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 8, 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 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.

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 8, 2021

Aquestive Therapeutics, Inc.

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

Exhibit 99.1


Aquestive
Aquestive Therapeutics
Corporate Presentation
January 2021
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 therapeutic benefits and plans and objectives for regulatory approvals of Libervant™ and AQST-108; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant and obtain FDA approval of Libervant for U.S. market access; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; about our growth and future financial and operating results and financial position; regulatory approval and pathway; clinical trial timing and plans; 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; business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are also 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; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of our drug candidate 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); risks and uncertainties concerning the royalty and other revenue stream of the KYNMOBI® monetization, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction, and of sufficiency of net proceeds of the monetization transaction after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable, and for funding the Company's operations; 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; 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; risk associated with Indivior's cessation of production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; 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.

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.

Advancing Medicines to Improve Therapeutics

- **Proven track record of success in developing, obtaining FDA approval, and manufacturing differentiated therapeutics with PharmFilm® technologies**
  - 5 FDA approved products, both proprietary and out-licensed

- **Advancing late-stage pipeline of differentiated therapeutics for complex conditions**
  - Received CRL from FDA for LIBERVANT™ in Sept. 2020, Type A meeting held on Nov. 12th and revised modeling submitted to FDA in Dec. 2020
  - Received FDA Fast Track designation for AQST-108 (epinephrine) in August 2020 and outlined topline results from second pilot PK study in Jan. 2021

- **Capital, including current cash, and revenue from licensed & proprietary therapeutics extends cash into 3Q21 and potentially beyond**
  - Executed KYNMOBI™ monetization agreement providing up to $125 million for royalty rights
  - Various capital sources may extend runway further

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Libervant™ (diazepam) buccal film 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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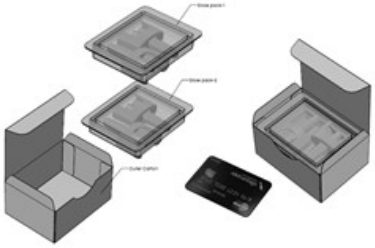
PharmFilm®: Usable Medication for Undertreated Patients

Diastat Rectal Gel

Alternative Nasal Sprays



Epinephrine Injection

VS

- Can deliver rapid onset of action with entry into systemic circulation
- Ease of administration
- Uniform distribution & reproducible delivery of API's
- Demonstrated bioequivalence, safety and tolerability
- Non-invasive
- Customizable taste masking profile

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Track Record of Success

Innovative formulation capabilities

- Novel and transformative products
- Expertise in oral transmucosal permeation
- Scalable technology for consistent performance

Clinical and regulatory success

- 5 FDA approved products, 2 under FDA review, several in development
- Multiple clinical studies planned
- 200+ worldwide patents

Commercial success in collaboration

- **Suboxone® Sublingual Film**
  Buprenorphine/Naloxone (Opioid Dependence)
  - Global license
  - Over 2 billion doses manufactured
- **Exservan™ Oral Film** Riluzole (ALS)*
- **Zuplenz®** Ondansetron (CINV/PINV)

Commercial success on our own

- **SYMPAZAN® Oral Film** Clobazam (Lennox-Gastaut syndrome)
  - FDA approved in October 2018
  - Prescriber base exceeds 750 HCPs
  - Precursor for LIBERVANT™ launch with significant overlap in prescribers
  - For information and **Boxed WARNING:** https://www.sympazan.com/pdfs/pi.pdf

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*Exservan is in EMA approval process

