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): September 25, 2020

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.

On September 25, 2020, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing the receipt of a complete response letter from the U.S. Food and Drug Administration (FDA) for Libervant™ (diazepam) buccal film for management of seizure clusters. A copy of the Company's press release is attached hereto as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

As announced in the press release, the Company will be holding a conference call today, September 25, 2020, at 7:00 p.m. to discuss the FDA's decision. A copy of the Company's slide presentation and FAQs for use during the conference call are attached hereto as Exhibits 99.2 and 99.3, respectively, and incorporated into this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibits 99.1, 99.2 and 99.3) is being furnished pursuant to Item 7.01 and 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	Press Release, dated September 25, 2020, announcing receipt of a complete response letter from the U.S. Food and Drug Administration (FDA) for Libervant™ (diazepam) buccal film for management of seizure clusters.
99.2	Slide presentation for use during conference call to be held on September 25, 2020.
99.3	FAQs for use during conference call to be held on September 25, 2020.

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: September 25, 2020

Aquestive Therapeutics, Inc.

By: /s/ John T. Maxwell
Name: John T. Maxwell
Title: Chief Financial Officer

Aquestive Therapeutics Receives Complete Response Letter from FDA for Libervant™ (diazepam) Buccal Film for Management of Seizure Clusters

- Complete Response Letter cites exposure levels (Cmax) in certain weight groups
- No additional clinical studies anticipated by Aquestive
- No Clinical Safety issues or Non-Clinical Chemistry, Manufacturing and Controls (CMC) issues identified
- Conference call and webcast today at 6:30 p.m. ET

Warren, NJ, September 25, 2020 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, announced today that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) regarding the New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film for management of seizure clusters. The FDA issues a CRL to indicate that the review cycle for an application is complete but the application cannot be approved in its current form.

In the CRL, the FDA cited that, in a study submitted by the Company with the NDA, certain weight groups showed a lower drug exposure level than desired. The Company intends to provide to the FDA additional information on PK modeling to demonstrate that dose adjustments will obtain the desired exposure levels. There were no other safety, clinical pharmacology/biopharmaceutics or CMC issues identified in the CRL. The FDA did cite a small number of protocol deviations in blood draws in one of the studies in the NDA. The Company believes, based on discussions with the FDA, that the Company will not need to conduct any further clinical studies in order to cure the items cited in the CRL, and will confirm that view in its upcoming follow-up meeting with the FDA.

Based on interactions with the Agency, the Company believes that this CRL will not be a barrier to ultimate approval, as the CRL was limited to providing additional information on PK modeling for an adjusted dosing regimen for a limited subset of patient weight categories. The Company plans to request a Type A meeting with the FDA in the coming weeks and to resubmit the NDA prior to the end of 2020 with the adjusted dosage regimen for the identified weight groups at issue. A submission before the end of the year should result in a PDUFA Action Date in the 1st half of 2021. The Agency did not include any indication regarding approval of U.S. market access for Libervant at this time.

"While we are surprised by and disappointed with the Agency's decision, we remain committed to continuing to work with the FDA toward approval of Libervant to provide epilepsy patients with the first orally administered treatment for breakthrough and seizure clusters," said Keith J. Kendall, President and Chief Executive Officer of Aquestive. "We look forward to quickly scheduling a meeting with the FDA to solidify Libervant's path forward and in-turn move toward the NDA resubmission before year's end. Epilepsy patients have been underserved for some time with little choice beyond device-based products such as rectally administered gels and nasal sprays and Libervant represents a meaningful and improved therapy for patients who can't or won't use the alternatives. We believe that the Company will be able to provide the necessary data to the FDA to allow for Libervant's approval," concluded Mr. Kendall.

Conference Call on September 25, 2020 at 6:30 p.m. ET
The Company will host a conference call today, September 25, 2020 at 6:30 p.m. to discuss the FDA's decision. To access the conference call dial (866) 417-5886 from the U.S. and (409) 217-8235 internationally, followed by the conference ID: 3205078. The Company has prepared FAQs and other materials for discussion during the conference call which have been filed today under a Form 8-K filed with the United States Securities and Exchange Commission. A live webcast and these materials will be available on the Investors section of the Company's website at https://investors.aquestive.com/events-and-presentations. The webcast and these materials will be archived for 30 days.

