UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. AQUESTIVE THERAPEUTICS, INC., KEITH J. KENDALL, and JOHN T. MAXWELL, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff ____ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through

Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Aquestive Therapeutics, Inc. ("Aquestive" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Aquestive securities between December 2, 2019 and September 25, 2020, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Aquestive was founded in 2004 and is headquartered in Warren, New Jersey. Aquestive is a specialty pharmaceutical company that focuses on identifying, developing, and commercializing various products to address unmet

medical needs. The Company's most advanced proprietary product candidate is Libervant (diazepam), a buccal soluble film formulation of diazepam for the treatment of recurrent epileptic seizures.

3. On December 2, 2019, Aquestive announced the completion of the rolling submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for Libervant Buccal Film for the management of seizure clusters (the "Libervant NDA").

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) data included in the Libervant NDA submission showed a lower drug exposure level than desired for certain weight groups; (ii) the foregoing significantly decreased the Libervant NDA's approval prospects; (iii) as a result, it was foreseeable that the FDA would not approve the Libervant NDA in its current form; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On September 25, 2020, Aquestive announced receipt of a Complete Response Letter ("CRL") from the FDA indicating that the review cycle for the Libervant NDA was complete but the application could not be approved in its current form. Specifically, Aquestive advised investors that "[i]n 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."

6. On this news, Aquestive's stock price fell $2.64 per share, or 34.69%, to close at $4.97 per share on September 28, 2020.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

10. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Aquestive is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

11. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

12. Plaintiff, as set forth in the attached Certification, acquired Aquestive securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Aquestive is a Delaware corporation with principal executive offices located at 30 Technology Drive, Warren, New Jersey 07059. Aquestive securities trade in an efficient market on the Nasdaq Global Market ("NASDAQ") under the symbol "AQST."

14. Defendant Keith J. Kendall ("Kendall") has served as Aquestive's Chief Executive Officer at all relevant times.

15. Defendant John T. Maxwell ("Maxwell") has served as Aquestive's Chief Financial Officer at all relevant times.

16. Defendants Kendall and Maxwell are sometimes referred to herein as the "Individual Defendants."

17. The Individual Defendants possessed the power and authority to control the contents of Aquestive's SEC filings, press releases, and other market

communications. The Individual Defendants were provided with copies of Aquestive's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Aquestive, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

18. Aquestive and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

19. Aquestive was founded in 2004 and is headquartered in Warren, New Jersey. Aquestive is a specialty pharmaceutical company that focuses on identifying, developing, and commercializing various products to address unmet medical needs. The Company's most advanced proprietary product candidate is Libervant (diazepam), a buccal soluble film formulation of diazepam for the treatment of recurrent epileptic seizures.

20. On December 2, 2019, Aquestive announced the completion of the rolling submission of the Libervant NDA to the FDA.

Materially False and Misleading Statements Issued During the Class Period

21. The Class Period begins on December 2, 2019, when, during pre-market hours, Aquestive issued a press release touting that "the completion, as planned, of the rolling submission of a[n] [NDA] to the [FDA] for its therapeutic candidate Libervant™ (diazepam) Buccal Film for the management of seizure clusters." That press release also quoted Defendant Kendall, who touted, in relevant part:

> We are very pleased to have completed our NDA filing for Libervant as we had committed. We look forward to sharing the results from the single dose crossover study at the upcoming American Epilepsy Society 2019 Annual Meeting. We believe these results confirm our dosing algorithm and satisfy the final clinical requirement requested by the FDA [. . .] We believe that Libervant has the potential to be the first oral therapy approved by the FDA for the management of seizure clusters in the population of 1.2 million refractory epilepsy patients and the first diazepam based treatment usable by and delivering a consistent predictable dose to virtually all patients to whom it will be prescribed.

22. On January 10, 2020, Aquestive issued a press release entitled, "Aquestive Therapeutics Exceeds Top End of Guidance Range for Preliminary Unaudited Full Year 2019 Total Revenues and Provides Initial Full Year 2020 Guidance." The press release stated, in relevant part:

> "In addition to exceeding the top end of our revenue guidance, we achieved significant milestones, as promised, in 2019. First, we completed our rolling submission of the New Drug Application (NDA)

> for our therapeutic candidate Libervant™ (diazepam) Buccal Film for the management of seizure clusters to the U.S. Food and Drug Administration (FDA) in November 2019. [. . .] These milestones establish a path forward in 2020 to advance our pipeline and commercial opportunities," said Keith J. Kendall, Chief Executive Officer of Aquestive. [. . .] We anticipate current capital and revenues from monetization of our rights in APL-130277, subject to approval by the FDA, to fully support our commercial activities, the expected launch of Libervant, the continued development of AQST-108 and the identification, investigation and development of additional product candidates."

