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): October 25, 2021

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 October 25, 2021, the Company issued a press release providing a business update in connection with the positive topline data from the Company's Phase 1 Pharmacokinetic Trial of AQST-109. 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 October 25, 2021.

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: October 25, 2021

Aquestive Therapeutics, Inc.

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

Aquestive®

Anaphylaxis and Epinephrine
AQST-109: Topline Results from Phase 1 PK Study (Study 210010)

October 25, 2021

Advancing medicines.
Solving problems.
Improving lives.

Forward Looking Statement

Certain statements in this presentation 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 potential for AQST-109 as the first orally administered epinephrine prodrug for the treatment of anaphylaxis, 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, our drug candidate 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 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 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, 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 presentation whether as a result of new information, future events or otherwise, except as may be required by applicable law.

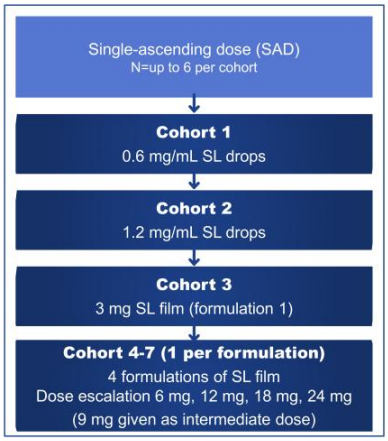
This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities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

Executive Summary

- Successful development of a sublingual epinephrine product relies on pharmacokinetic (PK) and pharmacodynamic (PD) comparability to existing epinephrine injection products
- AQST-109 has delivered promising results from a First in Human PK/PD study in healthy volunteers
  - Median time to maximal concentration (T_{max}) is 15 minutes (target formulation)
  - Mean maximal concentration (C_{max}) values meet or exceed the target range
  - The treatment was well-tolerated, with no serious adverse events reported, and most treatment-emergent adverse events were mild in severity
- The next clinical study in the development program will begin dosing in December, and aims to establish a final dose and formulation for the pivotal trial

AQST-109: Study 210010* (First in Human) Overview

Aquestive Therapeutics recently completed Study 210010, a first in human study that evaluated four film formulations at multiple dosage strengths.



Study 210010 ("010 Study")

- Single-ascending dose study in healthy young male volunteers
  - **Film dose levels of 3 mg, 6 mg, 9 mg, 12 mg, 18 mg, and 24 mg**
- Four different film formulations
- Up to 6 subjects per formulation received up to 4 escalating doses, 24 subjects total
- PK and PD measurements
  - Frequent sampling from pre-dose to 240 minutes post-dose

** From ongoing clinical trial 210010*

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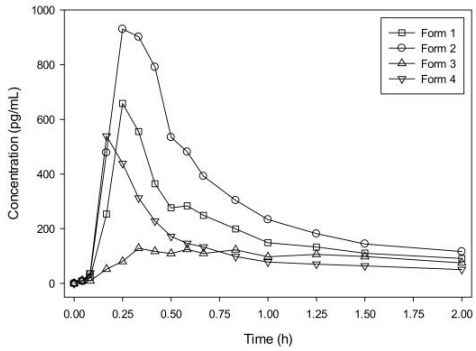
AQST-109: Absorption and Conversion

The results from Study 210010 demonstrate that AQST-109 is rapidly absorbed and converted into epinephrine.

Baseline-Corrected Mean Epinephrine Concentration over Time Following Administration of AQST-109 12 mg



Represents data from top-line results. Figure derived from arithmetic means.

Description	Form 1 12 mg	Form 2 12 mg	Form 3 12 mg	Form 4 12 mg	EpiPen®*	EpiPen®^	Auvi-Q®*
Cmax (pg/ml)	552	762	164	307	518	341	484
AUC 0-t (hr*pg/ml)	634	603	329	303	560	328	526
Tmax (min)	15	15	20	10	10	22	20
Tmax Range (min)	15-25	10-35	20-50	5-50	4-60	5-90	5-60

Represents data from top-line results. Geometric means presented for Cmax and AUC0-t, Median Tmax.

* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201739Orig1s000ClinPharmR.pdf
^ Data on file, AQST Study 160445

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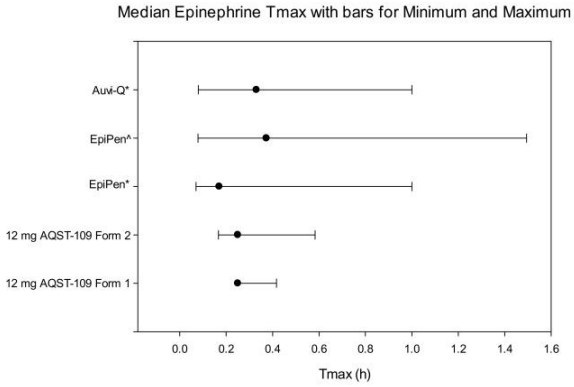
AQST-109: Tmax Range Comparison

AQST-109 and Autoinjector Tmax Values



Represents data from top-line results.
* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201739Orig1s000ClinPharmR.pdf
^ Data on file, AQST Study 160445

- Tmax (or time to maximum concentration) is a critical parameter for rescue medications
- The highest observed Tmax values for AQST-109 at 12 mg were below the highest Tmax values for autoinjectors
- The median Tmax values for AQST-109 were comparable to the known values from the autoinjectors

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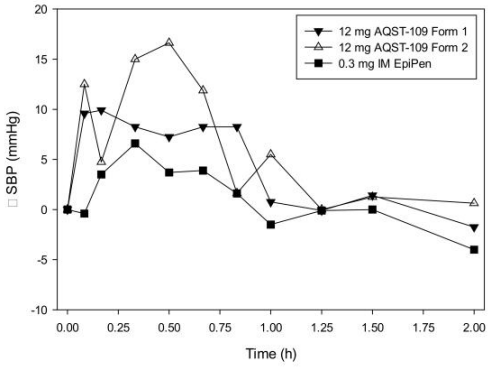
AQST-109: Pharmacodynamic (PD) Results Consistent with Observed EpiPen Responses

Mean Change from Baseline Systolic Blood Pressure over Time



Represents data from top-line results. EpiPen data overlay is from Study 160445.
SBP=Systolic Blood Pressure

- Literature indicates that subjects should see a change in systolic blood pressure over time after the administration of epinephrine*
- AQST-109 shows a similar change from baseline systolic blood pressure when compared to EpiPen data
- This pharmacodynamic 'marker' provides a secondary indication that AQST-109 is working as intended after administration

* **1.** Dworaczyk D, Hunt A. Presented at the American Academy of Allergy, Asthma and Immunology (AAAAI) National Conference, March 16, 2020. https://brynpharma.com/media/content/docs/comparative-delivery-poster.pdf; **2.** Worm M et al. *Clin Transl Allergy.* 2020;10:21; **3.** Duvauchelle T et al. *J Allergy Clin Immunol Pract.* 2018;6(4):1257-1263; **4.** Breuer C et al. *Eur J Clin Pharmacol.* 2013;69:1303-1310.

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Epinephrine Autoinjector Safety History

Epinephrine delivered by autoinjectors (EpiPen, Auvi-Q) have affirmed a well-established AE profile

	Auvi-Q Doses = 67		EpiPen Doses = 135	
	N	(%)	N	(%)
General and Admin. Site Conditions	34	(50.7)	79	(58.5)
Nervous System Disorders	12	(17.9)	23	(17)
CV	2	(3)	3	(2.2)
Psychiatric Disorders	8	(11.9)	14	(10.4)

Source: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/201739Orig1s000MedR.pdf

AQST-109: Adverse Events Following 12 mg Dose

The treatments have been generally well-tolerated. Most AEs were of mild severity and there have been no serious adverse events.*

