UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

___, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. AQUESTIVE THERAPEUTICS, INC. and DANIEL BARBER, Defendants.	Case No. **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Demand for Jury Trial

Plaintiff ___ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Aquestive Therapeutics, Inc. ("Aquestive" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Aquestive's public documents, earnings calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the Defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Aquestive securities between June 16, 2025 to January 8, 2026, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information pertaining to the timeline for approval and launch for Aquestive's New Drug Application (NDA) for Anaphylm (Dibutepinephrine) sublingual film. Defendants' statements included, among other things, confidence in the Company's NDA submission and optimistic claims that Anaphylm would be approved by the Prescription Drug User Fee Act (PDUFA) date, January 31, 2026.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true state of Aquestive's NDA for Anaphylm; pertinently, Aquestive concealed or otherwise minimized the significance of the human factors involved in the use and deployment

of its sublingual film, such as packaging, use, administration, and labeling. Such statements absent these material facts caused Plaintiff and other shareholders to purchase Aquestive's securities at artificially inflated prices.

4. The truth emerged on January 9, 2026, when Aquestive announced that the Company was in receipt of a letter from the FDA identifying deficiencies that precluded labeling discussions for Anaphylm. Moreover, Aquestive revealed that the letter from the FDA confirmed that the Agency's review of Anaphylm NDA was ongoing and no final decision had been made, which effectively delayed the approval of Anaphylm well beyond the January 31, 2026 PDUFA date.

5. Investors and analysts reacted immediately to Aquestive's revelation. The price of Aquestive's common stock declined dramatically. From a closing market price of $6.21 per share on January 8, 2026, Aquestive's stock price fell to $3.91 per share on January 9, 2026, a decline of over 37% in a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

7. The claims asserted herein arise under and pursuant to §§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).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Aquestive's offices are located in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District, including but not limited to the transmission of public statements to the market from Aquestive's offices in Warren, New Jersey.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased Aquestive common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Aquestive is attached hereto.

12. Aquestive Therapeutics, Inc. is a Delaware corporation with a principal executive office located at 30 Technology Drive, Warren, NJ 07059 through which

the Company frequently communicates with investors. During the Class Period, the Company's common stock traded on the Nasdaq Global Select Market (the "NASDAQ") under the symbol "AQST."

13. Defendant Danniel Barber ("Barber") was, at all relevant times, the Chief Executive Officer, President, and Director of Aquestive.

14. Defendant Barber is sometimes referred to herein as the "Individual Defendant." Aquestive together with the Individual Defendant are referred to herein as the "Defendants."

15. The Individual Defendant, because of his position with the Company, possessed the power and authority to control the contents of Aquestive's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. The Individual Defendant was provided with copies of the Company's reports 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 cause them to be corrected. Because of his position and access to material non-public information available to them, the Individual Defendant knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendant is liable for the false statements pleaded

herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendant.

16. Aquestive is liable for the acts of the Individual Defendant, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

17. The scienter of the Individual Defendant, and other employees and agents of the Company are similarly imputed to Aquestive under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

18. Aquestive is a pharmaceutical company committed to advancing medicines to bring improvement to patients' lives through innovative science and delivery technologies.

19. Aquestive's main focus is treatments for anaphylaxis and epilepsy. One of the Company's key pharmaceuticals is its Anaphylm allergic reaction treatment.

The Defendants Materially Misled Investors Concerning

the Timeline for Anaphylm

June 16, 2025

20. On June 16, 2025, Aquestive published a press release announcing FDA acceptance of New Drug Application (NDA) and Prescription Drug User Fee Act (PDUFA) date for Anaphylm for the treatment of severe allergic reactions. CEO Barber stated, in pertinent part:

> Anaphylm represents a breakthrough in anaphylaxis treatment, if approved by FDA, being the first and only device-free, orally delivered epinephrine medicine. We designed Anaphylm to fit seamlessly into the patient's daily life. It's thinner than a credit card and requires no special storage, so patients can keep it in their phone case, wallet, or pocket – Anaphylm can go everywhere you go, without the bulk of even the smallest FDA-approved device for this patient population.
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> Our clinical data demonstrates Anaphylm's ability to rapidly deliver epinephrine absorption orally. With the FDA's acceptance of our NDA, we're one step closer to getting this life-saving innovation in the hands of the patients and caregivers who need it most.

