Aquestive Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

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- Reaffirms guidance to resubmit Anaphylm™ (dibutepinephrine) sublingual film NDA in Q3 2026; Type A meeting with FDA expected to occur within 30 days
- On track to submit regulatory applications for Anaphylm in Canada and the EU in 2026
- Extends revenue sharing agreement with RTW to June 30, 2027
- Excluding one-time items, meets 2025 guidance for revenue and non-GAAP adjusted EBITDA loss
- Guides to end FY2026 with cash and cash equivalents of $70 million
- Company to host investment community conference call on March 5, 2026

WARREN, N.J., March 04, 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 reported financial results for the fourth quarter and full year ended December 31, 2025, and provided a progress update on the Company's key 2026 objectives.

"We are well-positioned in 2026 to advance Anaphylm, the first and only oral epinephrine rescue medication, towards approval for patients around the world," said Daniel Barber, President and Chief Executive Officer of Aquestive. "We continue to believe the value proposition will be transformative and ultimately save lives. We are focused on rapidly addressing the human factors focused deficiencies cited by the FDA in their recent Complete Response Letter. Our commercial infrastructure is intact and transferable to our new timeline, the allergy market continues to grow, and patient preference remains strongly in favor of the innovation Anaphylm represents. As recently announced, we have strengthened our leadership with the addition of Dr. Greenhawt, an internationally recognized expert in allergy and immunology, as the Chief Medical Officer of the Company. Additionally, we remain well-positioned financially to launch Anaphylm in the U.S., if approved by the FDA. We've never been more confident in Anaphylm's potential to make a meaningful difference for the allergy community."

Anaphylm™ (dibutepinephrine) Sublingual Film
Anaphylm is a non-device based 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).

On January 30, 2026, Aquestive received a Complete Response Letter (CRL) from the FDA for the New Drug Application (NDA) for Anaphylm in patients weighing 30 kilograms or more. The CRL identified deficiencies related to human factors validation, including potential challenges associated with pouch opening and film placement, as well as a request for a single pharmacokinetics (PK) study to assess the impact of packaging and labeling modifications. The FDA also provided labeling comments intended to inform the final label, if approved by the FDA.

The CRL did not identify any chemistry, manufacturing, or controls (CMC) deficiencies, and clinical results submitted as part of the NDA regarding comparability to auto-injectors (such as EpiPen® and Auvi-Q®), such as bracketing, repeat dose, and sustainability, were not questioned. No additional studies beyond the requested human factors validation study and related PK study were identified. The FDA indicated that the human factors and PK studies may be conducted in parallel.

To address the items outlined in the CRL, a new human factors validation study and a PK study are planned. A Type A meeting with the FDA has been requested to discuss the most efficient path forward for resubmission, with the NDA anticipated to be resubmitted in the third quarter of 2026, subject to completion of the required studies and expected FDA response timelines. The Company plans to request an accelerated review upon resubmission, but no expedited review can be guaranteed.

The Company continues to advance its global expansion strategy for Anaphylm, including ongoing regulatory engagement in Canada and preparatory activities in the European Union. These efforts are intended to support potential future submissions and expand access to the Company’s non-invasive epinephrine therapy globally.

Aquestive will continue to prepare for the launch of Anaphylm, a potentially transformative product for the emergency treatment of severe allergic reactions, including anaphylaxis. The initial focus of the Company's launch preparation is to optimize Anaphylm's market access for patients, if approved by the FDA. Aquestive is also increasing awareness of Anaphylm through the continued execution of its medical affairs strategy, including presenting scientific data at medical forums throughout 2026. The Company remains committed to a successful launch of Anaphylm, if approved by the FDA.

AQST-108 (epinephrine) Topical Gel
AQST-108 is a topical epinephrine prodrug gel product candidate being evaluated for alopecia areata (AA) and other potential

dermatologic or localized indications. In December 2025, the Company successfully opened an Investigational New Drug (IND) application for AQST-108 with the FDA and received supportive written feedback for continued development of this product candidate.

An initial first-in-human clinical trial of AQST-108 evaluated topical application and systemic exposure and did not identify any serious or topical adverse events. Building on these results, the Company successfully completed dosing in a second Phase 1 clinical trial in the first quarter of 2026 and the data readout from the study is expected in the second quarter of 2026. The intent of this study is to further characterize the safety, tolerability, and pharmacologic profile of the program and to inform potential future development opportunities, including indication selection.

An estimated 6.7 million people in the United States have been affected by AA. Of those affected, 43% are considered severe. The existing therapies for AA are janus kinase (or JAK) inhibitors. These systemic treatments with known side effects come with a "black box" warning and are expensive for patients. Even with these limitations, the current estimated market opportunity for JAK inhibitors is over One Billion U.S. dollars. Since AQST-108 is topical and there is evidence that it acts at the application site, it may not have systemic side effects. As a result of these conditions, AQST-108, if approved by the FDA as a treatment for AA, has the potential to capture meaningful market share for the treatment of these patients.

The topical formulation of AQST-108 is designed to act locally at the site of application, which may support evaluation in settings where minimizing systemic exposure is desirable. This localized delivery approach provides an opportunity to explore additional value for this product beyond a single indication, while maintaining a disciplined, data-driven development strategy.

Commercial Collaborations
Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 47 million doses in the fourth quarter 2025, compared to approximately 43 million doses in the fourth quarter 2024. 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 Assertio Holdings, 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, with the gradual decline of Suboxone being offset by growth across newer collaborations.

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® (clobazam) Oral Film for the treatment of seizures associated with Lennox-Gastaut Syndrome in patients two years of age and older, and Azstarys® (serdexmethylphenidate and dexmethylphenidate) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years of age and older, continued to contribute to the Company's revenue in the fourth 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.

RTW Amendment, Warrant and Share Purchase Agreement
On March 3, 2026, the Company entered into Amendment No. 1 to the Purchase and Sale Agreement, dated August 13, 2025, with funds managed by RTW Investments, LP ("RTW"). The Amendment extends the marketing approval deadline for Anaphylm from its original date to June 30, 2027. Concurrently, the Company entered into a Warrant Issuance Agreement with funds managed by RTW, pursuant to which the Company agreed to issue a warrant to such funds to purchase up to 375,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an exercise price of $4.00 per share, expiring on March 3, 2029. On March 3, 2026, the Company also entered into a Share Purchase Commitment Agreement with certain RTW-affiliated funds, pursuant to which such funds committed to purchase, in the aggregate, not less than $5,000,000 of Common Stock during the 90-day period following the effective date of the agreement, at the then current market price as of the date of such purchase(s), as determined in accordance with Rule 415(a)(4) under the Securities Act of 1933, as amended.

Legal Settlement
In December 2025, Aquestive entered into a confidential legal settlement with Neurelis, Inc. related to a civil tort case filed by Neurelis, Inc. in December 2019. Net of insurance payments and reduced ongoing legal costs, Aquestive expects the cash impact in 2026 of such settlement to be the same as or lower than forecasted prior to the settlement.

Fourth Quarter 2025 Financials
Total revenues increased to $13.0 million in the fourth quarter 2025, from $11.9 million in the fourth quarter 2024. This 10% increase in revenue was primarily driven by increases in manufacture and supply revenue.

Manufacture and supply revenue increased to $12.0 million in the fourth quarter 2025 from $10.7 million in the fourth quarter 2024, primarily due to increases in Suboxone revenues and Ondif revenues.

Research and development (R&D) expenses decreased to $3.2 million in the fourth quarter 2025 from $4.9 million in the fourth quarter 2024. The decrease in R&D expenses was primarily due to a decrease in clinical trial costs associated with the continued advancement of the Anaphylm development program and decreases in R&D personnel costs and share-based compensation.

Excluding one-time legal expenses, selling, general and administrative expenses increased to $19.6 million in the fourth quarter 2025 from $16.0 million in the fourth quarter 2024. Including the one-time legal expenses, selling, general and administrative expenses increased to $32.8 million in the fourth quarter 2025 from $16.0 million in the fourth quarter 2024, primarily due to higher legal expenses of approximately $13.6 million, higher commercial spending of approximately $3.7 million in preparation for the planned launch of Anaphylm, higher personnel expenses of approximately $0.8 million, and higher share-based compensation of approximately $0.2 million, partially offset by lower severance expenses of approximately $1.7 million, and lower regulatory and licensing fees of approximately $0.5 million.

Excluding one-time legal expenses, Aquestive's net loss for the fourth quarter 2025 was $18.7 million, or $0.15 for both basic and diluted loss per share, compared to the net loss for the fourth quarter 2024 of $17.1 million, or $0.19 for both basic and diluted loss per share. Including one-time legal expenses, Aquestive's net loss for the fourth quarter 2025 was $31.9 million, or $0.26 for both basic and diluted loss per share, compared to the net loss for the fourth quarter 2024 of $17.1 million, or $0.19 for both basic and diluted loss per share. The increase in net loss was primarily driven by increases in selling, general and administrative expenses, and manufacture and supply expenses, partially offset by decreases in research and development expenses and increases in revenues and interest income and other income, net.

Excluding one-time legal expenses, Non-GAAP adjusted EBITDA loss was $14.1 million in the fourth quarter 2025, compared to Non-GAAP adjusted EBITDA loss of $11.0 million in the fourth quarter 2024. Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses and one-time legal expenses was $10.8 million in the fourth quarter 2025, compared to a Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses of $6.6 million in the fourth quarter 2024.

Full Year 2025 Financials

Excluding the impact of one-time recognition of deferred revenues during the full year 2024, total revenues decreased by $1.5 million, or 3% to $44.5 million for the full year 2025. As a reminder, the one-time recognition of deferred revenue in the prior year was due to the termination of licensing and supply agreements. Including the deferred revenue recognized in the prior year, total revenues decreased to $44.5 million for the full year 2025 from $57.6 million for the full year 2024.

Manufacture and supply revenue increased to $40.2 million for the full year 2025 from $40.0 million for the full year 2024, primarily due to increases in Ondif revenues, partially offset by decreases in Suboxone revenues.

R&D expenses decreased to $17.2 million for the full year 2025 from $20.3 million in the full year 2024. The decrease in R&D expenses was primarily due to lower clinical trial costs associated with the continued advancement of the Anaphylm development program, partially offset by increases in product research expenses as well as R&D personnel costs and share-based compensation.

Excluding one-time legal expenses, selling, general and administrative expenses increased to $66.6 million for the full year 2025 from $50.2 million for the full year 2024. Including one-time legal expenses, selling, general and administrative expenses increased to $79.8 million for the full year 2025 from $50.2 million for the full year 2024. The increase primarily represents higher legal expenses of approximately $14.3 million, higher commercial spending of approximately $9.6 million in preparation for the planned launch of Anaphylm, Anaphylm PDUFA fee of $4.3 million, higher personnel expenses of approximately $1.9 million, higher regulatory expenses related to Anaphylm of approximately $1.0 million, and higher share-based compensation expenses of approximately $0.9 million, partially offset by lower severance expenses of approximately $2.8 million, and lower insurance expenses of approximately $0.6 million.

Excluding one-time legal expenses, Aquestive's net loss for the full year 2025 was $70.6 million, or $0.66 for both basic and diluted loss per share, compared to the net loss for the full year 2024 of $44.1 million, or $0.51 for both basic and diluted loss per share. Including one-time legal expenses, Aquestive's net loss for the full year 2025 was $83.8 million, or $0.78 for both basic and diluted loss per share, compared to the net loss for the full year 2024 of $44.1 million, or $0.51 for both basic and diluted loss per share. The increase in net loss was primarily driven by increases in selling, general and administrative expenses, and manufacture and supply expenses, and decreases in revenues, partially offset by decreases in R&D expenses and increases in interest income and other income, net.

Excluding one-time legal expenses, Aquestive's Non-GAAP adjusted EBITDA loss was $49.7 million for the full year 2025, compared to Non-GAAP adjusted EBITDA loss of $23.0 million for the full year 2024. Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses and one-time legal expenses was $34.4 million for the full year 2025, compared to Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses of $4.0 million for the full year 2024.

As of December 31, 2025, cash and cash equivalents were $121.2 million.

2026 Outlook

Aquestive is providing its full year 2026 financial outlook. The Company expects:

	Guidance

Total revenue (in millions)	$46 to $50
Non-GAAP adjusted EBITDA loss (in millions)	$35 to $30

Our Non-GAAP adjusted EBITDA loss guidance for 2026 includes costs associated with the resubmission of the NDA for Anaphylm, continued pre-commercial infrastructure spending for Anaphylm, clinical trial for AQST-108, and regulatory applications for Anaphylm in Canada and the EU. Current guidance does not include costs associated with the sales and marketing of Anaphylm, if approved by the FDA.

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. EST on Thursday, March 5, 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 the "Events and Presentations" page of the Investor section of Aquestive's website: Fourth Quarter 2025 Earnings Call. The webcast will be archived for 30 days.

About Anaphylm™
Anaphylm™ (epinephrine) 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. AQST-108 is based on Aquestive's Adrenaverse™ platform which contains a library of over twenty epinephrine prodrug product candidates 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 recent 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 prodrug) topical gel for various potential dermatological conditions, including alopecia areata. 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 one-time legal expenses, non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses and one-time legal expenses, non-GAAP adjusted gross margins, 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, the timing of our resubmission of the NDA and a Type A meeting with the FDA and expedited review for Anaphylm; the advancement and related timing of potential international regulatory filings and marketing authorization of 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; that the Company's commercialization plans and programs for Anaphylm will enable the Company to effectively compete in the market, if approved by the FDA; the advancement, growth and related timing of our AdrenaVerse™ pipeline epinephrine prodrug product candidates, including AQST-108 (epinephrine) topical gel, through clinical development and FDA regulatory approval process, including 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 and AQST-108 should Anaphylm and AQST-108 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; 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 and the ability to fund our business operations; 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.

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 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 the approval of our product candidates, including Anaphylm, Libervant and AQST-108; 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 for Anaphylm and whether the FDA may request further information from us (including additional clinical studies), disagree with our findings or otherwise undertake a lengthy review of the resubmission of our NDA, and challenges regarding the following commercial launch of Anaphylm, if approved by the FDA; 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 ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements to support our growth strategy, and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Senior Secured Notes in 2026, 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; 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 and the payment of principal and interest on our debt; the risk of our obligations under such Purchase Agreement and Royalty Rights Agreement impacting our ability to refinance our 13.5% Senior Secured Notes; 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 sunsetting 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 and Libervant, 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 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 and Israel 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.

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 121,169	$ 71,546
Trade and other receivables, net	17,763	7,344
Inventories, net	6,169	6,044
Prepaid expenses and other current assets	4,168	3,286
Total current assets	149,269	88,220
Property and equipment, net	3,893	3,799
Right-of-use assets, net	4,621	5,182
Other non-current assets	2,642	4,223
Total assets	$ 160,425	$ 101,424
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 29,862	$ 10,287
Accrued expenses	5,029	5,907
Lease liabilities, current	631	510
Deferred revenue, current	1,092	1,048
Liability related to the sale of future revenue, current	1,000	1,000
Royalty obligations, current	—	87
Loans payable, current	9,994	26
Total current liabilities	47,608	18,865
Loans payable, net	27,519	32,500
Royalty obligations, net	25,941	20,129
Liability related to the sale of future revenue, net	62,023	62,718
Lease liabilities	4,337	4,968
Deferred revenue, net of current portion	19,390	20,005
Other non-current liabilities	7,269	2,395
Total liabilities	194,087	161,580
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 122,044,299 and 91,413,742 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	122	91
Additional paid-in capital	413,214	302,967
Accumulated deficit	(446,998)	(363,214)
Total stockholders' deficit	(33,662)	(60,156)
Total liabilities and stockholders' deficit	$ 160,425	$ 101,424