23. On February 10, 2020, Aquestive issued a press release announcing the FDA's acceptance of the Libervant NDA, stating, in relevant part:

> Aquestive [. . .] announced today that, as anticipated, the [FDA] accepted the Company's [NDA] for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of September 27, 2020. If approved by the FDA, Libervant will be the first oral diazepam-based therapy approved for management of seizure clusters in the population of 1.2 million refractory epilepsy patients. Libervant was designated by the FDA as an orphan drug in November 2016.
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> "The FDA filing acceptance for Libervant is an important milestone in our mission to provide epilepsy patients with a broader array of treatment options, that represent major contributions to patient care," said Keith J. Kendall, Chief Executive Officer of Aquestive. "Aquestive is committed to helping people affected by seizure clusters through bringing important and innovative products to the market. Epilepsy patients have been underserved for some time with little choice beyond device-based products such as rectally administered gels and nasal sprays. We believe that our drug candidate Libervant will, if approved by the FDA, represent a major contribution to patient care, as compared to available treatment options, and further expand patient choice as the first orally administered dosage form available to manage seizure clusters in epilepsy patients."

> "The FDA has recently indicated that, when evaluating clinical superiority for drugs demonstrating a 'major contribution to patient care,' it may consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration," continued Mr. Kendall. "We look forward to working with the FDA in the coming months in seeking to demonstrate why we believe that our product candidate Libervant, as an orally delivered product for this indication, has one or more of the attributes required by the FDA to be considered a major contribution to patient care relative to the currently approved products."

24. On March 11, 2020, Aquestive filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2019 (the "2019 10-K"). In discussing the Company's strategies, the 2019 10-K stated, in relevant part:

> We are a patient-centric pharmaceutical company developing and commercializing products that address unmet needs and improve the lives of patients and their caregivers. We focus on developing medicines for patient populations suffering from the shortcomings of available treatment options, which can create an opportunity for differentiated medicines. Our pipeline is initially focused on developing treatments for CNS diseases, as well as orally administered complex molecules that we believe can be alternatives to invasively administered standard of care therapies. Our strategy leverages our global intellectual property portfolio, know-how, demonstrated research and development capabilities and proprietary manufacturing platform.
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> To achieve these goals, our strategy includes the following key elements:
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> - ***Advance our late stage proprietary portfolio of CNS product candidates to solve critical healthcare problems and make a meaningful improvement in the lives of patients and caregivers***.

> We have focused development efforts on three proprietary CNS products, two of which have been approved and one product candidate in development. These products and product candidates address treatment challenges associated with epilepsy and ALS. [. . .] We completed the rolling submission for our NDA filing with the FDA for our drug candidate Libervant, with a PDUFA goal date of September 27, 2020. A competitor was approved for a diazepam nasal product in January 2020 and was granted orphan exclusivity. As described in more detail above under "Our Product Portfolio and Pipeline" and below under "Competition", we believe and intend to seek to demonstrate to the FDA that our product candidate Libervant is clinically superior to the two existing approved products utilizing the same active moiety in that it represents a major contribution to patient care when compared to device driven rectal and nasal applications, although there can be no assurances that we will be successful.

(Emphasis in original.)

25. Further, in describing the Company's Proprietary CNS Product Candidate, the 2019 10-K stated, in relevant part:

> We are developing Libervant, which has been designated an orphan drug and received a PDUFA goal date of September 27, 2020, as an alternative to currently approved diazepam products in the form of a rectal gel and a recently approved nasal spray, the latter of which received orphan drug market exclusivity for this drug. It is anticipated that Libervant, if approved by the FDA, will enable a portion of the patient population who do not receive adequate treatment or forego treatment altogether to receive an alternative treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. As a first oral product available utilizing this active moiety for this indication, we believe, and we intend to seek to demonstrate to the FDA that, Libervant is clinically superior in that it represents a major contribution to patient care for this group of patients within the meaning of the FDA regulations and guidance. The FDA has recently indicated that, when evaluating clinical superiority for drugs demonstrating a "major contribution to patient