August 11, 2025

21. On August 11, 2025, Aquestive reported second quarter 2025 financial results. As part of the press release, CEO Barber stated, in relevant part:

> The second quarter marked a pivotal step forward for our Company with the FDA's acceptance of our NDA for Anaphylm which, if approved by the FDA, will be the first and only oral, sublingual film epinephrine product. As we advance preparations for a potential U.S. launch in 2026, we are also laying the groundwork for global expansion with initial regulatory engagements now underway with Canada and the EU. With regulatory progress on track, we remain focused on execution

> across clinical, commercial, and operational fronts, and continue to evaluate all available paths to bring Anaphylm to global markets efficiently and effectively, as we have done with other Aquestive products. I'm proud of our momentum and confident in our ability to bring forward a solution that makes epinephrine emergency treatment more accessible, portable, and patient-friendly.

August 12, 2025

22. On August 12, 2025, Aquestive hosted an earnings call associated with the Company's second quarter 2025 earnings release. CEO Barber stated in pertinent part:

> We are now less than 6 months away from our FDA action date for Anaphylm epinephrine sublingual film, potentially the first and only oral product for the treatment of severe allergic reactions, including anaphylaxis. As a reminder, our action date is scheduled for January 31, 2026. I'm pleased to tell you this morning that we are on track across the important elements of Anaphylm. We are on track in our FDA review process, our Anaphylm advisory committee preparations, which may or may not occur, and our pre-commercial launch activities. We are on track in responsibly securing launch financing for the company, and we are on track in our international expansion efforts for Anaphylm.
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> Let's start with the FDA review of our Anaphylm application. We recently submitted our 120-day safety update to the FDA. I'm pleased to say that there was nothing new or of consequence to report in this safety update. We also believe the FDA is about to conclude its mid-cycle review. While we do not participate in this review, we would expect to have more clarity on whether we will have an advisory committee meeting once the FDA has fully processed its mid-cycle review meeting.

23. As part of the earnings call, Aquestive management participated in a question-and-answer segment with analysts in attendance. In pertinent part:

<Q: Jason Nicholas Butler – Citizens JMP Securities – Analyst> Two for me. First one, you mentioned that you submitted the 120-day safety update. Just wondering if there has been any other substantial data analysis or information request from FDA during the review so far? And then second, on the commercial prep, you talked about the reimbursement piece. Can you also just talk about the work you've done to increase awareness of Anaphylm, and where you think you've -- whether or not you've moved the needle there?

<A: Daniel Barber – CEO> Jason, good to hear your voice. So on the first one, we have had the usual back and forth with the FDA that you would expect to date. There is nothing that I would describe as a major data set or anything to that standpoint beyond the standard 120-day safety update.

November 5, 2025

24. On November 5, 2025, reported third quarter 2025 financial results. As part of the press release, CEO Barber stated, in relevant part:

> The third quarter was another period of strong execution for Aquestive as we move closer to the launch of Anaphylm, if approved by the FDA. The FDA's decision not to convene an Advisory Committee further advances our regulatory path, and our NDA remains on track for the scheduled January 31, 2026 PDUFA goal date. We are fully engaged in U.S. launch preparations, continuing to build commercial readiness across distribution, medical affairs, and marketing channels, while also advancing regulatory discussions in Canada and the EU. Following our recently completed equity financing and strategic funding commitments, we believe we are well positioned to deliver on our mission to make epinephrine emergency treatment more accessible, portable, and patient-friendly.

November 6, 2025

25. On November 6, 2025, Aquestive hosted an earnings call associated with the Company's third quarter 2025 earnings release. CEO Barber stated in pertinent part:

> As we approach our FDA scheduled action date of January 31 for Anaphylm, we are well positioned from an allergist awareness perspective. In case anyone hasn't been paying attention, Anaphylm, if approved by the FDA, will be the first and only oral medication for the treatment of severe allergic reactions including anaphylaxis. Today, health care providers, caregivers and patients must choose between two types of medical devices: auto-injectors and nasal sprays. We believe our portability, low barrier to use and fast absorption profile creates a transformational offering for the allergy community.
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> Following our equity raise and strategic financing agreement that we announced this past August, our prelaunch activities have accelerated and remain on track for a first quarter 2026 launch if Anaphylm receives FDA approval. Our marketing materials are ready to go and are only awaiting a final label. We are in the process of hiring our district managers and will hire sales reps upon FDA approval. Our market access team is in full swing and interacting with payers under acceptable preapproval guidelines. Our supply chain is prepared to rapidly produce material once final labeling has been provided by the FDA. And importantly, our medical affairs team is fully deployed, as you heard from my opening statements, regarding this week conference. Simply put, we are ready to go.
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> Now let's turn to the FDA. Given the government shutdown, we requested the FDA to provide us with a status update on the review timing of our filings. I am pleased to say that as of this last update, the FDA confirmed they are aiming for an on-time review of our application. As we reported to you in September, the FDA has informed us that we will not have an Advisory Committee meeting. However, we remain ready to provide further information if necessary to the FDA reviewers. We will keep everyone appropriately updated as we learn more and as we get closer to our action date.

26. As part of the earnings call, Aquestive management participated in a question-and-answer segment with analysts in attendance. In relevant part:

> <Q: Andreas Argyrides – Oppenheimer – Analyst> We'll go with a couple from us, not just the one that you guys suggested. So how are the current launch dynamics with neffy informing your initial commercialization strategy? Particularly, what are some of the tools you can use to create awareness? Are you considering DTC? And then in your dialogue with the FDA, can you remind us what components of the data they are focused on and key considerations for approval? And then lastly, given the product profile, how should we think of scripts per patient per year? Is it multipack? I'll stop there.
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> * * *
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> <A: Daniel Barber – CEO> Got you. I thought we were giving you questions. How about that. That was news to me. I think that was more trying to manage the time. But Andreas, of course, happy to answer your questions and spend time with you. So let me take a couple of those. In terms of awareness, I will hand that over to Sherry in a minute here.
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> In terms of where the FDA has been focused, it has -- and just to remind everyone, we have 6 FDA approvals in our past. So when you go through the FDA approval process, there's a cadence, there's a pace, there's a feel. And you look for the questions to come from a variety of areas. And that's what we're seeing here that the different functions in the FDA are doing their jobs, completing their checklists and asking us the questions you would expect. So that feels really good.
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> <A: Denis Reznik - Raymond James – Analyst> This is Denis Reznik on for Gary Nachman. So you recently announced two new patents for Anaphylm. Can you just talk more about them and how important these

two specifically are for the overall patent portfolio? And then on supply chain, assuming an on-time approval, how quickly could you get drug into channel? And then how quickly can you get the first prescription filled?

And then if I could just squeeze in one more. Regarding the uncertainty at the FDA that we've been hearing about recently, can you just mention if there's been any high-level individuals that are involved in your review that have been either replaced or have moved on?

<A: Daniel Barber – CEO> Sure. Thanks, Denis. Good to hear your voice. So in terms of the patents, yes, we had two new patents issued just over a month ago. And both of those patents are focused on the ability to gain absorption and then rapid release of epinephrine cleavage of -- enzymatic cleavage of epinephrine back into its native form. So we believe those are significant Orange Book listable patents. When we're approved, that will be very expansive in blocking for the product. So definitely fundamental to our position.

From a supply chain perspective, look, there's a little bit of work that has to happen, right, when you get approval. So you have to work on the final label, get all the pieces and parts together. We have a great supply chain component of our business. It does go to the core of where we've come from as an organization. I think you know we manufacture in-house. So that will be something we're very ready for and will allow us to have supply in the channel in Q1.

And then the third question, the uncertainty at the FDA, I'm actually -- thank you, Denis, for bringing it up. I'm actually, I guess, pleasantly surprised that we got this far into the Q&A before that question came up. Clearly, the FDA is going through some pains. From our perspective, our review group has remained the same. We did -- as you heard in my prepared comments at the beginning, we've heard from our project manager that our application is not affected. Obviously, we saw the Head of CDER left over the weekend. But from our perspective, the leadership at CDER is more of just a sign-off on our application than an active reviewer. So we continue to believe we're in good shape on that front.

[Emphasis added].

