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): January 10, 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 and replaces in its entirety all prior investor presentations filed by the Company. 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 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Investor presentation dated January 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: January 10, 2022

Aquestive Therapeutics, Inc.

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


Aquestive
Aquestive Therapeutics
Corporate Presentation
January 2022
Advancing medicines.
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Forward-Looking Statement

This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “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-108, 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-108, AQST-109 and our other drug candidates; risk of delays in FDA approval of our drug candidate Libervant and AQST-108, 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 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; our and our competitors’ orphan drug approval and resulting drug exclusivity for our products or products of our competitors; 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; 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 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.

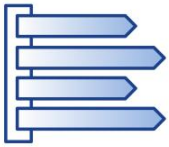
Our Path

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

- Libervant™ Buccal Film (Diazepam)*
  - NDA filed on June 23, 2021
  - PDUFA date December 23, 2021
  - Under current FDA review
- Epinephrine prodrug platform with 2 clinical stage sublingual film candidates (SF) AQST-108 & AQST-109



Multiple cash-generating opportunities

- 12+ 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.

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Improving lives.

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

Our Team

Keith J. Kendall
Chief Executive Officer
and Director

Daniel Barber
Chief Operating Officer

Peter Boyd
SVP, Business Process &
Information Technology

Lori J. Braender
General Counsel and
Chief Compliance Officer

Ken Marshall
Chief Commercial Officer

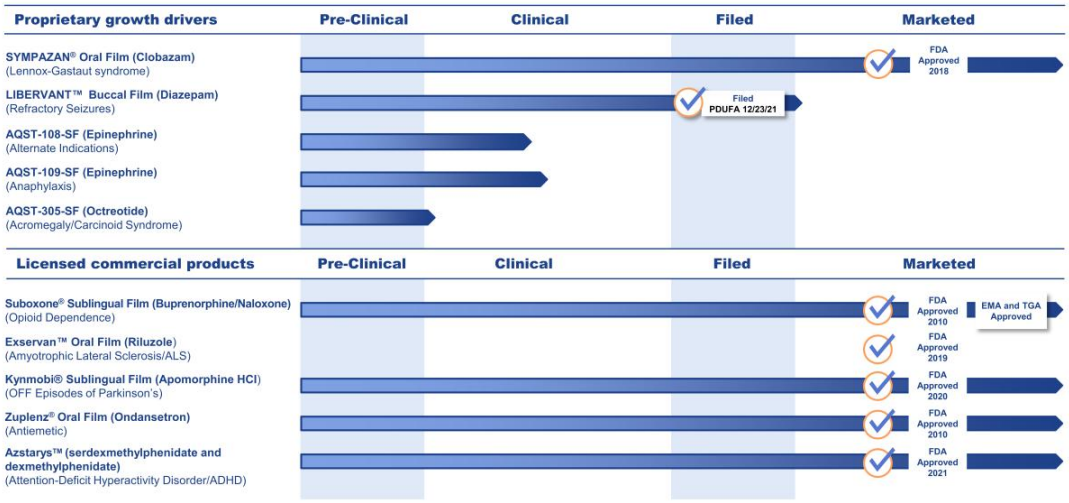
Mark Schobel
Chief Innovation &
Technology Officer

Gary H. Slatko, MD
Chief Medical Officer,
Neurology

Ernie Toth
Chief Financial Officer

Theresa Wood
SVP, Human Resources

Our Products



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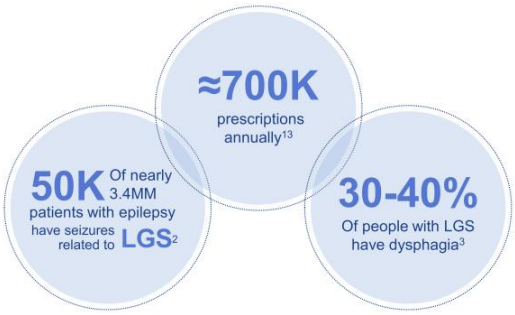
Solving problems in EPILEPSY:

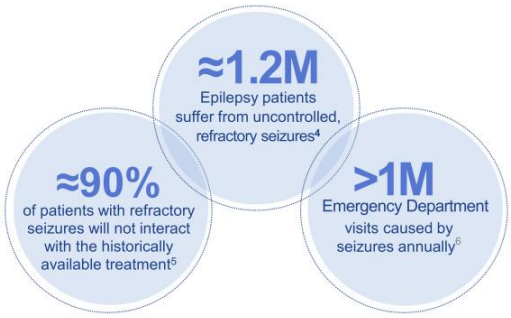
SYMPAZAN Oral Film (Clobazam)

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



LIBERVANT Buccal Film (Diazepam)

