



# Aquestive Therapeutics Corporate Presentation

May 2020

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 AQST-108, Libervant™ and our other product candidates; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; statements about our growth and future financial and operating results and financial regulatory approval and pathways, 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 also 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 of 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 the 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, costs 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 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 and there can be no assurance that we will be successful in obtaining FDA approval to overcome orphan drug exclusivity granted to an earlier approved competitor orphan drug; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active mojety as any of our other drug candidates 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 time 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 Suboxone as a sunsetting product; risks related to the outsourcing of certain sales, 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 presentation whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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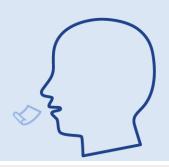
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## Why to Invest – Investment Thesis

## **Advancing medicines to improve therapeutics**

- Proven track record of success in developing, obtaining FDA approval, and manufacturing differentiated therapeutics with PharmFilm® technology
  - 4 FDA approved products, both in partnership and on our own



- Advancing a late-stage pipeline of differentiated therapeutics for complex conditions. Multiple value inflection points near term
  - Libervant™ PDUFA date assigned for September 27 with review discussions underway with FDA
  - On track to submit AQST-108 (epinephrine) IND in June on 505(b)(2) pathway



- Capital through 2020, including current cash, and revenue from licensed & proprietary therapeutics
  - Non-dilutive capital sources extend runway into 2021 and possibly beyond





# Track Record of Success – Who We Are

### Innovative formulation capabilities

- Novel and transformative products
- Expertise in oral transmucosal permeation
- Scalable technology for consistent performance
- 200+ worldwide patents

### Clinical and regulatory success

- 4 FDA approved products, 3 under FDA review, several in development
- Multiple clinical studies underway
- Non-binary risk

### Success in collaboration

- Suboxone® Sublingual Film -Buprenorphine/Naloxone (Opioid Dependence)
- Exservan® Oral Film Riluzole (ALS)
- Zuplenz® Ondansetron (CINV/PINV)
- Sunovion Apomorphine (Parkinsons)
- KemPharm Multiple (ADHD)

# Suboxone® Sublingual (buprenorphine and naloxone) © Film

### **Proprietary commercial platform**

- Sympazan® Oral Film Clobazam (Lennox-Gastaut Syndrome). Approved October 2018
- Precursor/complement for Libervant<sup>™</sup> (diazepam) Buccal Film launch significant overlap in prescribers
- Successful buildout of sales, marketing, access capabilities





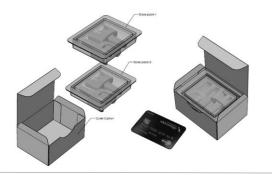
## PharmFilm®: Usable Medication for Undertreated Patients

Diastat Rectal Gel





**Alternative** Nasal Sprays



Epinephrine Injection







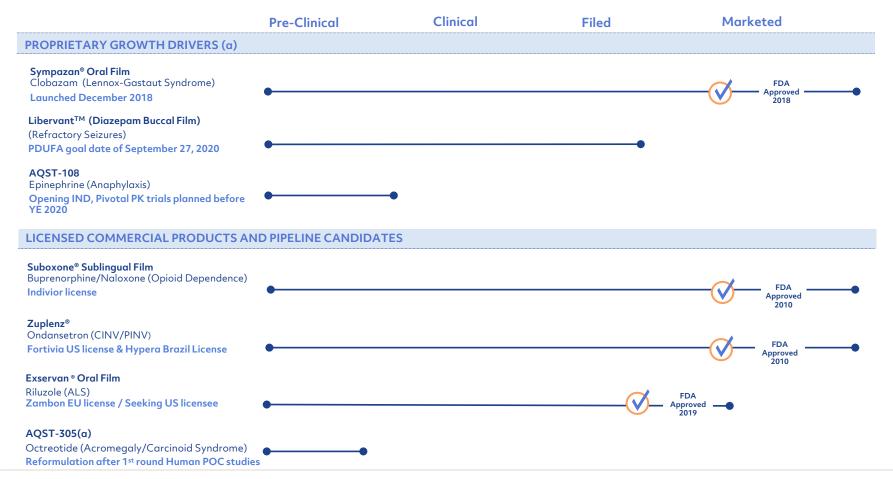
- Ease of administration
- Uniform distribution & reproducible delivery of API's

- Demonstrated bioequivalence, safety and tolerability
- Non-invasive
- Customizable taste masking profile





## Diversified Portfolio and Pipeline





## Key Value Drivers Near Term

## Solving problems in EPILEPSY: Libervant™ (diazepam buccal film)

- In development for management of select patients with refractory epilepsy who require treatment to control episodes of increased seizure activity, or "seizure clusters"
- Potential to become the preferred rescue medication by patients and providers looking for clinically differentiated treatment in an oral dosage form