27. The above statements in Paragraphs 20 to 26 were false and/or materially misleading. Defendants created the false impression that Aquestive was on track to receive approval for the Company's New Drug Application (NDA) for Anaphylm by the January 31, 2026 PDUFA date. In contrast, the FDA identified deficiencies with Aquestive's NDA for Anaphylm precluding labeling discussions and post-marketing commitments. In order for the FDA to grant approval for any NDA, any deficiencies must be remedied, therefore the launch of Anaphylm was delayed, indicating that Aquestive failed to obtain approval for Anaphylm by the PDUFA date.

The Truth Emerges

January 9, 2026

28. On January 9, 2026, Aquestive published a press release announcing a regulatory development for Anaphylm. In particular, the Company disclosed that it was in receipt of an FDA letter identifying deficiencies that preclude labeling discussions for Anaphylm at this time. CEO Barber stated, in pertinent part:

> As part of its ongoing review of the Company's NDA for Anaphylm, the FDA notified us that it had identified deficiencies in the NDA that preclude discussion of labeling and post-marketing commitments at this time. Although the notification did not specify the deficiencies, Aquestive is working to understand and resolve the concerns. The FDA stated that the notification does not reflect a final decision on the pending application and the FDA's review remains ongoing.

> While we await further information from the FDA, we remain confident about Anaphylm and its potential to be the first and only FDA-approved sublingual film. Designed to be easy-to-use, fast-acting, and highly portable, we continue to believe Anaphylm represents a major step forward for people living with severe allergies. We are advancing our global expansion of Anaphylm with plans to submit for regulatory approval in Canada, Europe, and the United Kingdom in 2026. We believe our long-term growth strategy remains compelling with the potential approval and subsequent launch of Anaphylm in the U.S. and around the world. With the recent equity raise and our current cash position, we also believe that we have the necessary capital to execute on our current growth strategy.

29. The aforementioned press releases and statements made by the Individual Defendant or otherwise about the Company are in direct contrast to their public statements made during the Class Period. In those releases and calls, Defendants continually touted the Company's expectation that Aquestive's NDA for Anaphylm was on track for approval. Particularly, Aquestive stated on multiple occasions that management was in contact with the FDA, that Aquestive was familiar and comfortable with the FDA approval process, and did not indicate any reason to be concerned that the January 31, 2026 PDUFA date could not be met.

30. Investors and analysts reacted immediately to Aquestive's revelation. The price of Aquestive's common stock declined dramatically. From a closing market price of $6.21 per share on January 8, 2026, Aquestive's stock price fell to $3.91 per share on January 9, 2026, a decline of over 37% in a single day.

31. A number of well-known analysts who had been following Aquestive lowered their price targets in response to Aquestive's disclosures. For example, on January 9, 2026, Cantor published a report lowering Aquestive's price target to $8 from $15. The report stated, in pertinent part:

> While there are multiple unknowns, foremost being the exact deficiencies, the history of CRLs following similar letters increases the risk of a potential delay for Anaphylm.

32. Similarly, on January 12, 2026, Oppenheimer published a report detailing concerns regarding Aquestive's NDA for Anaphylm given the FDA's January 9, 2026 letter, in relevant part:

> Aquestive's (AQST) announcement that the FDA has flagged unspecified deficiencies in the review of the NDA puts Anaphylm at risk of CRL ahead of 1/31/2026 PDUFA. Disappointingly, the deficiencies currently preclude labeling/postmarketing commitment discussions. We view the Agency's late communication as a meaningful setback and believe the stock is currently pricing in a CRL, the most likely scenario playing out (we think), similar to SPRY (neffy), ASND (Yorvipath) which led to 12-15-month approval delays. The best case scenario would be a potential major amendment to the NDA, causing a ~3-month delay that allows FDA to review additional data/proceed with labeling. In a 3rd scenario, Anaphylm's product profile could face more uncertainty depending on FDA's consideration of the Citizen Petition, potentially sending shares below cash (~$1/sh).

33. The fact that these analysts, and others, discussed the FDA's regulatory update and the delays likely to be caused by its issuance suggests the public placed significant weight on Aquestive's prior statements of confidence in the regulatory timeline for Anaphylm. The frequent, in-depth discussion of Aquestive's New Drug

Application for Anaphylm and the weight placed on the regulatory timeline, including the January 31, 2026 PDUFA date, confirms that Defendants statements during the Class Period were material.