care," it may consider, where appropriate, such factors as convenience of treatment location, duration of drug administration, longer periods between doses, and potential for self-administration. On January 10, 2020, a competitor of Aquestive obtained FDA approval of its diazepam nasal spray drug candidate and was granted orphan-drug-exclusivity for this drug commencing as of January 10, 2020. A company that obtains FDA approval for a designated orphan drug receives orphan market exclusivity for that drug for the designated indication for a period of seven years from the grant date in the United States. This orphan drug exclusivity approval may prevent a subsequent product seeking FDA approval from being marketed in the United States during the exclusivity period for the same active moiety for the same orphan drug indication except in the case where the drug candidate sponsor is able to demonstrate, and the FDA concludes, that the later drug is "clinically superior" to the approved products, e.g., safer, more effective, or providing a major contribution to patient care within the meaning of FDA regulations and guidance. In assessing whether a drug candidate sponsor has demonstrated that its drug candidate provides a "major contribution to patient care" over and above the currently approved drugs, which is evaluated by the FDA on a case by case basis, there is no one objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration. We believe that our product candidate Libervant is "clinically superior" to the two currently FDA-approved products with the same moiety and for the same indication as Libervant, as qualifying as "a major contribution to patient care" within the meaning of the FDA regulation and guidance. However, such a demonstration to overcome such seven-year market exclusivity is difficult to establish with limited precedents and there can be no assurance that we will be successful in these efforts. Any failure to obtain FDA approval of and to demonstrate clinical superiority for Libervant would have a material adverse effect on our business, financial condition and results of operations in 2021 and later.

26. Appended to the 2019 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 by the Individual Defendants, attesting

that "the information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the [2019 10-K] and the results of operations of the Company for the period covered by the [2019 10-K]."

27. Corresponding with the 2019 10-K, Aquestive issued a press release entitled, "Aquestive Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Business Highlights." The press release stated, in relevant part:

> "Following the FDA's acceptance of our NDA in February, our drug candidate, Libervant™ (diazepam) Buccal Film, the first oral diazepam-based therapy for management of seizure clusters, is advancing through the FDA review process and has been assigned a September 27, 2020 PDUFA goal date. We believe that Libervant, if approved by the FDA, will potentially provide a major contribution to patient care to epilepsy patients who can benefit from another rescue medication. We look forward to working with the FDA in the coming months in seeking to demonstrate that Libervant, as the only orally delivered diazepam-based product for this indication, has one or more of the attributes required by the FDA to be considered a "major contribution to patient care," within the meaning of FDA regulations and guidance, relative to the currently approved products. Although FDA approval of Libervant cannot be assured, we remain committed to helping epilepsy patients affected by seizure clusters by working to bring important innovative products to the market."

28. On March 12, 2020, Aquestive hosted an earnings call with investors and analysts to discuss the Company's Q4 2019 results (the "Q4 2019 Earnings Call"). During the scripted portion of the Q4 2019 Earnings Call, Defendant Kendall stated, in relevant part:

> We believe that we can demonstrate why Libervant as an orally delivered product for this indication has one or more of the attributes required by the FDA to be considered a major contribution to patient care relative to the currently approved and device-driven rectal and nasal products. We believe the Libervant will potentially contribute up to $300 million in peak net revenues within three to four years post launch.
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> Over one million patients in the U.S. have active uncontrolled epilepsy and a need for rescue medication. Less than 10% of these patients are successfully treating their seizures with the current standard of care, a rectal gel application of diazepam. A medicine is only as good as its ability to be used by patients where they need it, when they need it and in a form they accept. And we strongly feel that Libervant represents this type of improvement to patient care as compared to device-driven alternatives.
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> That said, we cannot ignore the potential risk to the timing of a Libervant launch based on the FDA's actions in January. We have an accepted filing for a product with a very strong value proposition, and we believe that we can demonstrate to the FDA that Libervant is clinically superior to the currently approved alternatives.

29. Further, when asked a question regarding the Company's confidence in Libervant's contribution to patient care and its eligibility for orphan drug exclusivity, Defendant Kendall responded, in relevant part:

> For Libervant, there are many paths for us to follow that we think get us to approval and market access. We don't think there's any scenario that keeps us out of the market for the period -- the seven-year period of the exclusivity that the agency granted to VALTOCO earlier in the year. The path that we are currently focused on is demonstrating that we are clinically superior as a major contribution to patient care.
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> The agency was very clear in their writing to us about the criteria that they use to consider what is a major contribution to patient care. We believe at the end of the day that Libervant will be able to demonstrate that against the two device-driven alternatives available to people based

> on diazepam for this indication. But their criteria includes patient comfort, convenience of treatment, treatment location, reduced treatment burden, ease and comfort of drug administration and potentially for self-administration.