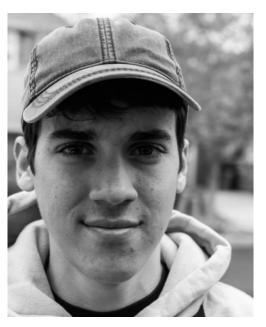
≈92%

of patients with refractory seizures will not interact with the current standard of care1



**Epilepsy** suffer from uncontrolled, refractory seizures

**Epilepsy** patient visits to **EMERGENCY DEPARTMENTS** annually



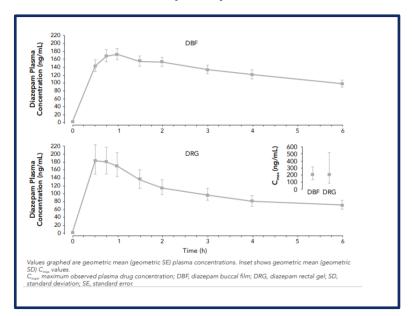
### **Suboptimal Device-Based Treatments**

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



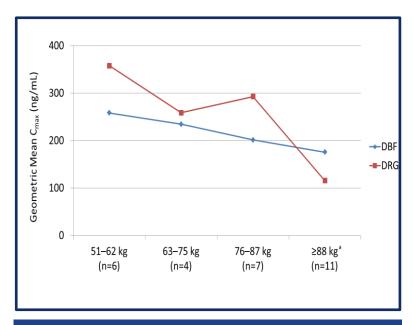
# **ℂ** Libervant™ NDA Under Review by FDA

Diazepam Plasma Concentration Over Time After Diazepam Buccal Film and after Diazepam Rectal Gel (N=28)<sup>6</sup>



Geometric mean Cmax for diazepam after DBF comparable to DRG, but less variable (P<0.0001)

Maximum Diazepam Plasma Concentration by Different Patient Weight Groups (N=28)<sup>6</sup>



Geometric mean Cmax for diazepam after DBF more consistent across different patient weight groups than DRG



## Clinical Superiority Based on Major Contribution to Patient Care

Libervant™ represents an orally delivered therapy that is positioned to meet one or more of criteria outlined by the FDA to be considered a major contribution to patient care, versus currently approved and device-driven rectal and nasal products. The criteria include 10:



✓ Convenience of treatment location



✓ Patient comfort

✓ Reduced treatment burden

Longer periods between doses

✓ Potential for selfadministration



## **C**AQST-108: Solving problems in ANAPHYLAXIS

- Sublingual film formulation of epinephrine for the treatment of anaphylaxis and severe allergic reactions
- Phase 1 dose escalation proof-of-concept study in healthy subjects demonstrated ability to deliver systemic epinephrine using proprietary PharmFilm® formulation
- At constructive pre-IND meeting held on February 4, 2020, FDA confirmed
  - o clinical development will be reviewed under the 505(b)(2) pathway as proposed by Aquestive
  - o no additional studies would be necessary prior to opening the proposed IND application
- Plan to file IND in 2Q2020 and commence PK trials before year end 2020
  - o Anticipate development program follow typical crossover study design

Affects up to of U.S. population 11

Increases
Emergency
Department
and hospital visits

Approximately
186<sup>to</sup>225
deaths per year<sup>12</sup>





### Suboptimal Treatment EpiPen®

- Difficult administration<sup>13</sup>
- Inaccurate dosing<sup>13</sup>
- Painful intramuscular injections<sup>13</sup>
- Inconvenient portability<sup>13</sup>





### **Financial Results and Cash Position**

- First quarter 2020 total revenues of \$8.8 million
- First quarter 2020 net loss was \$16.5 million, or \$0.49 loss per share
- Cash and cash equivalent of \$35.5 million at 3/31/20

### **Full Year 2020 Guidance**

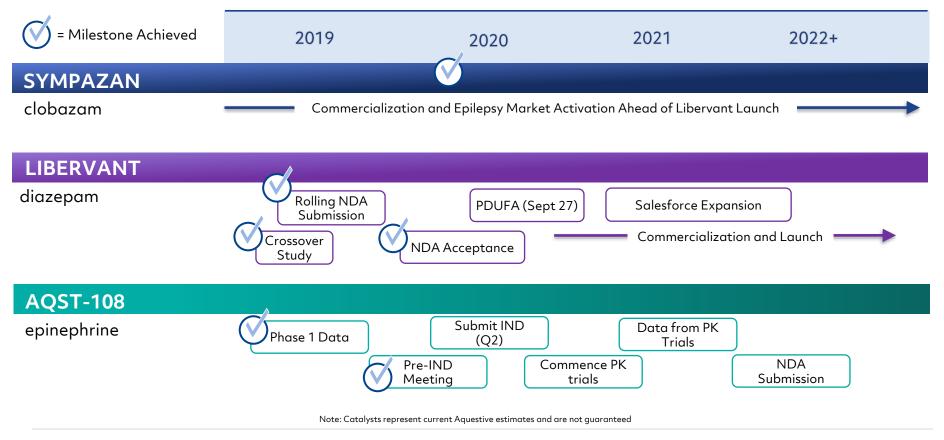
- Total revenues of approximately \$35 million to \$45 million
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
- Non-GAAP adjusted EBITDA loss of \$45 million to \$50 million
- Cash burn of approximately \$45 million to \$50 million

