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): November 2, 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 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.

Exhibit Number	Description
99.1	Aquestive Therapeutics Corporate Presentation dated November 2022
99.2	Aquestive Therapeutics Q3 2022 Earnings Supplemental Materials dated November 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: November 2, 2022

Aquestive Therapeutics, Inc.

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


Aquestive
Aquestive Therapeutics
Corporate Presentation
November 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, clinical advancement and related timing of AQST-109 through the regulatory and development pipeline; the potential for AQST-109 as the first orally administered epinephrine product candidate for the treatment of anaphylaxis; statements regarding the approval of Libervant by the FDA for U.S. market access and timing of launch if approved by the FDA for U.S. market access; profitability of the Company's manufacturing operations and the 2022 financial outlook of the Company; 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 AQST-109 and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA "clinical superiority" of Libervant within the meaning of the FDA regulations relative to the FDA-approved diazepam nasal spray product of another company, including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved product 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 product, 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 or may be 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, securities, business torts, investigative and antitrust litigation matters and associated costs, including that the ruling in the Company's favor in the Suboxone® states' antitrust litigation case could be appealed by the plaintiffs in the case and that, thereafter, the Company could be required to continue its defense of the claims asserted in that case and that said plaintiffs could be entitled to judgment against the Company; risk of 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 acceptance.

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

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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

Cassie Jung
Vice President, Operations and Product Management

Ken Marshall
Chief Commercial Officer

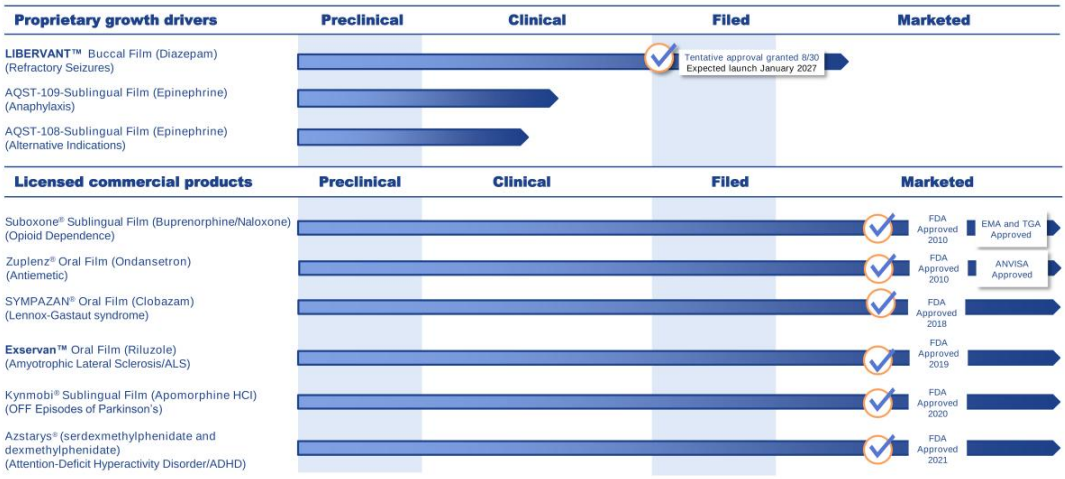
Mark Schobel
Chief Innovation & Technology Officer

Ernie Toth
Chief Financial Officer

Ken Truitt
Chief Medical Officer

Steve Wargacki
Vice President, Research and Development

Product Portfolio



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Improving lives.

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

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

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]

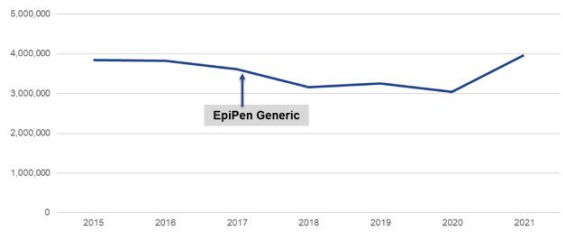
Prevent improper administration or suboptimal dosing, including associated adverse events such as injection site necrosis and/or infections[2]