Post-Class Period Disclosures

February 2, 2026

34. On February 2, 2026, Aquestive issued a press release announcing the issuance of an FDA Complete Response Letter (CRL) on January 30, 2026, for Anaphylm, a sublingual film formulation of dibutepinephrine. CEO Barber stated, in pertinent part:

> While it is unfortunate to have received a CRL, we believe that, with the clarity we now have from the FDA, we have made significant progress toward approval. We are encouraged that the issues in the letter are limited to human factors and a supportive PK study, once human factors are addressed, and we noted several labeling comments that will inform the final label for Anaphylm, if approved by the FDA. We remain confident in the effectiveness and safety of Anaphylm and its potential as an easy-to-use, easy-to-carry, fast-acting epinephrine treatment. We look forward to working with the FDA to achieve approval for Anaphylm. Our commitment to bringing this innovative therapy to the allergy community remains steadfast.

35. The press release published by Aquestive also detailed the contents of the CRL, as well as next steps, in relevant part:

> In the CRL, which focuses on administration and labeling guidance, the FDA cited deficiencies in the Anaphylm human factors (HF) validation study. These included instances of difficulty opening the pouch and incorrect film placement which, if unaddressed, the FDA believes could cause significant safety issues in the setting of anaphylaxis. To resolve the FDA's concerns, the Company has modified the pouch opening,

> instructions for use, pouch and carton labeling, and plans to rapidly conduct a new HF validation study with these modifications. The Company also plans to further address potential tolerability issues in its resubmission. Comparability data submitted as part of the Anaphylm NDA, such as bracketing, repeat dose, and sustainability, were not questioned in the CRL. There were also no CMC issues noted in the CRL.
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> Due to the requirements related to HF, clinical pharmacology requested a single pharmacokinetics (PK) study to understand the impact of any modifications to packaging and labeling. The Agency indicated that the HF and PK studies can be conducted in parallel. No additional studies were requested in the CRL.
>
> The Company plans to closely work with the Agency to achieve approval for Anaphylm as expeditiously as possible. As an initial step, the Company will request a Type A meeting with the FDA to discuss the most efficient path forward for resubmission. ***Based on its initial review of the CRL, the Company estimates resubmission in Q3 2026, assuming completion of the HF and PK studies and typical response times from the FDA.*** The Company plans to request rapid review by the FDA.

[Emphasis added].

36. Also on February 2, 2026, Aquestive hosted a Special Call addressing the CRL. CEO Barber stated, in pertinent part:

> Regardless, let me walk you through the feedback from the FDA's human factors group called the Division of Medication Error Prevention and Analysis or DMEPA. DMEPA is concerned that individuals will have trouble opening our pouch and may also tear the film while opening it. In our human factor validation study, only one individual did not open a pouch. This individual was a child, and it should be noted that we are currently using a child-resistant pouch. We had 6 instances of participants tearing a film while opening the pouch. All 6 instances resulted in the individuals fully dosing the torn film.

We also want to remind everyone that we have shipped over 2.5 billion doses of products to 5 continents over the last 15 years. And after digging deep into our product complaint data, we only found one complaint related to a film being potentially torn and no data on difficulty opening the pouch. Having said that, we have previewed a revised opening mechanism to the FDA, and believe use of this alternate opening will meet the needs of the FDA.

DMEPA is also concerned about film administration location and sites chewing of the film. I should point out that 4 individuals out of 166 in our human factors validation study were recorded as chewing the film. Of those 4 individuals, only 1 was provided with the instructions for use prior to dosing. In reviewing the study videos, it is clear the individuals did not read the instructions on the pouch. Revising the pouch to include pictures should improve administration in those who did not read the instructions. Either way, we believe epinephrine absorption will still occur in the oral cavity and gastrointestinal tract. We have also demonstrated through our clinical studies, that there is a wide range of acceptable placement for the film.