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



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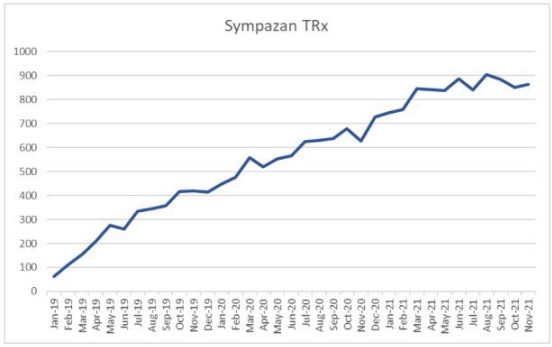
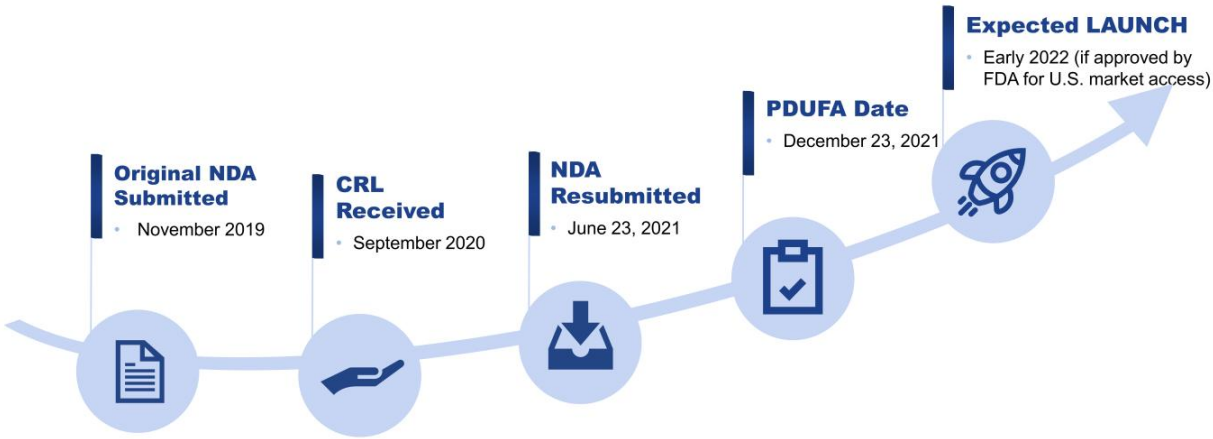
Continued Expansion of Epilepsy Franchise

SYMPAZAN: Sustained Script Growth for Over 12 Quarters

- Growing prescriber base, with over 30% penetration into the focused group of prescribers, with ~80% writing multiple scripts
- Launched as a precursor and compliment to Libervant
- 96% of Sympazan targets are Libervant targets
- Solid two product sales force efficiency



LIBERVANT: NDA Resubmission



Solving Problems in ANAPHYLAXIS

- Anaphylaxis is an unpredictable, severe systemic allergic reaction that is rapid in onset and potentially fatal[7]
- At-risk patients should always have immediate access to 2 doses of epinephrine[8]
- Delayed administration of epinephrine tied to increased fatalities[9]
- Aquestive is developing oral sublingual film formulations of epinephrine for treatment of allergic reactions (type 1), including anaphylaxis

The lifetime prevalence of anaphylaxis in the U.S. could be as high as **5%**[10]

Increased **Hospital Admissions** by 500-700% in last 10-15 years[11]

Approximately **186 to 225** deaths per year[12]

≈$1.5B market with ~3M total prescriptions[13]

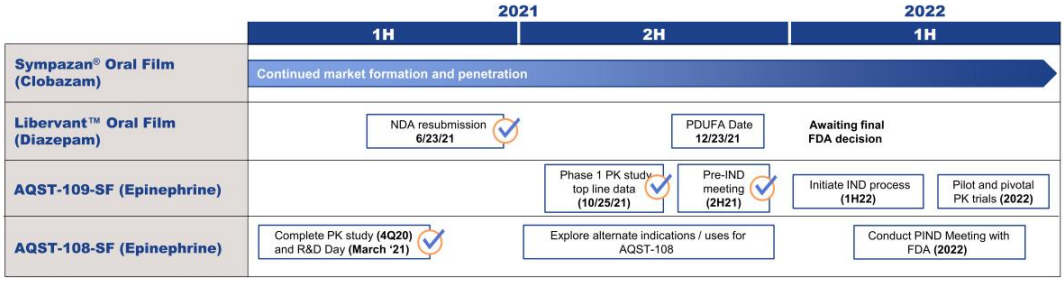
"As a treating physician and researcher in anaphylaxis, I believe the film dosing could represent a significant advance in treatment for patients at risk for anaphylaxis."