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

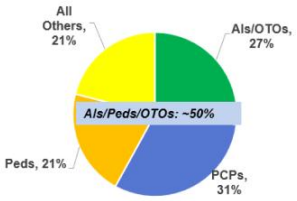
References: 1. Mcleon & Rogers M. J Adv Nurs. 2019;75(1):30-42. 2. Cardona V, et al. World Allergy Org J. 2020;13:13100472. 3. Rachid et al., (2020): Pharmaceutics. 2018;10(1):24

AQST-109: Significant & Addressable Market Opportunity

Total Epinephrine Auto-Injector Market **Rx's:** 2015-2021 (US)



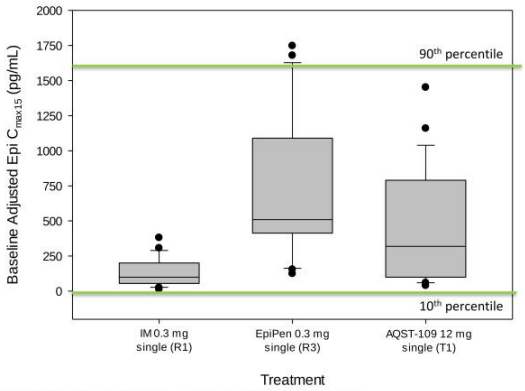
Allergists, Pediatricians, and Otolaryngologists (OTOs) prescribe roughly 1/2 of all EAI **Rx's**

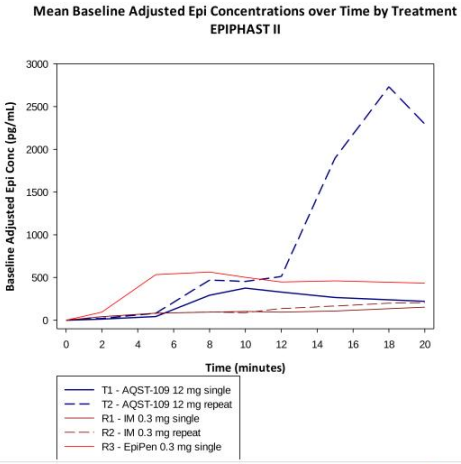


- Large portion of annual Rx's are written by a target audience addressable by Aquestive (i.e., high-decile Allergists, OTOs and Pediatricians)
- Further, many of the Rx's written by PCP's/Others, are "downstream" refill prescriptions, for patients that were originally seen and prescribed an epinephrine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

EPIPHAST II: Topline Results

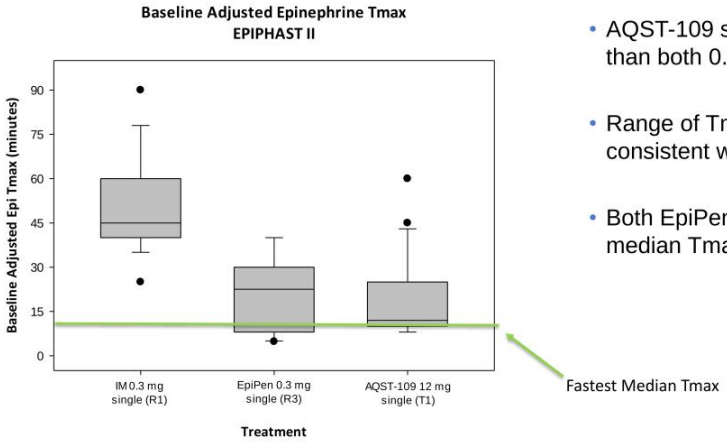
AQST-109 maximum plasma concentration (Cmax) values within the timeframe critical to abate the cascade of anaphylaxis are comparable to and well bracketed by the 0.3mg intramuscular injections (IM) and the EpiPen®





Represents data from top-line results. Geometric means presented for Cmax.
EPIPHAST II study was conducted with a 4-minute administration hold time. Administration instructions for future studies may vary.