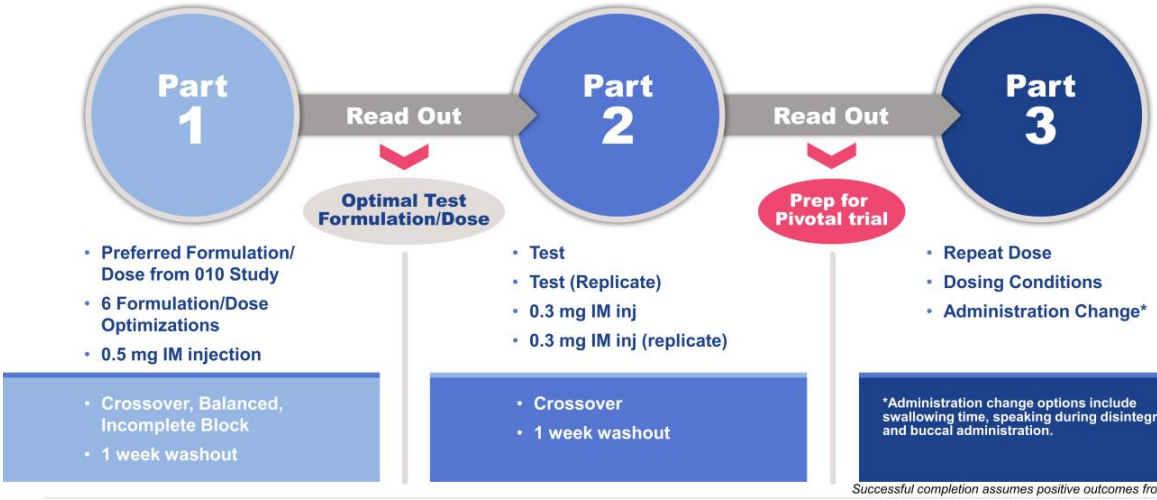
	Formulation 1 n=6		Formulation 2 n=8		Formulation 3 n=6		Formulation 4 n=7	
	Mild	Moderate	Mild	Moderate	Mild	Moderate	Mild	Moderate
Gen. Administration and Site Conditions	13	0	31	0	13	0	14	0
GI	2	0	2	1	0	0	1	0
CV	1	0	2	0	0	0	0	0
Other	1	0	3	0	1	0	0	0

n=number of dosings

- General Administration and Site Conditions include stinging, burning, pain, and pseudomembranes/ulcers
- GI AEs include nausea, vomiting, and abdominal pain/discomfort
- Cardiovascular (CV) AEs include heart racing, ECG changes

* Definition: https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

What Comes Next: Adaptive Design Study for AQST-109



Successful completion assumes positive outcomes from each Part

Aquestive

PharmFilm® Platform Projecting Robust Stability

Chemical Stability

- ≥ 2 years room temperature
- ≥ 6 months accelerated conditions

Environmental Stability

- Light resistant
- Water resistant
- Withstands extreme cold conditions
- Exploring high temperature excursions

Patent Applications Extending into 2042

Title	Patent Status
ENHANCED DELIVERY EPINEPHRINE COMPOSITIONS	• 1 US patent application allowed • 8 Foreign applications • **Priority date:** May 5, 2016 • Possible patent term to 2037
ENHANCED DELIVERY EPINEPHRINE AND PRODRUG COMPOSITIONS	• 2 US applications • 8 Foreign applications • **Priority date:** May 4, 2017 • Possible patent term to 2037
PRODRUG COMPOSITIONS AND METHODS OF TREATMENT	• 2 US applications • 1 Foreign application • **Priority date:** late 2019 • Possible patent term to 2041
PHARMACEUTICAL COMPOSITIONS WITH ENHANCED STABILITY PROFILES	• 1 US application • **Priority date:** October 2021 • Possible patent term to 2042

Aquestive Therapeutics Reports Positive Topline Data from Phase 1 Pharmacokinetic Trial of AQST-109 (epinephrine prodrug sublingual film) Supporting its Development as an Oral Alternative to Epinephrine Autoinjectors for the Emergency Treatment of Allergic Reactions

