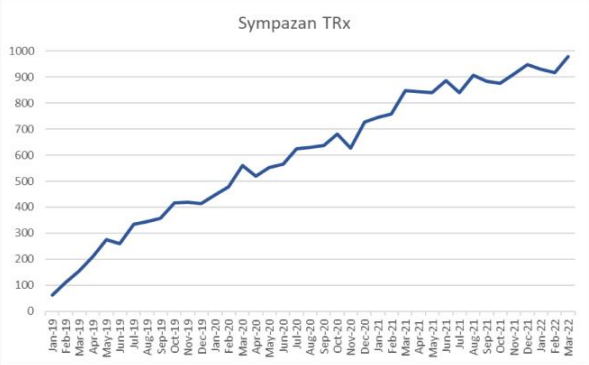


Aquestive
Advancing medicines. Solving problems. Improving lives.

Continued Expansion of Epilepsy Franchise

SYMPAZAN: Sustained Script Growth for Over 13 Quarters

- Growing prescriber base: over 35% penetration into the focused group of prescribers, with ~80% writing multiple scripts
- Launched as a precursor and compliment to Libervant
- ~90% of Sympazan targets are Libervant targets
- Solid 2-product sales force efficiency



LIBERVANT: NDA Resubmission

"...[FDA] is actively working on the orphan-drug exclusivity issues related to your NDA. OOPD is also diligently coordinating with the relevant FDA stakeholders in considering each of the arguments raised in your communications. [The Agency] assure[s] you that these issues are top-of-mind and have not *fallen off the Agency's radar. Although [we] cannot commit to a* precise date for providing a response, [we] can answer that we are making all efforts to respond in a reasonable timeframe.*"*

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

Aquestive
Advancing medicines.
Solving problems.
Improving lives.

Financial Summary (NASDAQ: AQST)

Full Year 2022 Guidance (as of May 3, 2022)

- Total revenues of approximately $42 to $47 million
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
- Non-GAAP adjusted EBITDA loss of $51 to $58 million

Capital

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

2022 Inflexion Points

Continue the expansion of our epilepsy franchise

- Launch of **LIBERVANT** if granted U.S. market access
- Continue to grow **SYMPAZAN** prescriptions

Advance our novel epinephrine delivery platform

- **AQST-109**
- **Q2/Q3:** EPIPHAST study completion
- **Q3:** Repeat dosing comparative study AQST-109 & 0.3 mg EpiPen
- **H2:** Request End-of-Phase 2 meeting with FDA
- **AQST-108**
  - Identify additional product opportunities

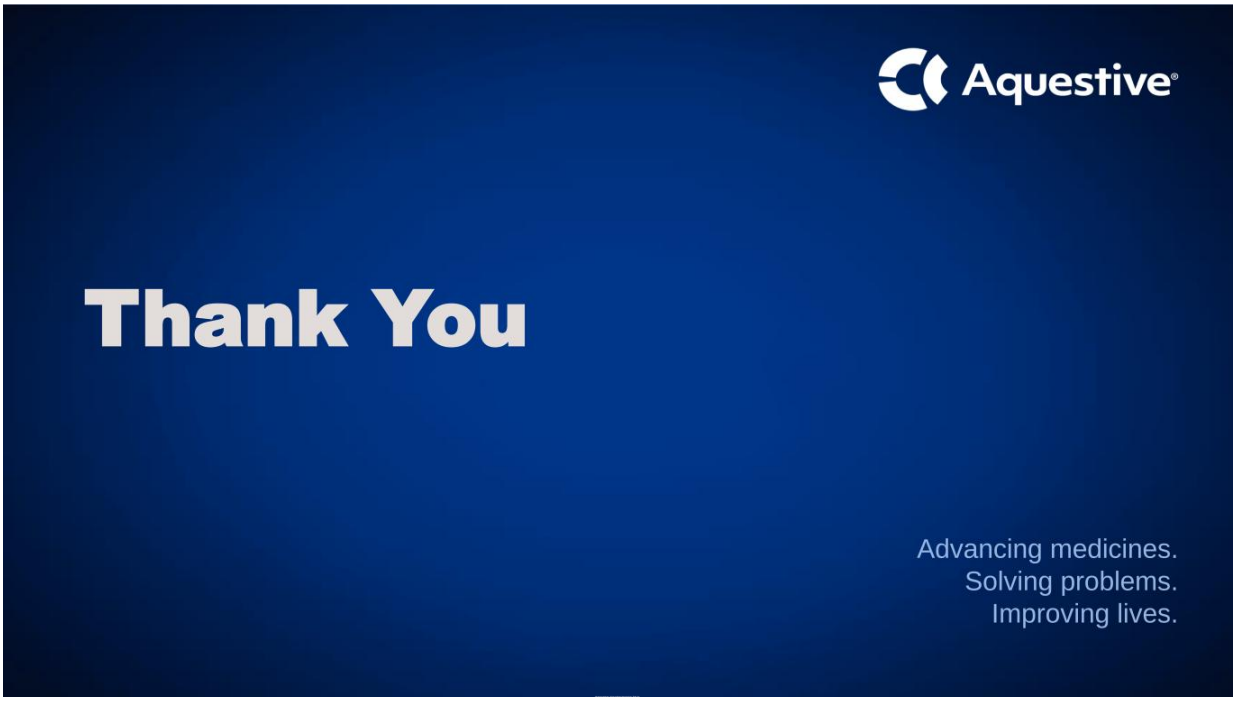
Continue to strengthen the capital position of the Company