EPIPHAST II: Time to Maximum Concentration (Tmax)



- AQST-109 showed a shorter median Tmax than both 0.3 mg IM and 0.3 mg EpiPen
- Range of Tmax values across study is consistent with EpiPen
- Both EpiPen and AQST-109 provide faster median Tmax values than 0.3 mg IM

EPIPHAST II: Trial Summary

AQST-109 compared to EpiPen 0.3mg (single dose)

- Confirmation of 12-minute median Tmax
- Faster observed median Tmax than either EpiPen (22 minutes) or 0.3mg IM injection (45 minutes)
- Safety profile in line with previous studies – no SAE's

AQST-109 compared to epi 0.3mg IM injection (repeat dose)

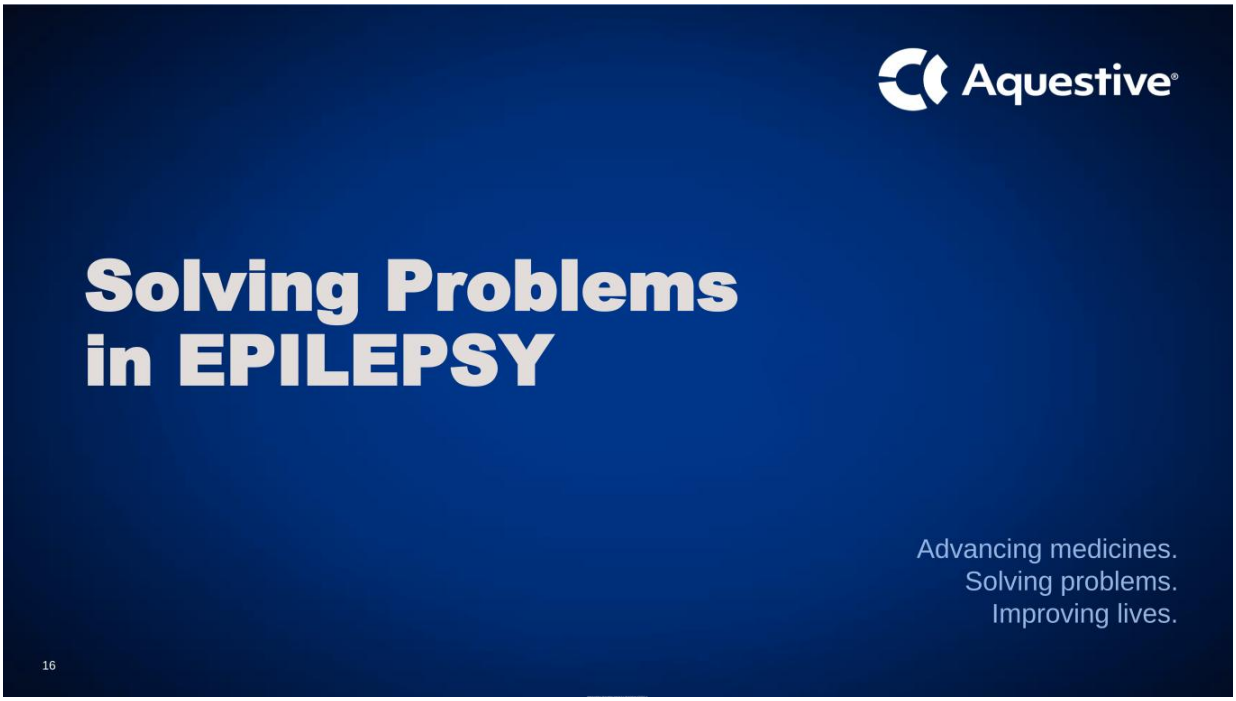
- Demonstrated successful absorption of a second dose of AQST-109 in all subjects
- Second dose had an observed median Tmax of 18 minutes (8 minutes after second dose administration)
- No severe or serious safety or tolerability events were reported

Regulatory Pathway

- End-of-Phase 2 meeting with FDA Division of Pulmonology, Allergy, and Critical Care scheduled during fourth quarter 2022
- Anticipate FDA meeting minutes before the end of the year