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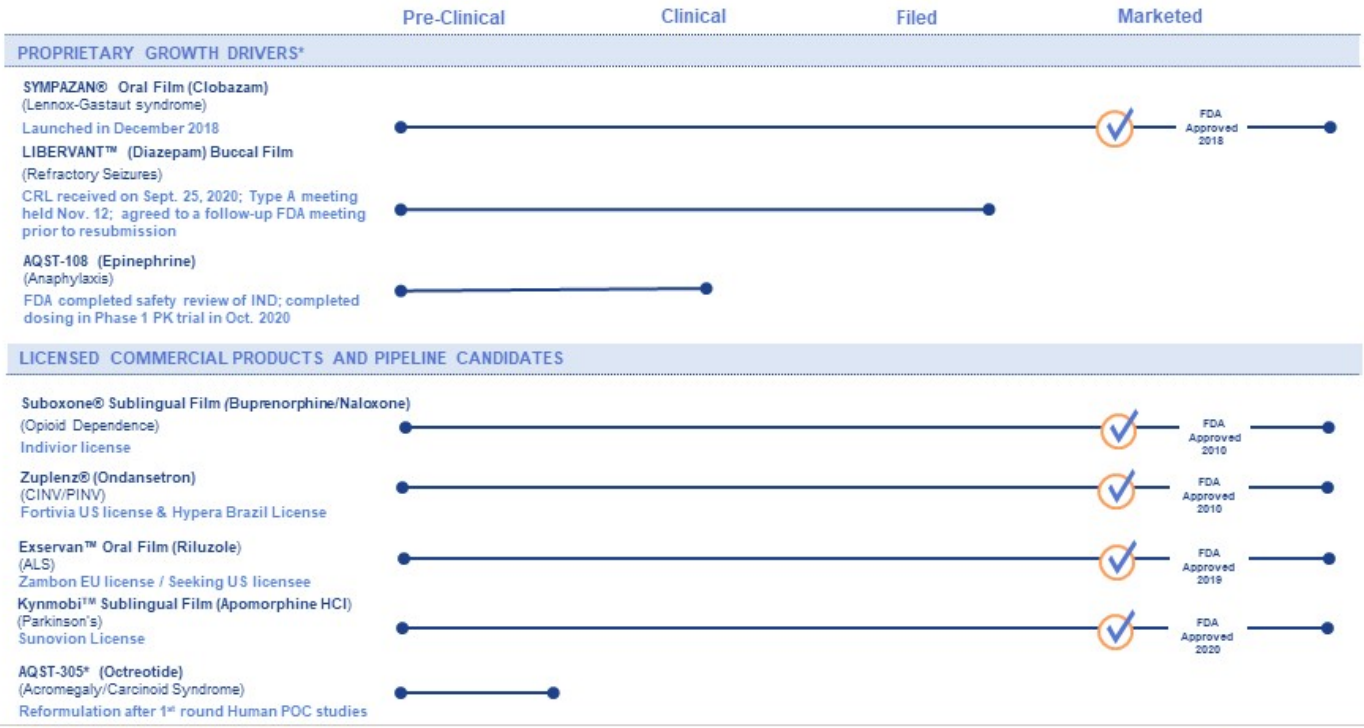
Diversified Portfolio and Pipeline



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*Aquestive holds rights for worldwide commercialization

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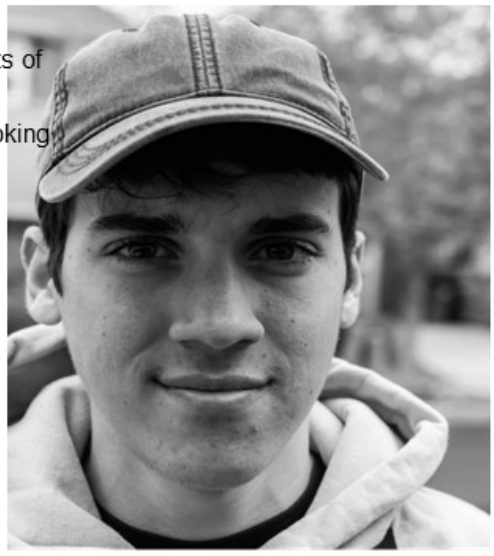
Solving problems in EPILEPSY: LIBERVANT™ (diazepam) Buccal Film

- In development for management of selected, refractory, patients with epilepsy, on stable regimens of AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity
- Potential to become the preferred rescue medication by patients and providers looking for clinically differentiated treatment in an oral dosage form



≈1M Epilepsy patients[1] suffer from uncontrolled, **refractory seizures**

≈92% of patients with refractory seizures will not interact with the historically available treatment[2]

Seizures account for 1M EMERGENCY DEPARTMENT visits annually[3]