DMEPA pointed to tingling, burning and taste as potentially leading to premature removal of the film. At a top level, they refer to this as tolerability. Let's dive into this for a minute. In our 11 clinical studies, including pediatrics, we had 0 instances of film removal. In our human factors validation study, we had 4 participants who removed the film. None cited the reason is tingling, 2 cited taste and 2 cited a burning sensation. Keep in mind, these participants were in a low-risk, healthy environment and had no need for the medication.

As 1 of the 4 individuals said during the study, "I don't like the taste of mint. But if we had to save my life, I'd even leave the film in for 10 minutes." Regarding the burning sensation, one of these participants administered 2 doses sequentially in an effort to get through the simulation quickly. As I stated earlier, engagement from DMEPA would have allowed us to discuss and explain this data.

The FDA also provided us with a variety of labeling updates for our instructions for use and carton labeling. We were pleased to see labeling items in the CRL and we'll implement these in our revised submission. These label updates will be confirmed for their effectiveness in the

human factors validation study, the FDA is asking us to conduct. As of this morning, we have already designed the protocol, and we'll look to move this forward rapidly.

The other additional work needed is a simple, easy-to-perform pharmacokinetic study that ties to DMEPA's feedback about film placement. While we have already evaluated this and again, believe this is unnecessary and repetitive, we see no issue in performing this work and providing it to the clinical team. We can do much of this work in parallel to the human factors study. As a reminder, we previously conducted a PK study on the impact of swallowing the film.

So what does all of this mean for Aquestive and more importantly, for Anaphylm? Well, from my perspective, this CRL, while unfortunate and seemingly unnecessary, represents a major derisking event towards approval. We have a straightforward path to resubmission and expect to do so by the third quarter of this year. We will also work with the FDA to press for a rapid review and approval of Anaphylm once submitted to the FDA.

37. During the associated question-and-answer segment of the call, Aquestive's management responded to questions from analysts, in relevant part:

<Q: Roanna Clarissa H. Ruiz – Leerink – Analyst> A couple of questions from me. First one, could you talk a bit about the resubmission time line? And are there any gating factors that you definitely need to complete before that and when you're thinking about planning for it?

<A: Daniel Barber – CEO> Sure. Roanna, you said a couple of questions. Did you have another one? Or do you want me to answer that one first?

<Q: Roanna Clarissa H. Ruiz> My second one was bigger picture. Just thinking about Anaphylm's launch trajectory with the new potential approval time line, like how would you think about that going forward as well?

<A: Daniel Barber> Got you. Okay. Thank you. Thank you for the questions. In terms of the resubmission time line gating factors, as we laid out in the press release, the 2 things that we need to accomplish prior to resubmission are a human factors validation study and a single pharmacokinetic study using the revised instructions that were used in our human factors validation study. At this time, we see no other gating factors to getting to a resubmission.

In terms of the bigger picture in our launch trajectory, I'll turn that over to Sherry Korczynski, our Chief Commercial Officer, here in a second. What I would say is, if you look at the market right now, the vast majority of the market remains auto-injector, and we believe that will continue to be the case in 2026.

<Sherry Korczynski – CCO> Thanks, Dan. Roanna, yes, as Dan mentioned, the market continues to grow. And if we look at what has happened over the last 18 months, patients, caregivers, HCPs are looking for choice. And the vast majority does remain in epinephrine auto-injector. So as we look at it, our investment in commercial in 2025 will be relevant to our new time line. We will be absolutely commercial ready.

And just one aside, we've been going through rounds and rounds of market research over the last 3 to 4 months. And I have to share with you, seeing is really believing. When we send samples of -- our demos, excuse me, of Anaphylm as well as the other products on the market, when a patient sees, feels, touches Anaphylm as well as the other products, 96% of the time, patients are choosing Anaphylm. So we absolutely believe the market with continued growth will be ready for our launch when we do launch the product.

* * *

> <Q: François Daniel Brisebois - LifeSci Capital – Analyst> Okay. Great. And then, I guess, maybe the last one. I think Ram mentioned it, but the timing there, so you mentioned that based on the data that you have to present and all that, usually it would be 6 months than a competitor had it done in 4 months. Is that normal review? Or is that rapid review like you mentioned in the press release? Or like could it be more than 6 months, I guess, is my question?
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> <A: Daniel Barber – CEO> No, the most it would be 6 months, but the longest clock is 6 months.