- Continue strong business performance to generate cash
- Access available funds on potential Libervant approval and U.S. market access
- Appropriate use of ATM facility and Common Stock Purchase agreement
- Utilize shelf registration under favorable conditions

References

CORPORATE INFORMATION , PHARMFILM® TECHNOLOGY, SYMPAZAN®, LIBERVANT™ AND EPINEPHRINE DATA

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 S. 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. Laxer KD, Trinka E, Hirsch LJ, et al. The consequences of refractory epilepsy and its treatment. Epilepsy Behav. 2014;37:59-70.
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.
8. Simons F.E., Clark S., Camargo C.A. Jr: Anaphylaxis in the community: learning from the survivors. J Allergy Clin Immunol 2009, 124 (2): 301–306
9. Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. J Allergy Clin Immunol. 2010;126(6 Suppl):S1- S58.
10. Song TT, Lieberman P. Epinephrine in anaphylaxis: doubt no more. Current opinion in allergy and clinical immunology. 2015;15(4):323-8.
11. Shaker et al. (2020). Anaphylaxis—a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis. J Allergy & Clin Immunology, Vol 143, Num 4
12. Yu, J., Lin,R. The Epidemiology of Anaphylaxis. Clin Rev Allergy Immunol. 2018 Jun;54(3):366-374.doi: 10.1007/s12016-015-8503-x.
13. Borish, L., Danoff, T., Ma, L. VOLUME 133, ISSUE 2, SUPPLEMENT . doi.org/10.1016/j.jaci.2013.12.834


Aquestive
Thank You
Advancing medicines.
Solving problems.
Improving lives.

Aquestive Therapeutics Reports Positive Initial Topline Data from Part 3 of EPIPHAST Trial Evaluating AQST-109 Epinephrine Oral Film

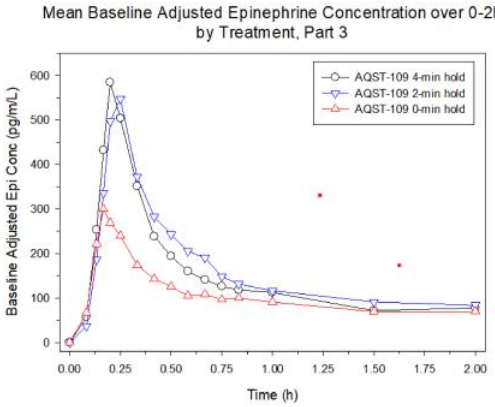
- *AQST-109 is the first and only orally delivered epinephrine product candidate in clinical development*
- *Fastest median time to maximum concentration (Tmax) in studies to date at 12 minutes*
- *Study continues to show AQST-109 is safe and well tolerated*
- *Head-to-head comparison study to EpiPen® scheduled to commence in third quarter 2022*
- *On track to request End-of-Phase 2 meeting with FDA in fourth quarter 2022 and thereafter to commence pivotal PK study*
- *Remaining data from Part 3 expected to be reported in early third quarter 2022*

WARREN, N.J., June 15, 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, today announced positive topline results from the first three arms of Part 3 of the EPIPHAST study for its AQST-109 epinephrine oral film.

The purpose of Part 3 was to continue to study the administration of the film under a variety of conditions and further characterize its pharmacokinetics, pharmacodynamics, and safety. The first three arms were designed to assess the impact of holding the film under the tongue and limiting swallowing for different periods of time. These time periods were (1) the target holding time of 4 minutes, (2) a 50% reduction in hold time to 2 minutes and (3) no hold time, or 0 minutes. The remaining two arms of the study for which data are not yet available include (4) dosing the film 2 minutes after eating a peanut butter sandwich and (5) swallowing the film immediately with 240 mL of water.