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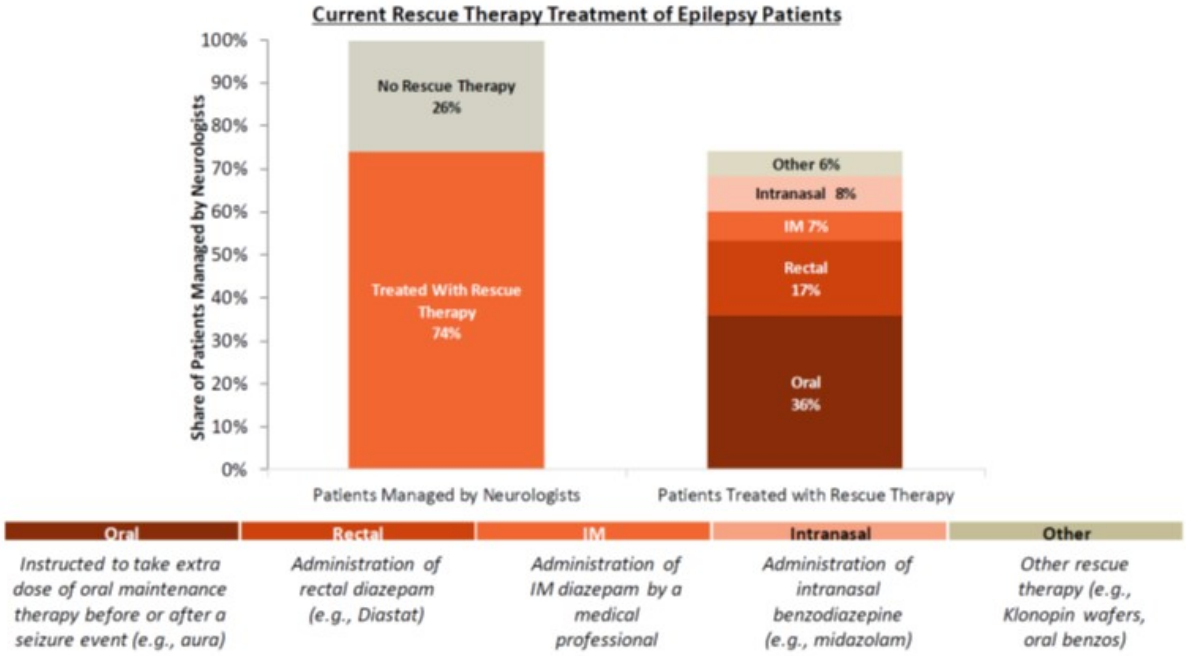
Historic Rescue Market – Highly Fragmented[2]



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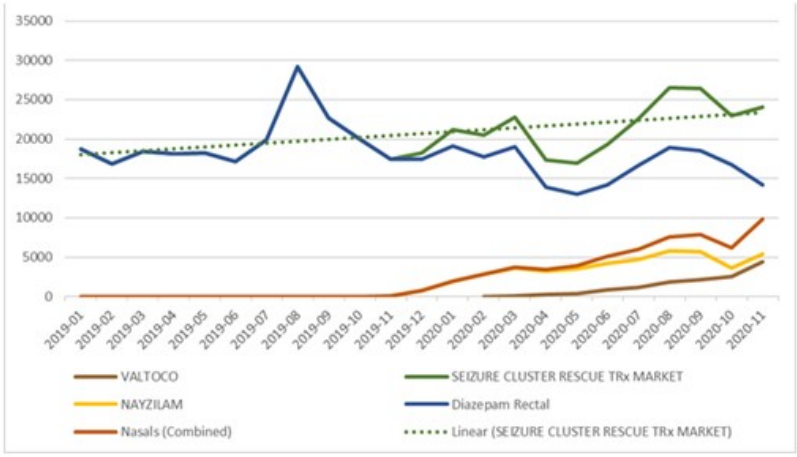
Refractory Epilepsy Rescue Market in 2020 – Introduction of Approved Nasal Products

Rescue Market[12]

- Labeled rescue market grew by:
  - ~15% in TRxs
  - ~45% product units*
- Rectal gel is on track to deliver:
  - ~200,000 in TRxs
  - Accounts for ~270,000 units*
  - TRxs down year over year, units relatively flat*
- Introduction of nasal added:
  - ~70,000 in TRxs
  - Accounts for ~105,000 units*

Labeled Seizure Cluster Rescue TRx Market



Continued prescription levels for diazepam rectal gel demonstrate the unmet need

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*Each unit contains 2 devices

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LIBERVANT: Contribution to Patient Care

Plan to demonstrate that LIBERVANT™, as an orally delivered product, meets one or more of criteria outlined by FDA to be considered a major contribution to patient care versus currently approved and device-driven rectal and nasal products[8]

- Convenience of treatment location
- Duration of treatment
- Patient comfort
- Reduce treatment burden
- Advances in ease and comfort of drug administration
- Longer periods between doses

Suboptimal Device-Based Treatments

- 10-14-step administration [4, 5]
- Length of time to administer [4, 5]
- Potential for inaccurate dosing [4,5]
- Unpredictable absorption [4, 5, 6]
- Issues with portability [4, 5, 7]
- Patient Positioning [4, 5]

Aquestive's Value Proposition

LIBERVANT, if approved, potentially represents a major contribution to patient care and further expand patient choice as the first orally administered dosage form available to manage seizure clusters in epilepsy patients

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LIBERVANT Commentary

Portability

"…what was found in the usability studies[9] was that a caregiver had no trouble administering this into the buccal space.