30. Finally, when asked whether the Company had contingency plans in place should the FDA disagree with Aquestive's assessment of Libervant's clinical superiority, Defendant Kendall responded, in relevant part:

> We do have multiple paths because clinical superiority is defined in three ways from the agency's perspective. You can be superior from an efficacy standpoint, you can be superior from a safety standpoint or you can be superior from a material contribution to patient care standpoint. We think all of those paths are available to us.
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> We feel strongly about the strength of Libervant versus those two device-based existing products and how it will perform in patients. But as we said, we're focused on using the current application and demonstrating major contribution to patient care.

31. On May 5, 2020, Aquestive issued a press release announcing the Company's financial and operating results for the first quarter of fiscal year 2020. That press release touted, in relevant part:

> At this time, Aquestive continues to produce therapies as expected and our R&D labs continue to advance key pipeline therapies including Libervant™ (diazepam) Buccal Film for the management of seizure clusters, and AQST-108 sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis. We are continuing to interact with the FDA and responding, as expected, to information requests by the FDA related to our NDA filing for Libervant."

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- Aquestive is engaging as expected with the FDA related to its [NDA] for Libervant, including continuing information requests from the review teams, leading up to the September 27, 2020 Prescription Drug User Fee Act (PDUFA) goal date. Aquestive is seeking to demonstrate to the FDA that Libervant will, if approved by the FDA for marketing in the U.S., represent a "major contribution to patient care" within the meaning of FDA regulations and guidance as compared to currently available treatment options, and further expand patient choice as the first orally delivered and non-device driven diazepam-based therapy available to manage seizure clusters in epilepsy patients especially for patients who may not be able to effectively use nasal sprays due to nasal congestion, irritation or seasonal allergies.

32. On May 7, 2020, Aquestive hosted an earnings call with investors and analysts to discuss the Company's Q1 2020 results (the "Q1 2020 Earnings Call"). During the scripted portion of the Q1 2020 Earnings Call, Defendant Kendall stated, in relevant part:

> We're completing the data analysis and will provide the findings to the FDA to further support the NDA currently under review. We're seeking to demonstrate to the FDA that Libervant, if approved for marketing in the U.S., would represent a major contribution to patient care within the meaning of FDA regulations and guidance as compared to the currently available device-dependent treatment options, and would further expand patient choice as the first orally administered product available for its proposed indication.
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> As we have shared, the FDA provided us the following criteria that it may consider when it evaluates clinical superiority for drugs demonstrating a major contribution to patient care. Convenient treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses and the potential for self-administration.

> We believe that we can demonstrate to the FDA why Libervant, as an orally delivered product for this indication, has one or more of these attributes quoted by the FDA to be considered a major contribution to patient care relative to currently approved rectal and nasal products. Currently we are also examining how nasal sprays can be used during bouts of seasonal allergies and/or common cold.
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> We have an accepted filing for a product with a very strong value proposition, and we believe that we can demonstrate to the FDA that Libervant is clinically superior to the currently approved alternatives. We will continue to be thoughtful and prudent about our choices, recognizing we may not successfully overcome the orphan drug exclusivity here.

33. Further, when asked a question regarding Aquestive's discussions with the FDA regarding Libervant and the possibility that it would be kept out of the market, Defendant Maxwell responded, in relevant part:

> We continue to believe that there is no way that Libervant will be shut out of the market for the exclusivity period granted to the recently approved me nasal spray. There are multiple paths that we can choose to go down to get to that access.
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> Some are more expedient than others. And what we're doing is attacking this in what we think are the most expedient ways while preparing, secondarily, as we always do for an eventuality of a decision perhaps that we were not anticipating. So our level of confidence, our level of belief and expectation has not changed. We believe strongly that this represents a major contribution to patient care, that it is clinically superior to the alternatives. And we're pursuing that with all the vigor that we can.

34. On August 4, 2020, Aquestive issued a press release entitled, "Aquestive Therapeutics Reports Second Quarter 2020 Financial Results and

Provides Business Update: AQST-108 Progress Remains On Track; Libervant PDUFA Goal Date Approaches." The press release stated, in relevant part:

> ["]Concurrently, we are continuing to advance through the FDA review process for our product candidate, Libervant™ (diazepam) Buccal Film for the management of seizure clusters, including providing information to the agency, responding to its information requests and working with the agency on its inspection of our manufacturing and clinical investigational sites. With the commercial foundation we have built for Sympazan, we will be prepared to launch Libervant quickly, if approved by the FDA for U.S. marketing access. The formal process for a potential monetization of our KYNMOBI royalty asset is ongoing."