–**David M. Fleischer, MD, FAAAAI**
Professor of Pediatrics
Section Head, Allergy and Immunology
Children's Hospital Colorado
University of Colorado Denver School of Medicine

AQST-109: Topline Phase 1 Results and Next Steps

- 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
  - Treatment was well-tolerated, with no serious adverse events reported, and most treatment-emergent adverse events were mild in severity
- Received Pre-Investigational New Drug (PIND) written response from FDA in December with confirmation that the 505(b)2 approval path is appropriate for AQST-109
- Latest AQST-109 study began dosing in December 2021
  - Study aim is to determine the final formulation and dose for AQST-109
  - Additional goal is to move forward to the manufacture of registration batches and a pivotal PK study in the 2nd half of 2022

Key Pipeline Milestones



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Financial Summary

Full Year 2021 Guidance (as of November 2, 2021)

- Total revenues of approximately $47 to $49 million, compared to $46 to $48 million prior guidance
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
- Non-GAAP adjusted EBITDA loss of $32 to $34 million, compared to $39 to $42 million prior guidance

Capital Adequacy

- Cash on hand of $31.2 million at 9/30/21
- Potential additional capital from debt facility, of up to $30 million after Libervant FDA approval and U.S. market access
- ATM remains an important tool to support capital needs
- Available shelf registration

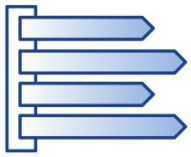
Our Focus in 2022

Continue to expand in our epilepsy franchise

- Focus on the FDA approval and launch of LIBERVANT
- Generate continued growth in SYMPAZAN prescriptions

Advance our novel epinephrine delivery platform

- Initiate IND process for AQST 109
- Final Dose and Pivotal PK trials
- Identify additional product opportunities



Continue to strengthen the capital position of the Company

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

References

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

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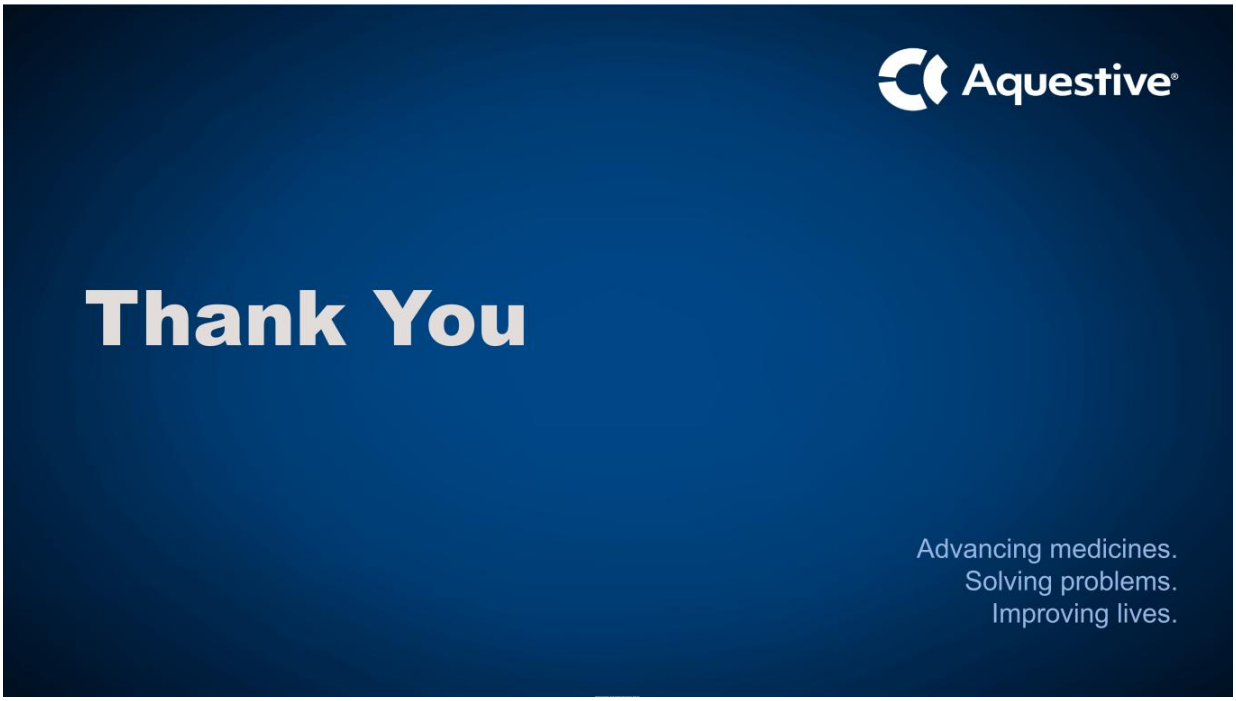
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