…They are at school and at work, but they always have a concern that a seizure could occur…We don't have an FDA-approved therapy that they can carry with them."

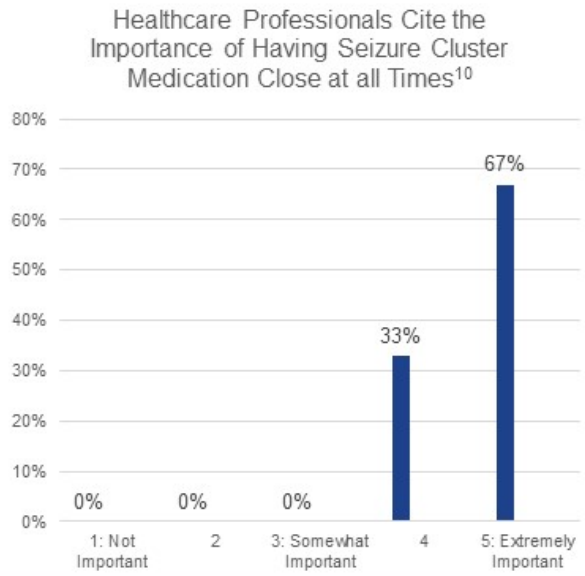
– Michael Rogawski, MD, PhD, Professor of Neurology and Pharmacology, School of Medicine, University of California, Davis

Advances in ease and comfort of administration, patient comfort

"I will say from a pediatric standpoint, getting a child to put something in their nose and hold it still is very difficult."

– Syndi Seinfeld, DO, MS, Director of Epilepsy, Joe DiMaggio Children's Hospital , Miami, FL

Convenience of treatment location



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LIBERVANT: Received CRL from FDA, Plan to Resubmit 1H21

- In PK Crossover Study 180323, FDA acknowledged overall Cmax geometric mean ratio (GMR) of Libervant™ versus Diastat was comparable
- FDA cited that two weight groups showed lower Cmax levels when compared to Diastat:
  - 51-62 kg (n=6) (12.5 mg Libervant/ 15.0 mg Diastat)
  - 76-87 kg (n=7) (15.0 mg Libervant / 17.5 mg Diastat)
- FDA noted that 4 subjects in the weight groups identified above and 1 additional subject in the 63-75 kg weight group had a median Cmax level that was approximately half of the median Diastat level (180 ng/mL vs. 375 ng/mL respectively)
- No other safety, clinical pharmacology / biopharmaceutics, CMC or other non-clinical issues identified in CRL*
- At a Type A meeting held November 12, 2020, FDA confirmed issues identified in the CRL related to the NDA for drug candidate LIBERVANT™ (diazepam) Buccal Film may be addressed by utilizing modeling and simulations based upon the information provided by Aquestive in its FDA meeting package submitted in October 2020
  - Aquestive resubmitted a revised weight-based dosing regimen along with modeling and simulations in December 2020
  - Based on correspondence from the FDA, Aquestive expects to receive feedback and guidance from the FDA in late January, which may require the need for additional meetings with the FDA
  - Aquestive intends to resubmit the NDA as quickly as possible, based on further FDA feedback, during the first half of 2021

*The FDA cited a small number of protocol deviations in blood draws in one of the studies in the NDA which the Company believes have been addressed in its FDA submitted meeting package.