- *First and only orally delivered epinephrine product candidate AQST-109 demonstrates clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions*
- *Median time to peak concentration (T_{max}) of 15 minutes or less achieved across multiple formulations of AQST-109 at 12 mg dose, comparable to autoinjectors*
- *T_{max} range for all formulations was narrower than published data for autoinjectors*
- *Mean peak concentration levels (C_{max}) meet or exceed the target range in published data for autoinjectors*
- *Anticipate starting crossover study before the end of 2021 and pivotal pharmacokinetic (PK) study in 2022*

WARREN, N.J., October 25, 2021 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, today announced positive topline data from its first-in-human Phase 1 PK study of AQST-109 sublingual film for the delivery of epinephrine in the emergency treatment of allergic reactions including anaphylaxis. Findings from this study support AQST-109's potential as the first orally administered epinephrine treatment for anaphylaxis, with safety, tolerability, PK and pharmacodynamics (PD) measures that fall within the target range of standard of care autoinjectors such as epinephrine pens which require patients or caregivers to inject into their thighs during an emergency allergic reaction.

"These findings represent a critical step forward in the development of our product candidate AQST-109 as the first oral product aiming to treat anaphylaxis," said Keith Kendall, Chief Executive Officer of Aquestive. "The optimized PK/PD profile of our epinephrine prodrug demonstrates that our oral alternative to epinephrine injection can, in fact, match the PK parameters of autoinjectors while lowering barriers to use and improving convenience, ultimately resulting in better, often life-saving outcomes for patients. Based on our review of published literature, AQST-109 is the only non-injection form of epinephrine to achieve a median Tmax of 15 minutes or less. We are encouraged by these findings and continue to believe patients will embrace this needle-free, user-friendly alternative."

AQST-109 is a polymer matrix-based film that can be applied sublingually (under the tongue) for the rapid delivery of epinephrine. The product is similar in size to a postage stamp 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. Current stability data is tracking favorably to support a two-year shelf life.

The Phase 1 randomized, single-ascending dose (SAD) study was performed with AQST-109 in order to assess safety, tolerability, PK, and PD profiles. The study was conducted in Canada pursuant to a clinical trial application approved by Health Canada. Subjects participating in the trial received, in ascending fashion, sublingually administered doses of AQST-109 across four different formulations. The four formulation compositions were varied to assess critical absorption factors including drug loading and the use of inventive excipients designed to influence absorption, stability, and the conversion of the prodrug. A target formulation ("formulation #2" highlighted below) was designed as the lead candidate for the study.

Study Highlights

- Key clinical measures for comparability to existing autoinjectors (C_{max}, T_{max}, and area under the curve, or AUC) were within expected ranges for formulations 1, 2 (target), and 4
- Observed PD values were comparable to existing data for autoinjectors
- AQST-109 was generally well tolerated with no serious adverse events

Study Results	**AQST-109 (epinephrine prodrug sublingual film) 12 mg**			
Film Formulation #	**1**	**2 (Target)**	**3**	**4**
Dosings (n)	6	8	6	7
C_{max} (pg/mL)	552	762	164	307
AUC 0-t (hr*pg/mL)	634	603	329	303
Median T_{max} (minutes)	15	15	20	10
T_{max} range (minutes)	15-25	10-35	20-50	5-50

Comparable Data from Previous & Published Studies		
EpiPen®[1]	**EpiPen®[2]**	**Auvi-Q®[1]**
135	10	67
518	341	484
560	328	526
10	22	20
4-60	5-90	5-60

This study indicated that AQST-109 was absorbed and rapidly converted to epinephrine with an observed median T_{max} of 15 minutes and an observed geometric mean C_{max} of 762 pg/mL for the target formulation. The findings for the target formulation are comparable to published study results for both EpiPen and Auvi-Q[1234567]. In addition, the target formulation had similar median T_{max} values at lower dose strengths (15 minutes and 17.5 minutes for the 6 mg and 9 mg doses, respectively, included in the study). Based on the study results, Aquestive plans on continuing development of the target formulation to take forward into a pivotal PK study.