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
- **Positive topline data from repeat dosing comparative study** of AQST-109 and 0.3 mg epinephrine auto injector was announced September 27, 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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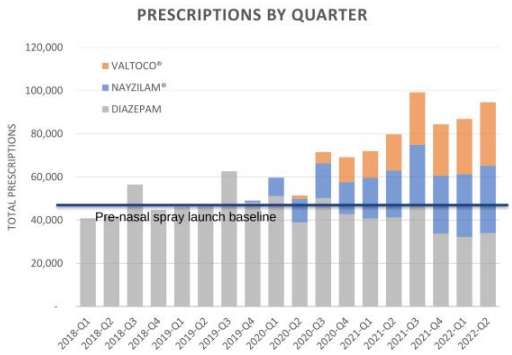
Libervant Path to Launch

Potential Path Forward

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

Seizure Cluster Acute Rescue Market



A significant unmet need exists for additional delivery options, which represents a majority of the diazepam rescue market.[1]

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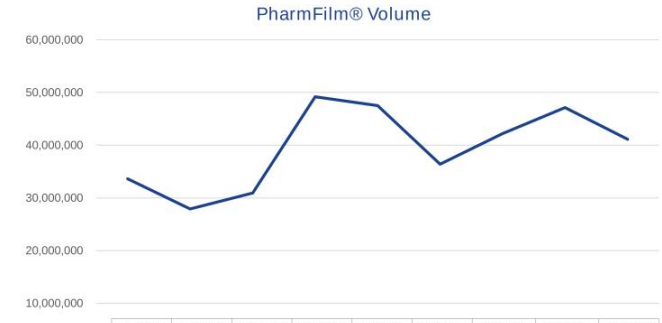
Manufacturing Operations



	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022
Doses (millions)	33,629	27,890	30,916	49,182	47,509	36,413	42,182	47,125	41,097

Manufacturing operations continues to meet the Company's expectations and provides positive cash flow to the Company.

2022 Outlook

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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 EBITDA loss of approximately $37 to $43 million

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

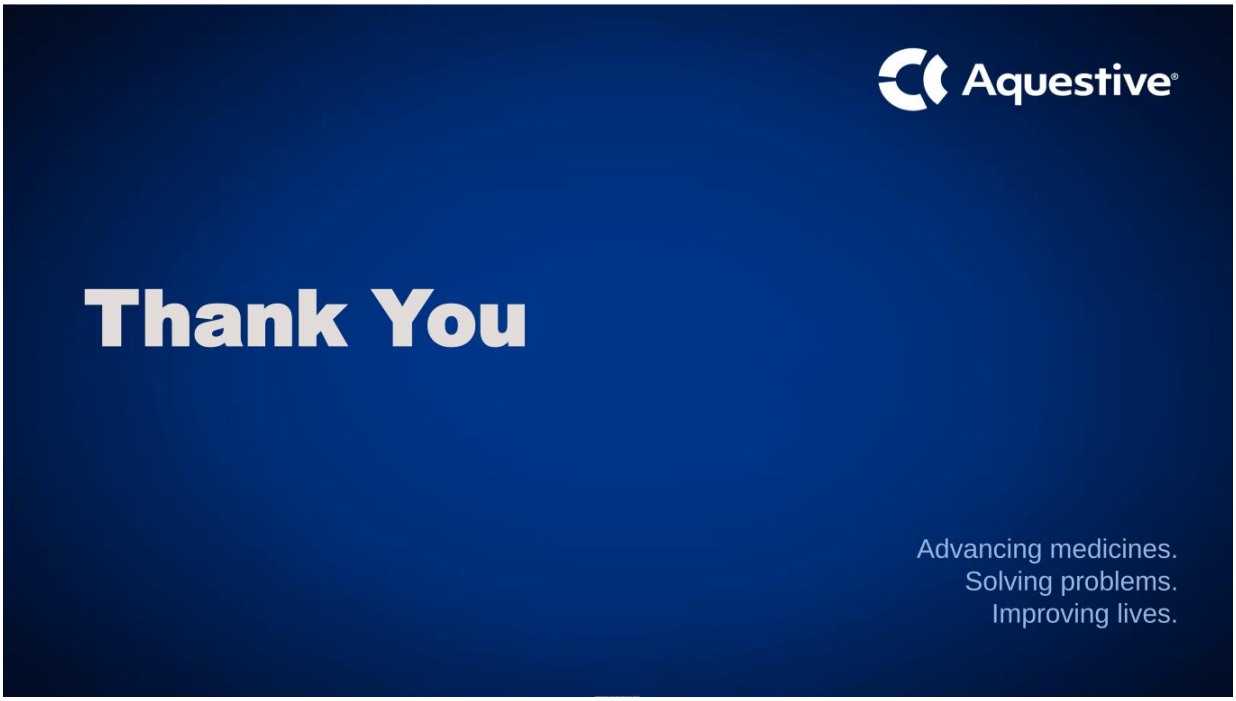
- **Q2:** Completed EPIPHAST trial
- **Q3:** Completed EPHIPHAST II trial
- **Q4:** End-of-Phase 2 meeting with FDA planned in Q4 and commence pivotal PK study thereafter