About Libervant
Libervant™ is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for rapid treatment of acute uncontrolled seizures in selected, refractory patients with epilepsy on stable regimens of AEDs who require intermittent use of diazepam to control bouts of increased seizure activity. Aquestive is developing Libervant as an alternative to Diastat (diazepam rectal gel), the current standard of care rescue therapy for patients with refractory epilepsy which as, a rectal gel, is invasive, inconvenient, and difficult to administer. As a result, a large portion of the patient population does not receive adequate treatment or foregoes treatment altogether. The Company believes that Libervant will enable a larger share of these patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures.

About Aquestive Therapeutics
Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. Aquestive is advancing a late-stage proprietary product pipeline to treat CNS conditions and 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
This press release 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 LibervantTM, ability to cure the deficiencies 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, timing of FDA review and approval of Libervant, pathways, clinical trials, and plans for approval of Libervant, our and our competitors' orphan drug approval and resulting drug exclusivity for Libervant or products of our competitors. 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 ability to obtain FDA approval and advance Libervant, AQST-108 and our other product candidates to the market, 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 any potential monetization of royalty and other revenue stream of KYNMOBI (apomorphine) and of sufficiency of net proceeds of any such monetization after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable; 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 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 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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Aquestive
Libervant Complete Response Letter Update
September 2020
Advancing medicines.
Solving problems.
Improving lives.

The Libervant development program has fully characterized the behavior of buccally-administered diazepam

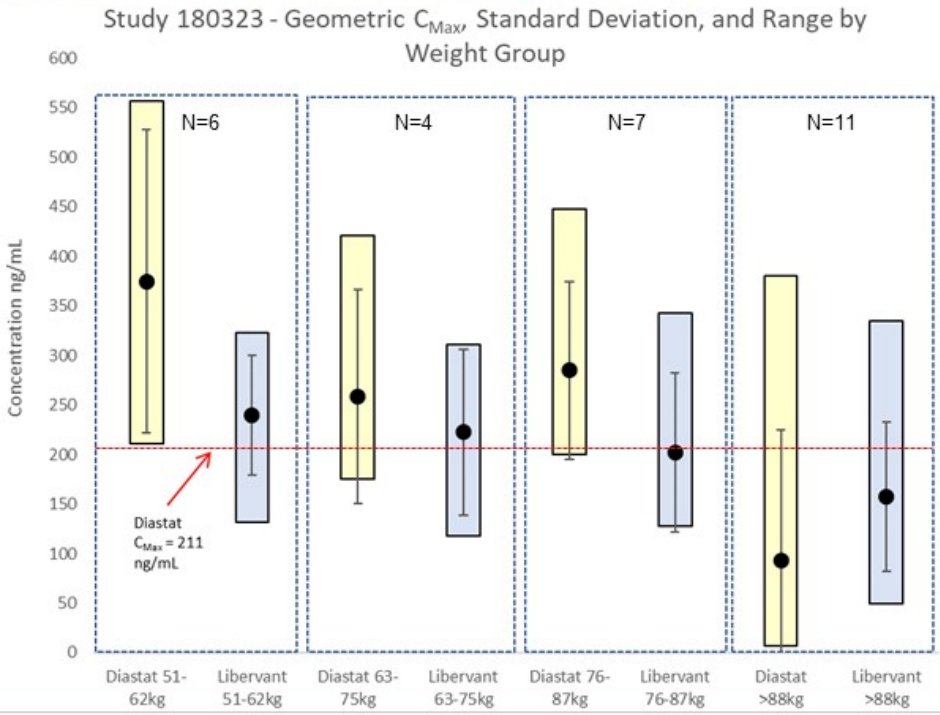
Study Description	Study Number
Comparative bioavailability profile to Diastat in healthy volunteers	Study 1899 Study 1900 Study 162021 Study 162022 Study 172018
Dose proportionality/ Linear pharmacokinetic (PK) behavior of Libervant	Study 162013
Effect of Seizure State on Libervant PK	Study 160326
Comparative bioavailability profile to Diastat in patients	Study 180323
Long term safety profile, >1100 exposures	Study 42-1703

The Libervant Complete Response Letter (CRL) is focused solely on Study 180323

- While the FDA acknowledged that the overall Cmax geometric mean ratio (GMR) of Libervant versus Diastat in Study 180323 was comparable, some patients in two weight groups showed lower C_{max} 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)
- The FDA is concerned that the C_{max} for patients in those weight groups are too low
- The FDA also noted that, also in Study 180323, 4 subjects in the weight groups noted above and 1 additional subject in the 63-75 kg weight group had a median C_{max} level that was approximately half of the median Diastat level (180 ng/mL vs. 375 ng/mL respectively)
- The FDA also noted protocol deviations on a small number of blood draws in a limited number of subjects for timepoints at 3 days or later
- No other concerns were cited in the CRL
- Aquestive plans to request a Type A meeting early in Q4