[1] Dworaczyk D., Hunt A., Presented at American Academy of Allergy, Asthma, Immunology (AAAAI) National Conference, March 16, 2020. https://brynpharma.com/media/content/docs/comparative-delivery-poster.pdf.

[2] Aquestive Therapeutics, Study 160455, on file.

[3] Dworaczyk D., Hunt A., *J Allergy Clin Immunol Pract.* 2021;147(2):(2 suppl) AB241 Presented at American Academy of Allergy, Asthma and Immunology (AAAAI) National Conference; March 16, 2020; Accessed March 2, 2021

[4] Worm M et al. *Clin Transl Allergy.* 2020:10:21.

[5] Duvauchelle T et al. *J Allergy Clin Immunol Pract.* 2018;6(4):1257-1263

[6] Breuer C et al. *Eur J Clin Pharmacol.* 2013;69:1303-1310

[7] Edwards ES et al. Ann Allergy Asthma Immunol. 2013;111(2):132-137.

Safety data indicated that AQST-109 was generally well tolerated with no serious adverse events (SAE's), significant medical events, or treatment-related severe adverse events reported within the trial. All treatment-emergent adverse events (TEAEs) deemed at least possibly related were mild to moderate in nature across cohorts.

The PD markers measured changes from baseline in heart rate, systolic blood pressure, and diastolic blood pressure. The changes observed suggest a comparable effect for AQST-109 when compared to autoinjectors in healthy volunteers.

David Fleischer, MD, Section Head, Pediatric Allergy and Immunology at Children's Hospital Colorado, Professor of Pediatrics at University of Colorado School of Medicine, commented, "An epinephrine delivery solution such as AQST-109 for cases of severe life-threatening allergic reactions could address the most important factor contributing to anaphylaxis fatality: the therapeutic time window. The needle-free, pocket-sized, and temperature safe attributes of this first-of-its-kind orally administered prodrug will make it the preferred choice for parents of children facing these risks."

Aquestive has submitted its request for a pre-investigational new drug (IND) meeting with the U.S. Food and Drug Administration (FDA) and anticipates receiving a written response from the FDA before the end of the year. In parallel, Aquestive is on track to conduct a crossover study using an adaptive design for AQST-109 in Canada beginning in the fourth quarter 2021. It is anticipated that this study will establish a final formulation and dose strength for commercial scale-up. The study will include comparisons to 0.3 mg and 0.5 mg epinephrine intramuscular (IM) manual injection and is anticipated to complete in the first half of 2022.

A presentation of the results of the Phase 1 PK study of AQST-109 is available on the events and presentation of the investor section of the Company's website at https://investors.aquestive.com/events-and-presentations# and has been filed with the SEC on Form 8-K.

About Anaphylaxis
Anaphylaxis is a potentially life-threatening systemic allergic reaction, with an estimated incidence of 50 to 112 episodes per 100,000 people per year. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years. 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
Aquestive Therapeutics is developing a sublingual (SL) film containing a prodrug of epinephrine as an alternative dosage form to epinephrine injection (1 mg/mL). The targeted indication for epinephrine prodrug sublingual film is the same as that for epinephrine injection in the emergency treatment of Type 1 allergic reactions, including anaphylaxis.

Aquestive's SL film contains a prodrug of epinephrine incorporated into a polymer-based film matrix utilizing its innovative PharmFilm® technology. Prodrugs are generally not active moieties and require biotransformation to the parent compound in vivo to allow for therapeutic activity. Treatment with AQST-109 has been generally well-tolerated, with treatment-emergent adverse events observed thus far being mild to moderate in severity. There have been no serious adverse events observed.

About Aquestive Therapeutics
Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, Sympazan® (clobazam) oral film, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven capabilities for drug development and commercialization.

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 potential for AQST-109 as the first orally administered epinephrine prodrug for the treatment of anaphylaxis, 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, our drug candidate 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 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 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, including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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