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AQST-108: Solving Problems in ANAPHYLAXIS

- Oral sublingual film formulation of epinephrine for the treatment of allergic reactions (Type 1), including anaphylaxis
- Phase 1 dose escalation proof-of-concept study in healthy subjects demonstrated ability to deliver systemic epinephrine using proprietary PharmFilm® technologies
- At constructive pre-IND meeting held on February 4, 2020, FDA confirmed clinical development will be reviewed under the regulatory 505(b)(2) pathway as proposed by Aquestive
- FDA completed safety review of IND in July 2020
- Received FDA Fast Track designation in August 2020

50 to 112 Episodes Per **100,000** people per year[11]

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]

Suboptimal Treatment

EpiPen®

- Difficult administration
- Painful intramuscular injections
- Inconvenient portability

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AQST-108: Solving Problems in ANAPHYLAXIS

Encouraging results from two pilot pharmacokinetic (PK) studies

- Clinical dosing as a sublingual film
- Generated median Tmax similar to subcutaneous and intramuscular injections
- Geometric mean Cmax ranges between approximately 200 pg/mL and 400 pg/mL depending on dosing strength
- As comparators, the 0.3mg subcutaneous and IM injections administered in the most recent Phase 1 study resulted in geometric mean Cmax levels of approximately 385 ng/mL and 475 ng/mL respectively

EpiPen studies indicate a range of potential Cmax outcomes

- Studies conducted by Aquestive indicate a Cmax range for EpiPen between 350 pg/mL and 400 pg/mL (n=18, n=9)
- Recent public presentations indicate a Cmax for EpiPen of approximately 310 pg/mL (n=55)*[14]
- Intellect Summary Basis of Approval (SBA) indicates a Cmax for EpiPen of 520 pg/mL (n=135)

Anticipate conducting a virtual R&D event in Q1 2021

- Outline the market need for new innovation
- Provide an in-depth understanding of our novel delivery system
- Outline clinical results and upcoming milestones

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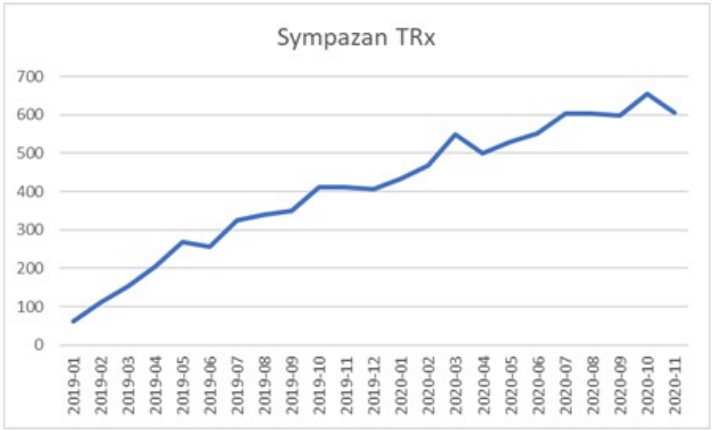
Continue to Expand in Our Epilepsy Franchise Cont'd

SYMPAZAN®: Continued Growth

- National trend for total prescriptions were down 7% below prior year trends driven by fewer new prescriptions
- In spite of Q2 and Q4 challenges from COVID SYMPAZAN grew ~110% in TRx and ~80% in prescriber base



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Financial Summary*

Financial Results and Cash Position

- Third quarter 2020 total revenues of $8.3 million
- Year-over-year 102% growth in SYMPAZAN® revenue
- Third quarter 2020 net loss of $16.6 million, or $0.49 loss per share
- Cash and cash equivalent of $17.1 million at 9/30/20

Full Year 2020 Guidance

- Total revenues of approximately $42 million to $46 million
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
- Non-GAAP adjusted EBITDA loss of $38 million to $42 million
- Cash burn of approximately $45 million to $50 million
- Impact on KYNMOBI™ monetization excluded from guidance

Capital Adequacy

- Cash position at end of 3Q20 combined with impact of KYNMOBI™ monetization expected to be adequate into third quarter 2021 or potentially beyond
- Executed KYNMOBI™ monetization agreement for up to $125 million for its worldwide royalty rights, including $50 million received at closing, including first milestone payment of $10 million, and an additional amount of up to $15 million by mid 2022
- Debt reduced to $51.5 million, $30 million of re-openers after Libervant approval available to year-end 2021
- Available Shelf Registration and ATM facility

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*Except as specifically set forth above, as of November 4, 2020; Based on Aquestive projections, estimates and/or expectations, which may not be realized, and audited preliminary information

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Our Focus in 2021

- **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**
  - Continue to pursue clinical development
  - Progress towards regulatory interactions and filings

- **Continue to strengthen the capital position of the company**
  - Evaluate various paths to capital

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References

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

- Data on file

LIBERVANT™ REFRACTORY SEIZURES

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ANAPHYLAXIS

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Thank You

Advancing medicines.
Solving problems.
Improving lives.