### **Capital Adequacy**

- Current capital position adequate into 2021
- Preparing to monetize apomorphine royalty for ~\$50 million to ~\$100 million after FDA approval of product
- Access to shelf registration

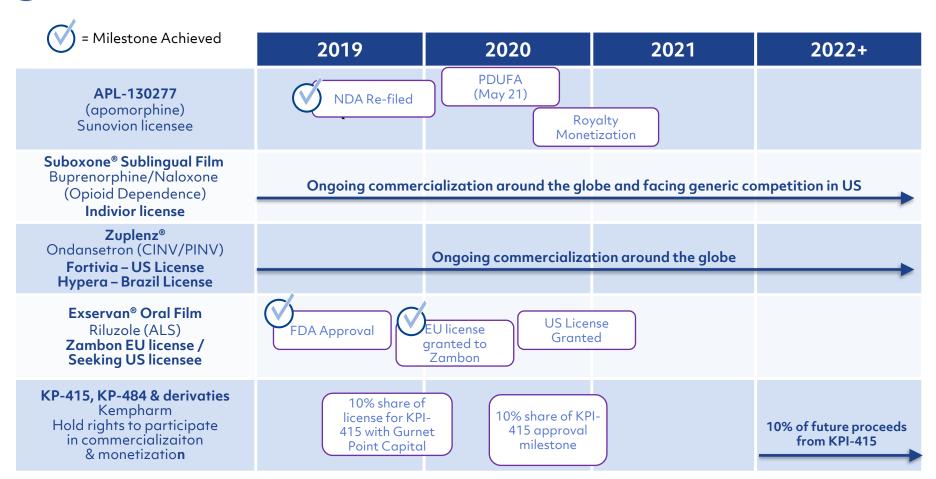


## Proprietary Pipeline: Upcoming Near-Term Catalysts





## Partnered Portfolio







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

Data on file

### LIBERVANT REFRACTORY SEIZURES (SLIDES 8-9)

- 1. Triangle Insights Group (2017). Synthesis of Epilepsy (ARS) Primary Research. Internal Aquestive report: unpublished.
- 2. Laxer, K. et al, The consequences of Refractory Epilepsy and its treatment; <u>Epilepsy & Behavior</u>; <u>Vol 37</u>, Aug 2014, Pgs 59-70; <a href="https://doi.org/10.1016/j.yebeh.2014.05.031">https://doi.org/10.1016/j.yebeh.2014.05.031</a>
- 3. Seizure visits to ED: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2657249/
- 4. Diastat administration and disposal instructions www.diastat.com
- 5. Valtoco instructions for use www.valtoco.com
- 6. Cereghino JJ. Identification and treatment of acute repetitive seizures in children and adults. Curr Treat Options Neurol 2007;9(4):249-255.
- 7. Penovich PE, Buelow J, Steinberg K, Sirven J, Wheless J. Burden of seizure clusters on patients with epilepsy and caregivers: survey of patient, caregiver, and clinician perspectives. Neurologist 2017;22(6):207-214.
- 8. Rogawski MA, et al. AES Poster. 2019.
- 9. Libervant under review by FDA
- 10. CFR Code of federal Regulations Title 21 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=316&showFR=1">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=316&showFR=1</a>

### **ANAPHYLAXIS (SLIDE 10)**

- 11. Turner P, Jerschow E, et al. Fatal Anaphylaxis: Mortality Rate and Risk Factors. J Allergy Clin Immunol Pract. 2017 Sep-Oct; 5(5): 1169–1178.
- 12. od, R., Camargo, et al Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States. J ALLERGY CLIN IMMUNOL VOLUME 133, Ma L, Danoff TM, Borish L. Case fatality and population mortality associated with anaphylaxis in the United States. J Allergy Clin Immunol. 2013;133(4):1075-83. doi: 10.1016/j.jaci.2013.10.029
- 13. EpiPen how to use https://www.epipen.ca/en/about-epipen/how-to-use







Advancing medicines. Solving problems. Improving lives.