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- Aquestive is engaging as expected with the FDA related to its New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. The review to date has progressed with our providing information to the agency, responding to its information requests and working with the agency on its inspections of the Company's manufacturing and clinical investigational sites. The Company expects that it will continue to have exchanges with the FDA as the September 27, 2020 Prescription Drug User Fee Act (PDUFA) goal date approaches. Aquestive is seeking to demonstrate to the FDA that Libervant will, if approved by the FDA for marketing in the U.S., represent a "major contribution to patient care" within the meaning of FDA regulations and guidance as compared to currently available treatment options, and further expand patient choice as the only orally delivered and non-device driven diazepam-based therapy available to manage seizure clusters in epilepsy patients. Although we cannot assure FDA approval of Libervant for U.S. marketing access, we remain committed to helping epilepsy patients affected by seizure clusters by working to bring innovative products to the market.

35. On August 5, 2020, Aquestive hosted an earnings call with investors and analysts to discuss the Company's Q2 2020 results (the "Q2 2020 Earnings Call"). During the scripted portion of the Q2 2020 Earnings Call, Defendant Kendall stated, in relevant part:

> [. . .] Aquestive continues to work with the FDA in seeking approval of Libervant. We have been providing information responding to their information requests and working with the agency on inspections of our manufacturing and clinical sites. In our view, there have been no surprises in their questions or during the inspections to date.
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> ***
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> As we have said before, we anticipate that Libervant, if approved for US marketing access, would represent a potential $300 million net revenue stream for the company at its peak.
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> We are seeking to demonstrate to the FDA that Libervant will, if approved, for US marketing access represent a major contribution to patient care within the meaning of the FDA regulations and guidance as compared to currently available device driven based treatment operations. Libervant would also expand patient choice as the first orally delivered diazepam-based product available to manage seizure clusters.
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> We believe we can demonstrate to the FDA why Libervant as an orally delivered product has one or more of the attributes required by the FDA to be considered a major contribution for patient care.

36. The statements referenced in ¶¶ 21-35 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational

and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) data included in the Libervant NDA submission showed a lower drug exposure level than desired for certain weight groups; (ii) the foregoing significantly decreased the Libervant NDA's approval prospects; (iii) as a result, it was foreseeable that the FDA would not approve the Libervant NDA in its current form; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

37. On September 25, 2020, during after-market hours, Aquestive announced receipt of a CRL from the FDA regarding the Libervant NDA. The press release stated, in relevant part:

> 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.

38. On this news, Aquestive's stock price fell $2.64 per share, or 34.69%, to close at $4.97 per share on September 28, 2020.

39. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

40. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Aquestive securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

41. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aquestive securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Aquestive or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

42. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

43. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

44. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Aquestive;

- whether the Individual Defendants caused Aquestive to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Aquestive securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

45. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

46. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Aquestive securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Aquestive securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

47. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

48. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

49. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

50. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

51. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Aquestive securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Aquestive securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

52. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or

issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Aquestive securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Aquestive's finances and business prospects.

53. By virtue of their positions at Aquestive, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

54. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Aquestive, the Individual Defendants had knowledge of the details of Aquestive's internal affairs.

55. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Aquestive. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Aquestive's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Aquestive securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Aquestive's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Aquestive securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

56. During the Class Period, Aquestive securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Aquestive securities at prices

artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Aquestive securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Aquestive securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

57. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

58. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

59. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

60. During the Class Period, the Individual Defendants participated in the operation and management of Aquestive, and conducted and participated, directly and indirectly, in the conduct of Aquestive's business affairs. Because of their senior positions, they knew the adverse non-public information about Aquestive's misstatement of income and expenses and false financial statements.

61. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Aquestive's financial condition and results of operations, and to correct promptly any public statements issued by Aquestive which had become materially false or misleading.

62. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Aquestive disseminated in the marketplace during the Class Period concerning Aquestive's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Aquestive to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Aquestive within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Aquestive securities.

63. Each of the Individual Defendants, therefore, acted as a controlling person of Aquestive. By reason of their senior management positions and/or being directors of Aquestive, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Aquestive to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Aquestive and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

64. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Aquestive.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.