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

	Three Months Ended December 31,	Year Ended December 31,

	2025	2024	2025	2024
Revenues	$ 13,015	$ 11,867	$ 44,545	$ 57,561
Costs and expenses:				
Manufacture and supply	5,836	4,520	18,555	17,872
Research and development	3,196	4,917	17,192	20,280
Selling, general and administrative	32,822	16,009	79,849	50,180
Total costs and expenses	41,854	25,446	115,596	88,332
Loss from operations	(28,839)	(13,579)	(71,051)	(30,771)
Other income (expenses):				
Interest expense	(2,778)	(2,779)	(11,120)	(11,122)
Interest expense related to royalty obligations	(1,433)	(1,384)	(5,737)	(5,459)
Interest expense related to the sale of future revenue	(62)	(61)	(243)	(236)
Interest income and other income, net	1,252	734	4,367	3,437
Net loss before income taxes	(31,860)	(17,069)	(83,784)	(44,151)
Income taxes benefit	—	14	—	14
Net loss	$ (31,860)	$ (17,055)	$ (83,784)	$ (44,137)
Comprehensive loss	$ (31,860)	$ (17,055)	$ (83,784)	$ (44,137)
Loss per share attributable to common stockholders:				
Basic and diluted (in dollars per share)	$ (0.26)	$ (0.19)	$ (0.78)	$ (0.51)
Weighted average common shares outstanding:				
Basic and diluted (in shares)	121,966,911	91,199,407	106,926,528	86,726,211

AQUESTIVE THERAPEUTICS, INC.
Reconciliation of Non-GAAP Adjustments - Net Loss to Adjusted EBITDA
(In Thousands)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
GAAP net loss	$ (31,860)	$ (17,055)	$ (83,784)	$ (44,137)
Share-based compensation expense	1,376	2,403	7,624	7,099
Interest expense	2,778	2,779	11,120	11,122
Interest expense related to the sale of future revenue	62	61	243	236
Interest expense related to royalty obligations	1,433	1,384	5,737	5,459
Interest income and other income, net	(1,252)	(734)	(4,367)	(3,437)
Income taxes benefit	—	(14)	—	(14)
Depreciation and amortization	129	147	548	718
Total non-GAAP adjustments	$ 4,526	$ 6,026	$ 20,905	$ 21,183
Adjusted EBITDA	$ (27,334)	$ (11,029)	$ (62,879)	$ (22,954)
Excluding one-time legal expenses	$ (13,200)	$ —	$ (13,200)	$ —
Adjusted EBITDA excluding one-time legal expenses	$ (14,134)	$ (11,029)	$ (49,679)	$ (22,954)
Excluding adjusted R&D expenses	$ (3,355)	$ (4,474)	$ (15,256)	$ (18,995)
Adjusted EBITDA excluding adjusted R&D expenses and one-time legal expenses	$ (10,779)	$ (6,555)	$ (34,423)	$ (3,959)

AQUESTIVE THERAPEUTICS, INC.
Reconciliation of Non-GAAP Adjustments - Total Costs and Expenses to Adjusted Costs and Expenses
(In Thousands)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Total costs and expenses	$ 41,854	$ 25,446	$ 115,596	$ 88,332
Non-GAAP adjustments:				
Share-based compensation expense	(1,376)	(2,403)	(7,624)	(7,099)
Depreciation and amortization	(129)	(147)	(548)	(718)
Adjusted costs and expenses	$ 40,349	$ 22,896	$ 107,424	$ 80,515
Manufacture and supply expense	$ 5,836	$ 4,520	$ 18,555	$ 17,872
Gross Margin on total revenue	*55%*	*62%*	*58%*	*69%*
Non-GAAP adjustments:				
Share-based compensation expense	(123)	(103)	(481)	(374)
Depreciation and amortization	(103)	(124)	(442)	(606)
Non-GAAP adjusted manufacture and supply expense	$ 5,610	$ 4,293	$ 17,632	$ 16,892
Non-GAAP Gross Margin on total revenue	*57%*	*64%*	*60%*	*71%*
Research and development expense	$ 3,196	$ 4,917	$ 17,192	$ 20,280
Non-GAAP adjustments:				
Share-based compensation expense	173	(427)	(1,875)	(1,215)
Depreciation and amortization	(14)	(16)	(61)	(70)
Non-GAAP adjusted research and development expense	$ 3,355	$ 4,474	$ 15,256	$ 18,995
Selling, general and administrative expenses	$ 32,822	$ 16,009	$ 79,849	$ 50,180
Non-GAAP adjustments:				
Share-based compensation expense	(1,426)	(1,873)	(5,268)	(5,510)
Depreciation and amortization	(12)	(7)	(45)	(42)
Non-GAAP adjusted selling, general and administrative expenses	$ 31,384	$ 14,129	$ 74,536	$ 44,628