AQST-108

- Identify additional product opportunities

Identifying cash-generating opportunities

- Continue strong business performance to generate cash
- Appropriate use of ATM facility
- Utilize shelf registration under favorable conditions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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.

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.

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.

Q3 2022 Earnings: Key Messages

AQST 109 Epinephrine Sublingual Film

- Reported positive results from EPIPHAST II Trial comparing AQST-109 to EpiPen® 0.3mg (single dose) and AQST-109 to epi 0.3mg intramuscular (IM) injection (repeat dose)
- Obtained positive written feedback from FDA for the Company's initial End-of-Phase 2 (EoP2) meeting request to discuss Chemistry, Manufacturing, and Controls (CMC)
- EoP2 meeting with the FDA scheduled for the fourth quarter 2022

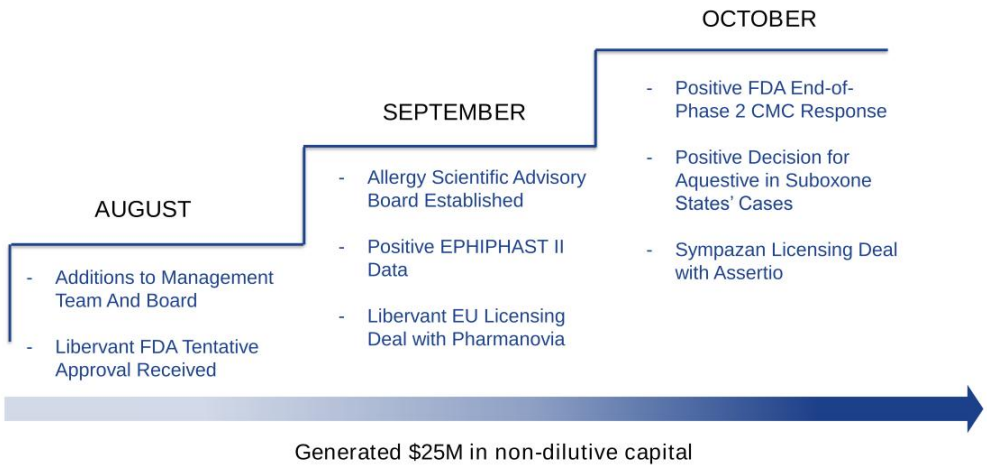
Generated over $25 million in near-term cash through multiple transactions

- Out-licensed Sympazan® (clobazam) Oral Film to Assertio Pharmaceuticals for $15 million (upfront and near-term milestones)
- Out-licensed Libervant™ to Pharmanovia for distribution in Europe, UK, Switzerland and Middle East and North Africa for $3.5 million upfront
- Received $7.0 million upfront payment from Haisco for Exservan (riluzole) Oral Film for distribution in China

LIBERVANT™ (diazepam) buccal film

- Received tentative approval of Libervant™ with expected U.S. market access in 2027
- Outlined strategic decision to prioritization of out-licensing opportunity for Libervant

Building Momentum Over the Last 90 Days….



Generated $25M in non-dilutive capital

AQST 109: Epinephrine Sublingual Film

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AQST-109: Epinephrine Sublingual Film

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.