Libervant demonstrates consistent PK performance, while staying within the observed range of the RLD, across the weight groups

Study 180323: A Randomized, Open-Label Crossover Study to Evaluate the Pharmacokinetics of Single Doses of Diazepam Buccal Film (DBF) Compared with Diastat Rectal Gel in Adult Subjects on a Concomitant Regimen of Antiepileptic Drugs (AED) for the Treatment of Epilepsy



Aquestive

The linear PK profile allows the prescriber to adjust dose with predictable impact (C_{max})

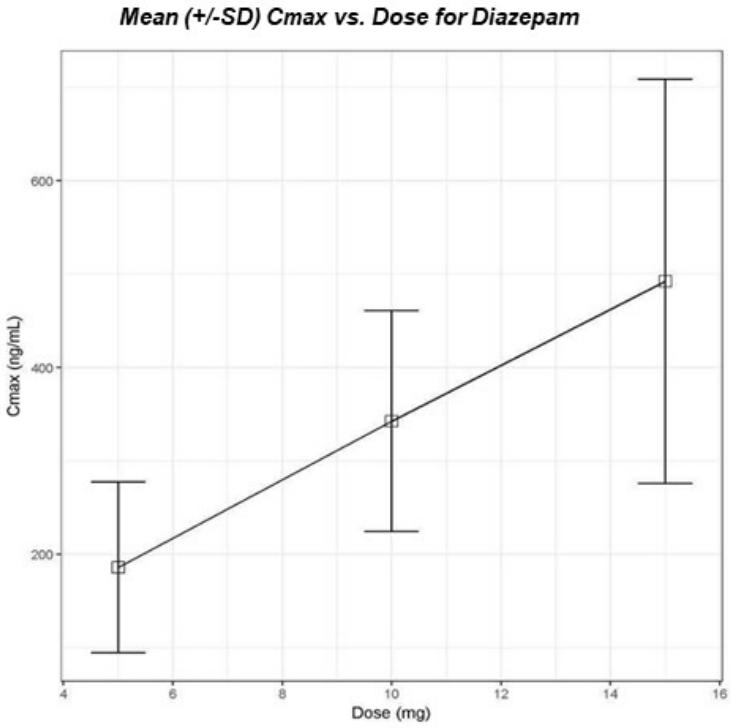


Figure 14.2.2-38a, Study 162013

Aquestive

LIBERVANT CRL Dated September 25, 2020

Frequently Asked Questions

What is a Complete Response Letter (CRL)?

- The FDA issues a CRL to indicate that the review cycle for an application is complete and that the application contains deficiencies that must be cured prior to approval.
- A sponsor who has received a CRL has the opportunity to submit additional information to the FDR for consideration of approval of a New Drug Application.

What is the content of the CRL for Libervant?

- The FDA cited that, in 5 subjects in two weight groups in our NDA Study 180323, there were lower absorption rates indicated in 2 out of 7 weight categories and that it seeks an increase in exposure in both weight groups before Libervant can be approved.
- At the overall study level, the FDA acknowledged that Libervant achieved comparable absorption rates (Cmax) when compared to Diastat (diazepam rectal gel)
- The FDA also noted protocol deviations in Study 180323 in a small number of blood draws in a limited number of patients for timepoints of 3 days or later
- There were no other safety, clinical pharmacology/biopharmaceutics, CMC or non-clinical issues identified in the CRL.

What is Aquestive's action plan to address the issues raised by the FDA in the CRL?

- The Company intends to provide to the FDA additional information on PK modeling to demonstrate that relatively minor adjustments to dosing in these two weight categories will reach the desired exposure levels.

- We expect this model to be completed within the next few weeks, and shortly thereafter the Company will request a Type A meeting with the FDA to review our proposed NDA re-submission.

- As reference on page [4] of the slide materials included in this Form 8-K, weight categories 51-62 kg and 76-87 kg are moderately lower at the mean, although less variable, than the same weight categories in Diastat. These weight categories will be re-modeled at modestly higher dosage levels in order to more closely align with the mean of the weight categories of Diastat, the RLD.

- Due to the dose-linearity of Aquestive's PharmFilm®, the required dosing adjustments are easily modeled and manufactured.

- We expect this Type A meeting to occur during the fourth quarter of this year.