In the first three arms of Part 3, AQST-109 12 mg continued to show rapid absorption with favorable pharmacokinetics across a variety of key metrics at the target hold time as follows:

- The median time to maximum concentration (Tmax) was observed to be 12 minutes for AQST-109 compared to 50 minutes for the epinephrine 0.3mg intra-muscular (IM) injection from Part 2 of the EPIPHAST study.
- The Area Under the Curve (AUC) within the clinically relevant periods of 10 minutes, 20 minutes, and 30 minutes in each of three arms were comparable for both AQST-109 and the 0.3mg IM injection.
- The median time to reach 100 pg/mL, which has been suggested to be the threshold for the onset of hemodynamic effects, was 8 minutes for AQST-109 and 10 minutes for the 0.3mg IM injection as reported in Part 2.
- Part 3 demonstrated maximum plasma concentration (Cmax) values that were consistent with the Part 2 findings, 0.3mg IM Injection, as well as those previously reported for approved injectable epinephrine devices such as EpiPen®.



Study Results	AQST-109 12mg 4-minute hold time (Target) (N=22 doses)	AQST-109 12mg 2-minute hold time (N=23 doses)	AQST-109 12mg 0-minute hold time (N=21 doses)	AQST-109 12 mg (from Part 2) (N=48 doses)	Epinephrine IM Injection 0.3 mg (from Part 2) (N=48 doses)
Arithmetic Mean Cmax (pg/mL)	678.4	663.9	359.8	426.1	396.7
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

“The latest study results from first three arms of Part 3 of the EPIPHAST study confirm, once again, our ability to deliver significant levels of epinephrine through the oral mucosa. We have achieved a Tmax of 15 minutes or faster in multiple studies, including last year’s Proof-of-Concept Study and now in Parts 1, 2, and 3 of the EPIPHAST study,” said Dan Barber, Chief Executive Officer of Aquestive. “We are anxious to share this data with the FDA following the completion of the upcoming head-to-head study with EpiPen. We continue to believe AQST-109 has the potential to transform how patients and caregivers treat anaphylaxis.”

"These results build on prior Phase 1 trials showing the promise of AQST-109 - as a sublingually administered medicine for Type I allergic reactions, including anaphylaxis - to improve upon the current standard of care, namely epinephrine auto-injectors," said David Golden, M.D., Allergy Division Chief at Medstar Franklin Square Hospital in Baltimore. "The data from this trial demonstrate that AQST-109 has the potential to fill an unmet medical need by providing an epinephrine treatment that patients can more easily carry and more quickly administer in a life-threatening emergency situation. I look forward to the next phase of clinical trials and the continued development of AQST-109."

EPIPHAST is a randomized, open-label, three-part adaptive design, crossover study in healthy adult subjects comparing the pharmacokinetics and pharmacodynamics of epinephrine delivered via Aquestive's AQST-109 oral film compared to intramuscular injection of epinephrine. The study is being conducted pursuant to clearance from Health Canada.

Aquestive received a written response from the U.S. Food and Drug Administration (FDA) in December 2021 to its Pre-Investigational New Drug Application (IND) meeting submission confirming that the development of AQST-109 for the treatment of anaphylaxis under the 505(b)(2) approval pathway is acceptable. Aquestive opened the IND for AQST-109 after receiving FDA clearance in February 2022. AQST-109 met the regulatory criteria for Fast Track designation as announced in March 2022.

Aquestive plans to conduct a repeat dosing comparative study of AQST-109 and 0.3 mg EpiPen during the third quarter 2022. This data, along with the complete EPIPHAST study data, will be the basis for the End-of-Phase 2 meeting with the FDA that the Company plans to request in the fourth quarter 2022.

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 acute anaphylactic episodes. Lifetime prevalence may be higher than 5%. Chronic allergic illness costs the US healthcare system more than $18 billion annually. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years. 52% of patients, who had previously experienced anaphylaxis, had never received an epinephrine autoinjector prescription, and 60% did not have an autoinjector currently available. The most common causes of reactions that can include anaphylaxis are medications, foods (such as peanuts), and venom from insect stings. Epinephrine injection is the current standard of treatment intended to reverse the potentially severe manifestation of anaphylaxis, which may include red 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 Therapeutics
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 AQST-109, Libervant™ (diazepam) Buccal Film 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.

Investor Inquiries
ICR Westwicke
Stephanie Carrington
Stephanie.carrington@westwicke.com
646-277-1282