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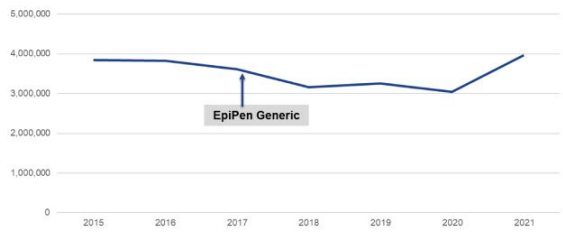
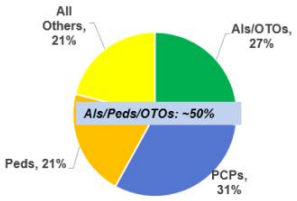
AQST-109: Significant & Addressable Market Opportunity

Total Epinephrine Auto-Injector Market **Rx's:** 2015-2021 (US)



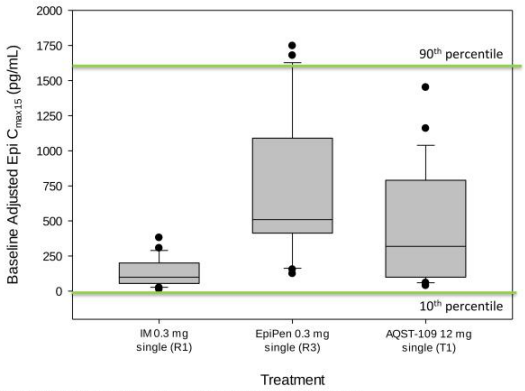
Allergists, Pediatricians, and Otolaryngologists (OTOs) prescribe roughly 1/2 of all EAI **Rx's**

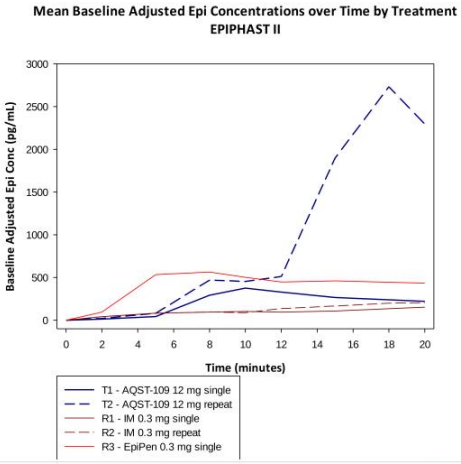


- Large portion of annual Rx's are written by a target audience addressable by Aquestive (i.e., high-decile Allergists, OTOs and Pediatricians)
- Further, many of the Rx's written by PCP's/Others, are "downstream" refill prescriptions, for patients that were originally seen and prescribed an epinephrine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

EPIPHAST II: Topline Results

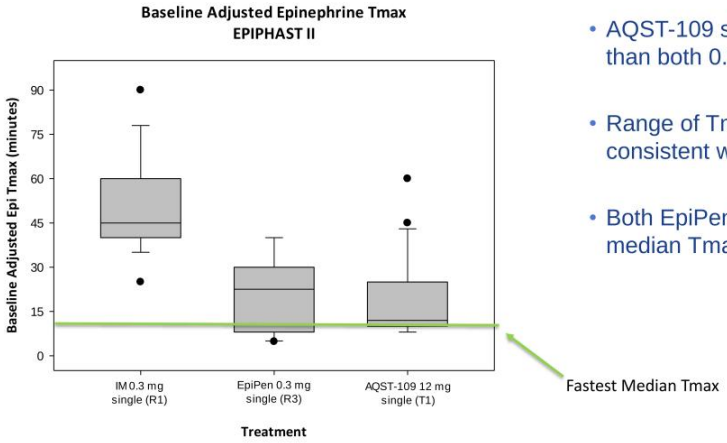
AQST-109 Cmax values within the timeframe critical to abate the cascade of anaphylaxis are comparable to and well bracketed by the 0.3mg IM and the EpiPen®





Represents data from top-line results. Geometric means presented for Cmax.
EPIPHAST II study was conducted with a 4-minute administration hold time. Administration instructions for future studies may vary.