Additional Scienter Allegations

38. During the Class Period, Defendants acted with scienter in that they knew or otherwise were deliberately reckless in not knowing that the public statements disseminated on behalf of Aquestive were materially false and misleading at the time they were made. Defendants had actual knowledge of, or access to, non-public information concerning Anaphylm's submission process and approval timeline, as well as the risks posed to approval. Despite such knowledge, Defendants repeatedly conveyed to investors that Anaphylm was on track for approval by the PDUFA date of January 31, 2026.

39. Furthermore, Defendants knew or deliberately disregarded that there were deficiencies with Aquestive's New Drug Application (NDA) for Anaphylm, which delayed the approval process for the drug. In particular, the FDA is unable to approve an NDA until deficiencies are resolved. Defendants knew or recklessly disregarded this when making overly confident statements pertaining to the timeline for approval and launch of Anaphylm.

Loss Causation and Economic Loss

40. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Aquestive's common stock and operated as a fraud or deceit on Class Period purchasers of Aquestive's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Aquestive's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Aquestive's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

41. Aquestive's stock price fell in response to the corrective event on January 9, 2026, as alleged *supra*. On January 9, 2026, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Aquestive's Anaphylm New Drug Application approval timeline.

42. In particular, on January 9, 2026, issued a press release announcing a regulatory development for Anaphylm. Specifically, the Company announced that it was in receipt of a letter from the FDA stating that the Agency identified deficiencies

in Aquestive's NDA for Anaphylm, ultimately delaying the drug's approval and Aquestive's ability to market Anaphylm.

Presumption of Reliance; Fraud-On-The-Market

43. At all relevant times, the market for Aquestive's common stock was an efficient market for the following reasons, among others:

a. Aquestive's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

b. Aquestive communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

c. Aquestive was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

d. Unexpected material news about Aquestive was reflected in and incorporated into the Company's stock price during the Class Period.

44. As a result of the foregoing, the market for Aquestive's common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Aquestive's stock price. Under these circumstances, all purchasers of Aquestive's common stock during the Class Period suffered similar injury through their purchase of Aquestive's common stock at artificially inflated prices, and a presumption of reliance applies.

45. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

46. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability

stems from the fact that they led investors to believe that Aquestive would be approved on or before the PDUFA date of January 31, 2026 by the FDA. Defendants provided the public with extensive plans to market and manufacture Anaphylm, which failed to account for the deficiencies identified by the FDA. In fact, Aquestive noted that the human factors would be easily resolved yet made no attempt to provide these solutions to the FDA during the NDA process.

47. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

48. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Aquestive who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic

performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

49. 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's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. 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.

50. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aquestive's common stock 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. As of November 3, 2025, there were approximately 122 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

51. 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.

52. 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.

53. 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:

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

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

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

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

e. whether the prices of Aquestive's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

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

54. 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.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

55. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

56. 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.

57. 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 common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Aquestive's securities

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.

58. 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's 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 the Company.

59. By virtue of their positions at the Company, 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.

60. 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 the Company, the Individual Defendant had knowledge of the details of Aquestive's internal affairs.

61. The Individual Defendant is liable both directly and indirectly for the wrongs complained of herein. Because of his positions of control and authority, the Individual Defendant was able to and did, directly or indirectly, control the content of the statements of the Company. As officer and/or director 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, intellectual property, 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's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Aquestive's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

62. During the Class Period, Aquestive's common stock was 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's common stock 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 common stock, 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's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Aquestive's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

63. 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.

64. 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 common stock

during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

65. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

66. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Aquestive's misstatements.

67. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Aquestive which had become materially false or misleading.

68. 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 the misrepresentations. Throughout

the Class Period, the Individual Defendant exercised his power and authority to cause Aquestive to engage in the wrongful acts complained of herein. The Individual Defendant therefore, was a "controlling person" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in the unlawful conduct alleged which artificially inflated the market price of Aquestive's common stock.

69. The Individual Defendant, therefore, acted as a controlling person of the Company. By reason of his senior management positions and/or being director of the Company, the Individual Defendant 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. The Individual Defendant exercised control over the general operations of the Company 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.

70. By reason of the above conduct, the Individual Defendant and/or Aquestive are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

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 representatives;

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 pre-judgment 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.

Dated: