



Aquestive Therapeutics Reports First Quarter 2026 Financial Results and Provides Business Update

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- *Reaffirms guidance to resubmit Anaphylm™ (dibutepinephrine) sublingual film NDA in Q3 2026*
- *Affirms existing clinical data is sufficient for submitting regulatory applications in Canada, European Union, and the United Kingdom*
- *Completed AQST-108 phase 1 study in subjects with androgenic alopecia with no safety issues observed*
- *Entered into a \$150 million debt facility with Oaktree Capital Management, L.P.*
- *Company to host investor call on May 14, 2026, at 8:00am ET*

WARREN, N.J., May 13, 2026 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive" or the "Company"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced financial results for the first quarter ended March 31, 2026, and provided a strategic business update.

"We made rapid and meaningful progress in the first quarter," said Daniel Barber, President and Chief Executive Officer of Aquestive. "We successfully completed our Type A meeting with the FDA, aligning on the study designs needed to support resubmission of the Anaphylm NDA, which we continue to target for the third quarter of 2026. In parallel, our commercial readiness efforts continue. We are making the most of this time by driving awareness of Anaphylm among healthcare professionals. We are building momentum for our AdrenaVerse™ platform and are excited by the recent results from our AQST-108 phase 1 study. Financially, we have taken steps to further strengthen our balance sheet and extend our cash runway, and we believe we are well-positioned to execute on our key objectives in 2026 and beyond."

Anaphylm™ (dibutepinephrine) sublingual film

Anaphylm is a no-needle, no-device epinephrine product candidate being developed for the treatment of Type I allergic reactions, including anaphylaxis. The Company believes Anaphylm has the potential to be the first and only non-invasive, orally delivered epinephrine product, if approved by the U.S. Food and Drug Administration (FDA).

In the first quarter of 2026, Aquestive successfully completed its Type A meeting with the FDA, aligning on the study designs for both the human factors validation and pharmacokinetics (PK) studies required to address the deficiencies identified in the Complete Response Letter (CRL) from the FDA dated January 30, 2026. The Company reaffirms its guidance to resubmit the Anaphylm New Drug Application (NDA) in the third quarter of 2026, subject to completion of the required studies and expected FDA response timelines. As previously disclosed, the CRL did not identify any chemistry, manufacturing, or controls (CMC) deficiencies, and clinical results supporting comparability to auto-injectors were not questioned. The Company will request an accelerated review upon resubmission, though no expedited review can be guaranteed.

In February 2026, Aquestive presented data at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting. Data presented demonstrated that Anaphylm achieved clinically relevant epinephrine plasma concentrations without the diastolic blood pressure dip associated with auto-injector administration, providing further clinical differentiation. Feedback from key opinion leaders (KOLs) and the broader allergy community continues to be positive, and physician enthusiasm for a non-invasive, non-device epinephrine treatment option remains strong.

Aquestive continues to advance its global regulatory strategy for Anaphylm. The Company remains on track to submit regulatory applications in Canada, the European Union and United Kingdom by utilizing its existing clinical data. The Company recently completed a meeting with the Medicines and Healthcare products Agency, which is the health regulatory agency for the United Kingdom. In addition, the Company submitted its initial Pediatric Investigation Plan (PIP) to the European Medicines Agency (EMA), an important step in preparing for full submission of the Company's Market Authorization Application for the European Union.

Aquestive has advanced its commercial infrastructure in preparation for a potential Anaphylm approval. The Company has expanded its planned field force to approximately 75 sales representatives - a 50% increase from its prior guidance of 50 representatives - better positioning the Company to reach patients and healthcare providers across the country. Current priorities include continued engagement with healthcare professionals through our recently expanded Medical Affairs team to increase Anaphylm awareness, market access preparation ahead of a potential approval, and active collaboration with leading patient

advocacy organizations in the allergy community.

AQST-108 (epinephrine) topical gel

AQST-108 is a topical epinephrine prodrug gel product candidate being evaluated for potential dermatologic indications. Aquestive made meaningful clinical development progress with AQST-108 in the first quarter of 2026. The Company recently completed its second phase 1 clinical trial, which was designed to further characterize the safety, tolerability, and pharmacologic profile of the topical epinephrine prodrug gel. There were no drug related adverse events observed in the study and the data did not indicate signs of systemic absorption. In addition, Aquestive identified a biomarker signal through the suppression of the cytokine thymic stromal lymphopoietin (TSLP) when compared to placebo. The TSLP signaling pathway involves the activation of Janus Kinase (JAK) 1 and JAK2. This signal will be explored further in upcoming studies.

Building on the IND opening and supportive FDA feedback received in December 2025, Aquestive continues to believe AQST-108 has potential application across a variety of dermatological conditions, including alopecia areata, atopic dermatitis, rosacea, and psoriasis. Aquestive plans to further study AQST-108 by utilizing an atopic dermatitis study design in the upcoming months. This disciplined, data-driven approach is consistent with the Company's strategy of maximizing the value of the AdrenaVerse™ platform while maintaining focus on the Anaphylm NDA resubmission.

Alopecia areata remains a significant unmet need, affecting an estimated 6.7 million people in the United States, with 43% classified as severe. JAK inhibitors, the current standard of care, are systemic agents carrying black box warnings in a market currently valued at over \$1 billion. AQST-108's topical, localized delivery profile may provide a differentiated option for these patients, if clinical development is successful.

Atopic dermatitis affects approximately 7%–10% of U.S. adults and 10–20% of children, making it one of the most common chronic inflammatory skin diseases in the U.S.

Aquestive's AdrenaVerse platform comprises approximately 20 epinephrine prodrugs designed to enable control of absorption and conversion rates across a range of dosage forms and delivery sites. The Company remains excited by the AdrenaVerse platform's long-term potential to address multiple indications.

Debt Refinancing

Aquestive entered into a new \$150 million debt facility with Oaktree Capital Management, L.P., a leading life sciences debt provider. Refinancing the Company's existing debt will save the Company \$45 million in principal payments over the next three years. Further, this new debt facility provides the Company with improved interest rate terms and principal payments that will not begin until maturity in 2031. In addition to the \$55.0 million provided at signing, Aquestive will have the ability to access \$20 million of capital in the event of FDA approval of Anaphylm. A third tranche of \$25.0 million will be available upon the achievement of specified sales milestones, with the final tranche of up to \$50.0 million available with the mutual consent of the lenders and the Company. This refinancing allows the Company to achieve one of the pre-approval requirements for Aquestive's \$75 million strategic funding agreement with funds managed by RTW Investments, LP. With the new debt facility and the strategic RTW funding agreement, the Company expects to have \$150 million in cash and cash equivalents for the launch of Anaphylm, if approved by the FDA in 2027.

Commercial Collaborations and Other

Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 33 million doses in the first quarter 2026, compared to approximately 27 million doses in the first quarter 2025. The Company continues to manufacture Indivior's Suboxone® Sublingual Film product and the Company's other global collaborations, including Sympazan® (clobazam) oral film product for Cosette Pharmaceuticals, Inc. in the U.S., Ondif® (Ondansetron) oral film product for Hypera Pharma in Brazil and Emylif® (riluzole) oral film product by Zambon S.p.A in Europe. Aquestive's manufacturing business remains steady.

On April 8, 2026, Cosette Pharmaceuticals, Inc. ("Cosette"), a United States-based, branded specialty pharmaceutical company, acquired the rights to Sympazan for the treatment of seizures associated with Lennox-Gastaut Syndrome in patients two years of age and older, from Assertio Holdings, Inc. ("Assertio"), including Assertio's rights under our License Agreement for Sympazan with Otter Pharmaceuticals, LLC, a subsidiary of Assertio (the "Assertio License Agreement"). Cosette will continue to purchase Sympazan® (clobazam) Oral Film Product and pay royalties and milestones to Aquestive under the Assertio License Agreement.

The Company, being a U.S. based manufacturer with intellectual property domiciled in the U.S., confirms that its supply chain currently remains largely unaffected by both implemented and proposed government tariffs, providing continued reliability and stability in production and global distribution for the near term.

Sales of royalty-based products, inclusive of Sympazan, contributed to the Company's revenue in the first quarter of 2025.

Libervant® (diazepam) buccal film remains tentatively approved until January 2027, the scheduled date of expiration of U.S. market orphan drug exclusivity of an FDA approved product of another company. Aquestive continues to believe that expanding patient access to non-invasive seizure rescue therapies is vital and remains committed to putting Libervant in the hands of patients when granted full approval for U.S. market access by the FDA.

First Quarter 2026 Financials

Total revenues increased to \$14.4 million in the first quarter 2026 from \$8.7 million in the first quarter 2025. The 66% increase

was primarily driven by increases in license and royalty revenue and increases in manufacture and supply revenue.

License and royalty revenue increased to \$5.4 million in the first quarter 2026 from \$0.8 million in the first quarter 2025, primarily due to royalty revenue from Zevra.

Manufacture and supply revenue increased to \$8.8 million in the first quarter 2026 from \$7.2 million in the first quarter 2025, primarily due to increases in Suboxone revenues, partially offset by lower Ondif revenues.

Research and development expenses decreased to \$4.2 million in the first quarter 2026 from \$5.4 million in the first quarter 2025. The decrease in research and development expenses was primarily due to lower clinical trial costs associated with the Anaphylm development program, partially offset by increases in R&D personnel costs.

Selling, general and administrative expenses decreased to \$11.0 million in the first quarter of 2026 from \$19.1 million in the first quarter of 2025. The decrease primarily represents the one-time Anaphylm PDUFA fee of \$4.3 million in the prior year period, lower legal fees of approximately \$3.4 million, lower commercial spending of approximately \$2.0 million, and lower regulatory and licensing fees of approximately \$0.5 million, partially offset by higher severance costs of approximately \$0.6 million, higher personnel costs of approximately \$0.5 million and higher share-based compensation expenses of approximately \$0.5 million.

Aquestive's net loss for the first quarter 2026 was \$8.1 million, or \$0.07 for both basic and diluted loss per share, compared to the net loss in the first quarter 2025 of \$22.9 million, or \$0.24 for both basic and diluted loss per share. The decrease in net loss was primarily driven by decreases in selling, general and administrative expenses and research and development expenses and increases in revenues, partially offset by decreases in interest income and other income, net.

Non-GAAP adjusted EBITDA loss was \$1.7 million in the first quarter 2026, compared to non-GAAP adjusted EBITDA loss of \$17.6 million in the first quarter 2025.

Cash and cash equivalents were \$110.7 million as of March 31, 2026.

2026 Outlook

Aquestive's full-year 2026 financial guidance remains unchanged.

The Company expects:

	<u>Guidance</u>
Total revenue (in millions)	\$46 to \$50
Non-GAAP adjusted EBITDA loss (in millions)	\$35 to \$30

Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. ET on Thursday, May 14, 2026.

In order to participate, please register in advance [here](#) to obtain a local or toll-free phone number and your personal pin.

A live webcast of the call will be available on Aquestive's website at: [First Quarter 2026 Earnings Call](#).

About Anaphylm™

Anaphylm™ (dibutepinephrine) sublingual film is a polymer matrix-based epinephrine prodrug product. Anaphylm is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The primary packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a pocket, and is designed to withstand weather excursions such as exposure to rain and/or sunlight. The Anaphylm trade name for AQST-109 has been conditionally approved by the FDA. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

About AQST-108

AQST-108 (epinephrine) topical gel is a topically delivered adrenergic agonist prodrug product candidate. Aquestive completed a first-in-human study for AQST-108 without any serious or topical adverse events observed. AQST-108 is based on Aquestive's AdrenaVerse™ platform which contains a library of over twenty epinephrine prodrug products intended to control absorption and conversion rates across a variety of possible dosage forms and delivery sites.

About Libervant®

Libervant® (diazepam) buccal film is a buccally, or inside of the cheek, administered film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy. Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products. The FDA approval for U.S. market access received in April 2024 for Libervant was for these epilepsy patients between two and five years of age. However, the FDA converted this approval to a "tentative approval" due to a subsequent court ruling finding that the FDA did not have authority to approve Libervant for U.S. market access for patients aged between two and five years due to the existing orphan drug market exclusivity granted by the FDA to an intranasal

spray of another company. The FDA granted tentative approval in August 2022 for Libervant for treatment of these epilepsy patients twelve years of age and older. U.S. market access for Libervant patients is currently subject to the expiration of the existing orphan drug market exclusivity of the previously FDA approved drug scheduled to occur in January 2027.

Important Safety Information

Do not give Libervant to your child between the ages of two and five if your child is allergic to diazepam or any of the ingredients in Libervant or has an eye problem called acute narrow angle glaucoma.

What is the most important information I should know about Libervant?

- **Libervant is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.** Get emergency help right away if any of the following happens:
 - shallow or slowed breathing,
 - breathing stops (which may lead to the heart stopping),
 - excessive sleepiness (sedation).

Do not allow your child to drive a motor vehicle, operate heavy machinery, or ride a bicycle until you know how taking Libervant with opioids affects your child.

- **Risk of abuse, misuse, and addiction.** Libervant is used in children 2 to 5 years of age. The unapproved use of Libervant has a risk for abuse, misuse, and addiction, which can lead to overdose and serious side effects including coma and death.
- **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including diazepam (the active ingredient in Libervant).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
 - **Your child can develop an addiction even if your child takes Libervant as prescribed by your child's healthcare provider.**
 - **Give Libervant exactly as your child's healthcare provider prescribed.**
 - Do not share Libervant with other people.
 - Keep Libervant in a safe place and away from children.
- **Physical dependence and withdrawal reactions. Libervant is intended for use if needed in order to treat higher than usual seizure activity. Benzodiazepines,** including Libervant, can cause physical dependence and withdrawal reactions, especially if used daily. Libervant is not intended for daily use.
 - **Do not suddenly stop giving Libervant to your child without talking to your child's healthcare provider.** Stopping Libervant suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures that will not stop (status epilepticus), sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, homicidal thoughts, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child gets any of these symptoms.
 - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning, or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - Physical dependence is not the same as drug addiction. Your child's healthcare provider can tell you more about the differences between physical dependence and drug addiction.
- Do not give your child more Libervant than prescribed or give Libervant more often than prescribed.

Libervant can make your child sleepy or dizzy and can slow your child's thinking and motor skills.

- Do not allow your child to drive a motor vehicle, operate machinery, or ride a bicycle until you know how Libervant affects your child.
- Do not give other drugs that may make your child sleepy or dizzy while taking Libervant without first talking to your child's

healthcare provider. When taken with drugs that cause sleepiness or dizziness, Libervant may make your child's sleepiness or dizziness much worse.

Like other antiepileptic medicines, Libervant may cause suicidal thoughts or actions in a small number of people, about 1 in 500.

- **Call a healthcare provider right away if your child has any of these symptoms, especially if they are new, worse, or worry you:**
 - thoughts about suicide or dying
 - new or worse depression
 - feeling agitated or restless
 - trouble sleeping (insomnia)
 - acting aggressive, being angry or violent
 - other unusual changes in behavior or mood
 - attempts to commit suicide
 - new or worse anxiety or irritability
 - an extreme increase in activity and talking (mania)
 - new or worse panic attacks
 - acting on dangerous impulses
- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your child's healthcare provider as scheduled.
- **Call your child's healthcare provider between visits as needed, especially if you are worried about symptoms.** Suicidal thoughts or actions can be caused by things other than medicines. If your child has suicidal thoughts or actions, your child's healthcare provider may check for other causes.

What are the possible side effects of Libervant?

- The most common side effects of Libervant are sleepiness and headache.
- These are not all the possible side effects of Libervant.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1 800 FDA-1088.

For more information about Libervant, talk to your doctor, and see Product Information: Medication Guide and Instructions For Use.

About Aquestive Therapeutics, Inc.

Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. The worldwide leader in delivering trusted, quality medications on oral film, Aquestive operates as both a developer of its own proprietary products and a Contract Development and Manufacturing Organization (CDMO) for licensees, with its headquarters in New Jersey and U.S.-based manufacturing facilities in Indiana. The Company is the exclusive manufacturer of four commercialized products marketed by its licensees across six continents using proprietary, best-in-class technologies like PharmFilm®. Aquestive's AdrenaVerse™ platform contains a library of more than 20 epinephrine prodrugs enabling the pursuit of various potential allergy and dermatological indications. The Company is advancing Anaphylm™ (dibutepinephrine) sublingual film for the treatment of severe allergic reactions, including anaphylaxis, and AQST-108 (epinephrine) topical gel for various potential dermatological conditions, including alopecia areata, atopic dermatitis and hypertrophic scars. For more information, visit Aquestive.com and follow us on LinkedIn.

Non-GAAP Financial Information

This press release and our webcast earnings call regarding our quarterly financial results contains financial measures that do not comply with U.S. generally accepted accounting principles (GAAP), such as non-GAAP adjusted EBITDA loss, non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses, non-GAAP adjusted costs and expenses and other adjusted expense measures, because such measures exclude, as applicable, share-based compensation expense, interest expense, interest expense related to the sale of future revenue, interest income, depreciation, amortization, and income taxes.

Specifically, the Company adjusts net loss for certain non-cash expenses, including share-based compensation expenses; depreciation and amortization; and interest expense related to the sale of future revenue, interest income and other income, net and income taxes, with a result of adjusted EBITDA loss. Similarly, manufacture and supply expense, R&D expense, and selling, general and administrative expense were adjusted for certain non-cash expenses of share-based compensation expense and depreciation and amortization. Adjusted EBITDA loss and these non-GAAP expense categories are used as a supplement to the corresponding GAAP measures to provide additional insight regarding the Company's ongoing operating performance.

These measures supplement the Company's financial results prepared in accordance with GAAP. Aquestive management uses these measures to analyze its financial results, and its future manufacture and supply expenses, gross margins, R&D expense and selling, general and administrative expense and to help make managerial decisions. In management's opinion, these non-GAAP measures provide added transparency into the operating performance of Aquestive and added insight into the effectiveness of our operating strategies and actions. The Company may provide one or more revenue measures adjusted for certain discrete items, such as fees collected on certain licensed products, in order to provide investors added insight into our revenue stream and breakdown, along with providing our GAAP revenue. Such measures are intended to supplement, not act as substitutes for, comparable GAAP measures and should not be read as a measure of liquidity for Aquestive. Adjusted EBITDA loss and the other non-GAAP measures are also likely calculated in a way that is not comparable to similarly titled measures reported by other companies.

Non-GAAP Outlook

In providing the outlook for non-GAAP adjusted EBITDA and non-GAAP gross margin, we exclude certain items which are otherwise included in determining the comparable GAAP financial measures. In order to inform our outlook measures of non-GAAP adjusted EBITDA and non-GAAP gross margin, a description of the adjustments which have been applicable in determining non-GAAP Adjusted EBITDA and non-GAAP gross margin for these periods are reflected in the tables below. In providing outlook for non-GAAP gross margin, the Company adjusts for non-cash share-based compensation expense and depreciation and amortization. The Company is providing such outlook only on a non-GAAP basis because the Company is unable to predict with reasonable certainty the totality or ultimate outcome or occurrence of these adjustments for the forward-looking period such as share-based compensation expense, income tax, amortization, and certain other adjusted items, which can be dependent on future events that may not be reliably predicted. Based on past reported results, where one or more of these items have been applicable, such excluded items could be material, individually or in the aggregate, to reported results.

Forward-Looking Statement

Certain statements in this press release include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the advancement and related timing of our product candidate Anaphylm™ (dibutepinephrine) sublingual film through clinical development and approval by the FDA, including our ability to address the concerns raised by the FDA in the CRL dated January 30, 2026 and the Type A meeting with the FDA, and the timing of our resubmission and FDA review of the NDA; the advancement and related timing of potential international regulatory filings and marketing authorizations for Anaphylm outside of the U.S.; that Anaphylm will be the first and only oral administration of epinephrine, if Anaphylm is approved by the FDA; the advancement, growth and related timing of our AdrenaVerse™ pipeline epinephrine prodrugs, including AQST-108 (epinephrine) topical gel, through clinical development and the FDA regulatory approval process, including with respect to the design and timing of clinical studies, including those necessary to support the targeted indication of alopecia areata, and potential other treatment indications for AQST-108; market access for Libervant® (diazepam) buccal film for epilepsy patients experiencing acute repetitive seizures (ARS) upon expiration of orphan drug market exclusivity of an approved FDA product of another company; the future commercial opportunity of Anaphylm, Libervant and AQST-108 should these product candidates be approved by the FDA; the potential benefits our product candidates could bring to patients, including with respect to Anaphylm, Libervant and AQST-108, if these product candidates are approved by the FDA, and acceptance by patients, prescribers and payors of our product candidates as an alternative to existing standards of care for the targeted medical indication of these product candidates; that the Company is sufficiently capitalized with sufficient cash in 2026 to perform the necessary clinical work and provide the additional information required to address the concerns of the FDA outlined in the CRL and Type A meeting; that our supply chain is largely unaffected by implemented and proposed government tariffs and will be reliable and stable in production and global distribution for the near term; our cash requirements, cash funding and cash burn; short-term and longer term liquidity, including access to additional funds if Anaphylm is approved by the FDA, and the ability to fund our business operations and key objectives in 2026 and beyond, including the launch of Anaphylm, if approved by the FDA; our growth and future financial and operating results and financial position, including with respect to our 2026 financial outlook; and business strategies, market opportunities, and other statements that are not historical facts. Such forward-looking statements also include statements regarding anticipated timelines, milestones, and guidance relating to regulatory submissions, clinical studies, regulatory interactions, and potential approvals, which are inherently uncertain and subject to change based on regulatory feedback, protocol alignment, data sufficiency, and other factors outside the Company's control.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans for Anaphylm and AQST-108; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates Anaphylm, Libervant and AQST-108, or failure to receive FDA approval at all of any or all of these product candidates; risk of the Company's ability to generate sufficient clinical and other human factor data, including with respect to our submission of pharmacokinetic and

pharmacodynamic (PK/PD) comparability data for FDA approval of Anaphylm; risks associated with our ability to address the FDA's comments on and identified deficiencies in our NDA, including the concerns raised by the FDA in the CRL and Type A meeting for Anaphylm, and whether the FDA may request further information from us (including additional clinical studies), disagree with our protocols, study designs, and findings or otherwise undertake a lengthy review of the resubmission of our NDA; challenges regarding the following commercial launch of Anaphylm, if approved by the FDA; risk of delays in advancement of the regulatory approval process of our product candidates, including Anaphylm and Libervant, outside of the U.S., or failure to receive approval at all of any or all of these product candidates by such foreign regulatory authorities; including risks that regulatory authorities outside the United States may require different, additional, or more extensive clinical, non-clinical, human factors, pharmacokinetic, or manufacturing data than anticipated, or may not accept data generated for U.S. regulatory purposes; risk of FDA inspections of manufacturing and clinical study sites for any of our product candidates, including Anaphylm, Libervant and AQST-108; risk of government shutdowns or actions to reduce government workforces on the ability of the FDA to act on a timely basis or at all on the approval of our product candidates, including Anaphylm, Libervant and AQST-108; risks associated with the success of any competing products, including generics; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of our product candidates, including Anaphylm, Libervant and AQST-108, if these product candidates are approved by the FDA; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product candidates, including Anaphylm, Libervant and AQST-108; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our debt and ATM facilities, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements to support our business operations, key initiatives and growth strategy, and other cash needs, at the times and in the amounts needed, and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, Libervant and AQST-108, should these product candidates be approved by the FDA, including risks that assumptions underlying projected cash runway, liquidity, and capital sufficiency may prove incorrect due to changes in operating plans, regulatory requirements, timing or scope of clinical activities, market conditions, or the availability, timing, and terms of financing; risk of the impact of our obligations under the Company's Purchase Agreement and the Royalty Rights Agreement with third parties, each of which agreements requires the Company to make payments to each counterparty thereof, respectively, of a portion of our revenues, on our ability to contribute to the funding of our operations; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates in the U.S. and abroad, including Anaphylm and Libervant, if such product candidates should be approved by the FDA and other regulatory authorities, and our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunset product, which accounts for a substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance in the U.S. and abroad of our product candidates, including Anaphylm, Libervant, and AQST-108 should these product candidates be approved by the FDA and other regulatory authorities, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets and expected related revenues and sales; risk associated with our compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office or, if issued, will be sufficient to provide long-term commercial success of these product candidates; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business, including relating to our products and product candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against us including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions, including due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and changing interest rates; risks related to the impact of pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine, Israel and Iran wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business, including imposition of government tariffs and other trade restrictions; and other uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

Libervant®, PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

Investor inquiries:

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AQUESTIVE THERAPEUTICS, INC.
Condensed Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 110,734	\$ 121,169
Trade and other receivables, net	6,867	17,763
Inventories	8,066	6,169
Prepaid expenses and other current assets	4,516	4,168
Total current assets	130,183	149,269
Property and equipment, net	3,839	3,893
Right-of-use assets, net	4,468	4,621
Other non-current assets	2,635	2,642
Total assets	\$ 141,125	\$ 160,425
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 11,889	\$ 29,862
Accrued expenses	3,449	5,029
Lease liabilities, current	662	631
Deferred revenue, current	1,092	1,092
Liability related to the sale of future revenue, current	1,000	1,000
Loans payable, current	13,661	9,994
Total current liabilities	31,753	47,608
Notes payable, net	25,099	27,519
Royalty obligations, net	26,914	25,941
Liability related to the sale of future revenue, net	62,083	62,023
Lease liabilities	4,159	4,337
Deferred revenue, net of current portion	19,118	19,390
Other non-current liabilities	6,053	7,269
Total liabilities	175,179	194,087
Contingencies		
Stockholders' deficit:		
Common stock, \$0.001 par value. Authorized 250,000,000 shares; 124,284,542 and 122,044,299 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	124	122
Additional paid-in capital	420,877	413,214
Accumulated deficit	(455,055)	(446,998)
Total stockholders' deficit	(34,054)	(33,662)
Total liabilities and stockholders' deficit	\$ 141,125	\$ 160,425

AQUESTIVE THERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data amounts)
(Unaudited)

Three Months Ended March 31,	
2026	2025

Revenues	\$	14,446	\$	8,720
Costs and expenses:				
Manufacture and supply		3,469		3,652
Research and development		4,204		5,361
Selling, general and administrative		10,977		19,072
Total costs and expenses		<u>18,650</u>		<u>28,085</u>
Loss from operations		(4,204)		(19,365)
Other income/(expenses):				
Interest expense		(2,903)		(2,782)
Interest expense related to royalty obligations		(973)		(1,437)
Interest expense related to the sale of future revenue		(60)		(59)
Interest income and other income, net		83		713
Net loss before income taxes		<u>(8,057)</u>		<u>(22,930)</u>
Net loss	\$	<u>(8,057)</u>	\$	<u>(22,930)</u>
Comprehensive loss	\$	<u>(8,057)</u>	\$	<u>(22,930)</u>

Loss per share attributable to common stockholders:

Basic and diluted (in dollars per share)	\$	(0.07)	\$	(0.24)
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Weighted average common shares outstanding:

Basic and diluted (in shares)		122,609,995		95,497,056
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AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - Net Loss to Non-GAAP Adjusted EBITDA

(In Thousands)

(Unaudited)

	Three Months Ended March 31,	
	2026	2025
GAAP net loss	\$ (8,057)	\$ (22,930)
Share-based compensation expense	2,318	1,587
Interest expense	2,903	2,782
Interest expense related to royalty obligations	973	1,437
Interest expense related to the sale of future revenue	60	59
Interest income and other income, net	(83)	(713)
Depreciation and Amortization	113	139
Total non-GAAP adjustments	\$ 6,284	\$ 5,291
Non-GAAP adjusted EBITDA	\$ (1,773)	\$ (17,639)
Excluding Non-GAAP adjusted R&D expenses	(3,954)	(5,016)
Non-GAAP adjusted EBITDA excluding Non-GAAP adjusted R&D expenses	\$ 2,181	\$ (12,623)

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - GAAP Expenses to Non-GAAP Adjusted Expenses

(In Thousands, except percentages)

(Unaudited)

	Three Months Ended March 31,	
	2026	2025
Total costs and expenses	\$ 18,650	\$ 28,085
Non-GAAP adjustments:		
Share-based compensation expense	(2,318)	(1,587)
Depreciation and amortization	(113)	(139)
Non-GAAP adjusted costs and expenses	\$ 16,219	\$ 26,359

Manufacture and Supply Expenses	\$	3,469	\$	3,652
<i>Gross Margin on total revenue</i>		76%		58%
Non-GAAP adjustments:				
Share-based compensation expense		(69)		(100)
Depreciation and amortization		(86)		(115)
Non-GAAP adjusted manufacture and supply expenses	<u>\$</u>	<u>3,314</u>	<u>\$</u>	<u>3,437</u>
<i>Non-GAAP Gross Margin on total revenue</i>		77%		61%
Research and Development Expenses	\$	4,204	\$	5,361
Non-GAAP adjustments:				
Share-based compensation expense		(236)		(330)
Depreciation and amortization		(14)		(15)
Non-GAAP adjusted research and development expenses	<u>\$</u>	<u>3,954</u>	<u>\$</u>	<u>5,016</u>
Selling, General and Administrative Expenses	\$	10,977	\$	19,072
Non-GAAP adjustments:				
Share-based compensation expense		(2,013)		(1,157)
Depreciation and amortization		(13)		(9)
Non-GAAP adjusted selling, general and administrative expenses	<u>\$</u>	<u>8,951</u>	<u>\$</u>	<u>17,906</u>