EPIPHAST II: Time to Maximum Concentration (Tmax)



- AQST-109 showed a shorter median Tmax than both 0.3 mg IM and 0.3 mg EpiPen®
- Range of Tmax values across study is consistent with EpiPen®
- Both EpiPen® and AQST-109 provide faster median Tmax values than 0.3 mg IM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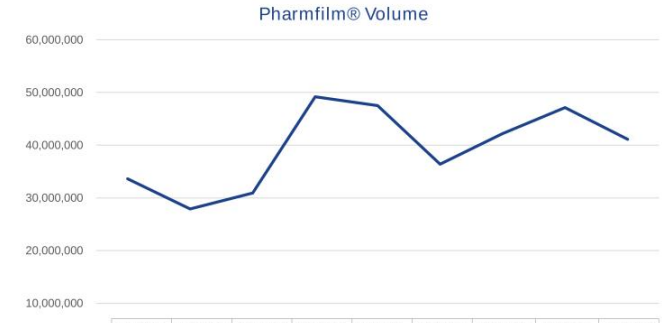
10

Manufacturing Operations



	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022
Doses (millions)	33,629	27,890	30,916	49,182	47,509	36,413	42,182	47,125	41,097

Manufacturing operations continues to meet the Company's expectations and provides positive cash flow to the Company.

2022 Outlook

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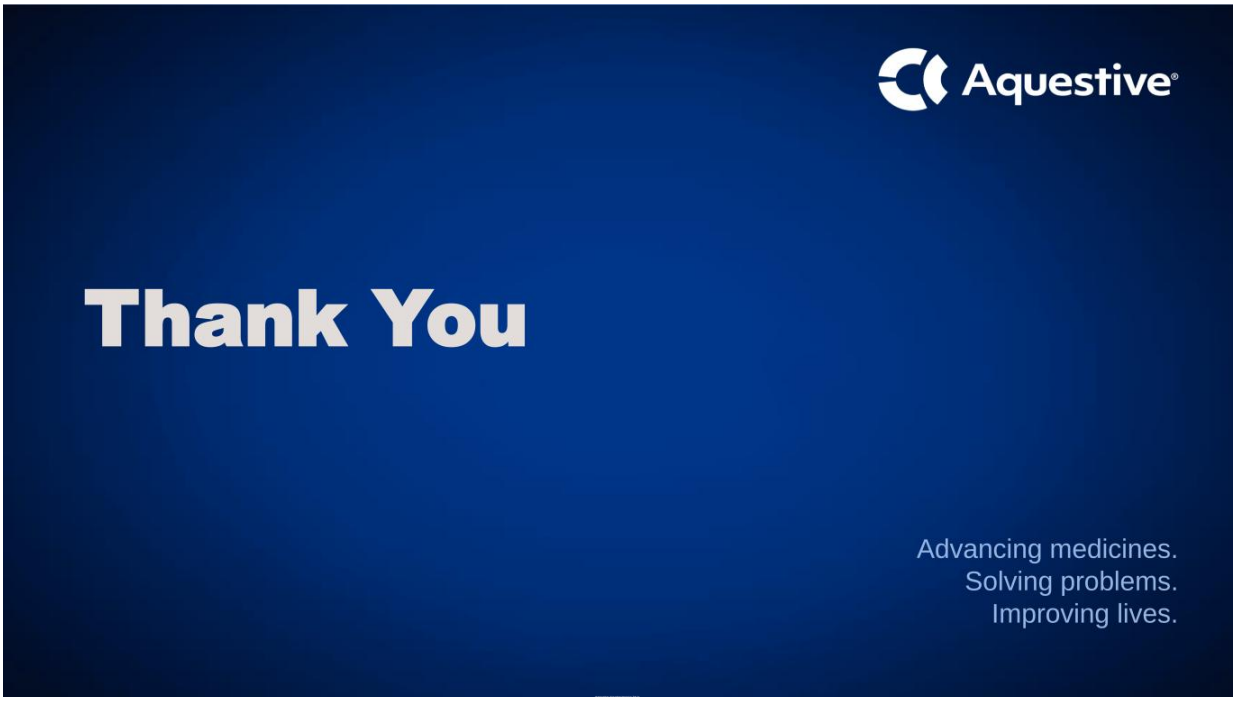
2022 Outlook

2022 Outlook

- Total revenues of approximately $46 to $49 million
- Non-GAAP adjusted EBITDA loss of approximately $37 to $43 million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