- The Company believes that it will not need to conduct any further clinical studies to cure the items cited in the CRL, although this has not been confirmed by the FDA. We will confirm this in the Type A meeting.

- We expect to be ready to re-submit our NDA immediately following the Type A meeting.

- We expect the FDA will grant a 6-month review, implying a PDUFA Action Date in the first half of 2021.

- We will strongly request a 2-month review in our dialogue with the FDA but there is no guarantee that we will receive a 2-month review.

How long will it take Aquestive to address the issues and re-file its NDA on Libervant?

- We expect the dosing modeling to be completed in the next few weeks, and shortly thereafter the Company will request a Type A meeting with the FDA to review our proposed NDA re-submission.

- We expect this Type A meeting to occur during the fourth quarter of 2020.

- We will be ready to re-submit the NDA immediately following the Type A meeting.

- We expect the FDA will grant a 6-month review, implying that the PDUFA action date will be moved to the second quarter 2021.

- We will strongly request a 2-month review in our dialogue with the FDA but there is no guarantee that we will receive a 2-month review.

Is it possible the FDA will require additional clinical studies before re-submission?

- While it is possible, the Company believes, based on its extensive dialogue with the FDA review team prior to receiving the CRL, that its resubmitted PK modeling data showing the appropriate dosing change and increased exposure in the two identified weight ranges will be sufficient to approve the NDA for Libervant and that it will not need to conduct any further clinical studies in order to cure the deficiencies cited in the CRL, although this has not been confirmed by the FDA. We will confirm this in the Type A meeting that we expect to take place in the fourth quarter of 2020.

What communications has the Company had with the FDA?

- Aquestive has had extensive dialogues with the FDA throughout the development and review of Libervant.

- The Company had discussions with the FDA when the FDA raised questions about this data and the Company submitted additional information that it believed would respond to the Agency's questions.

- Although the FDA did not accept this additional information as dispositive, our conversations with the Agency were constructive, and we believe these conversations support our view that we will be able move forward using our PK model-based dosing adjustments rather than conducting additional clinical trials. We will confirm this view with the FDA in our next meeting with the FDA.

How much will the additional work to re-submit the NDA cost and does that change the company's outlook or cash runway?

- Given that we believe no clinical trials will be required and the cost of the PK modeling is modest, there is no change to our previously issued guidance.

Do the comments in the CRL impact our development plan for AQST-108?

- This CRL has no impact on our AQST-108 development plan.

Has AQST seen this issue in other PharmFilm development programs?

- Each development program is unique and we have not encountered this specific issue in previous development programs.

Did the Agency address orphan drug exclusivity and market access for Libervant to Aquestive in the interactions with the Company or in the CRL?

- During these interactions with the FDA and in the CRL, the Agency did not provide any guidance on its approval for U.S. market access to Libervant. We do not expect any guidance from the FDA on this topic until the FDA provides a decision on approval for Libervant.

- We believe that Libervant provides a material contribution to patient care when compared to the currently approved medications in the market based on a number of factors including significant patient preference for an orally delivered buccal film over a device-based rectal or nasal alternative.

How does Libervant clinical data compare to the referenced listed drug, Diastat?

- We have provided relevant Diastat data in the Form 8-K filed with the SEC today and during our teleconference that relates to the variability and absorption rates (Cmax), demonstrating that Libervant's mean absorption levels in all weight categories are higher than publicly available data shows for Diastat as the referenced listed drug, and that Libervant's variability is lower than this product.

- We believe this comparison demonstrates that, after resubmitting the dosing levels in the two relevant weight groups identified in the CRL, we are in a favorable position to see Libervant approved.

- Aquestive's clinical submission included over [1,100] dosings in epileptic and healthy volunteers, with very strong treatment outcomes overall including comparability to Diastat, the RLD; and zero non-responders which is unlike Diastat.

Other possible questions not directly related to Libervant approval:

Does this delay change your view of the peak revenue outlook for Libervant?

Does the change in dosing levels in certain weight categories change the marketability of the product once approved?

Can you provide an update on the Kynmobi monetization?

Is Aquestive changing any of its marketing plans for Sympazan given the delay in Libervant's approval and launch?

Can you provide an update on the AQST-108 pilot PK trial? Have you seen any data to-date?

- In this update, we are entirely focused on the Libervant CRL, and we are not updating on other aspects of the Aquestive business.
- Further updates will be provided in the future as appropriate including during our third quarter business and earnings update in early November.
