Aquestive Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Update

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- *Submitted NDA for Anaphylm™ (epinephrine), the first and only oral sublingual film for patients with severe allergic reactions*
- *Advancing commercial readiness efforts with a planned Q1 2026 launch of Anaphylm, subject to FDA approval*
- *Company to host investor call on May 13, 2025, at 8:00am ET*

WARREN, N.J., May 12, 2025 (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, 2025, and provided a strategic business update.

“In the first quarter of 2025, we achieved a major milestone for Aquestive with the submission of the NDA for Anaphylm,” said Daniel Barber, President and Chief Executive Officer of Aquestive. “This represents a critical step toward delivering the first oral, non-invasive epinephrine treatment for patients experiencing severe allergic reactions, including anaphylaxis. We anticipate receipt of FDA's determination of acceptance of our NDA submission in the second quarter of 2025 and our full team is actively preparing for a potential U.S. launch in the first quarter of 2026, if approved by the FDA. We continue to gain enthusiasm from all of our expanding pre-commercial efforts for Anaphylm, as we believe that we are the potential best-in-class epinephrine therapy in a multi-billion dollar growing market. Going forward we will have complete focus on our pre-commercial preparedness and the FDA approval process for Anaphylm. From now until post-launch, we will de-emphasize other activities such as the advancement of AQST-108, and we will not appeal the court decision on Libervant. This will focus resources, both people and financial, towards the upcoming launch of Anaphylm, if approved by the FDA."

Anaphylm™ (epinephrine) Sublingual Film
Aquestive has completed the submission of its New Drug Application (NDA) for Anaphylm with the U.S. Food and Drug Administration (FDA). The NDA includes data from the full adult clinical program and the recently completed pediatric study. Topline results from the pediatric trial in patients aged 7 to 17 demonstrated a pharmacokinetic (PK) profile consistent with prior adult clinical data, supporting a proposed label aligned with the 0.3 mg epinephrine autoinjector. The Company anticipates receipt of notice from the FDA of the Agency's determination of acceptance of the NDA for review in the second quarter of 2025.

Launch preparations for Anaphylm are well underway in advance of a potential U.S. commercial introduction in the first half of 2026, if approved by the FDA. Aquestive is focused on establishing broad market access to support timely patient availability following a potential FDA approval. Commercialization efforts are expected to ramp up in the first quarter of 2026, ahead of the peak spring allergy season. The Company has expanded its market access and medical affairs teams and is advancing awareness of Anaphylm through peer-reviewed publications and planned scientific presentations. Following NDA acceptance, if granted by the FDA, Aquestive plans to initiate regulatory submissions in key international markets, including Europe, the United Kingdom, and Canada.

Aquestive is currently preparing for a potential Advisory Committee meeting during the FDA review process, which would provide an opportunity to present Anaphylm’s clinical profile and address the unmet need for additional epinephrine delivery options. The Company continues to maintain a constructive dialogue with the FDA, and recent changes at the U.S. Department of Health and Human Services (HHS) have not impacted the regulatory timeline for the review of the NDA submission for Anaphylm.

AQST-108 (epinephrine) Topical Gel
Aquestive plans to initiate its Phase 2a clinical trial of AQST-108, a topical gel formulation for the treatment of alopecia areata (AA), in the first half of 2026, after the launch of Anaphylm. The updated timeline will allow the Company to focus on the launch of Anaphylm while continuing to conduct additional preclinical studies ahead of clinical advancement of AQST-108.

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 alopecia areata 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 avoid 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.

Libervant® (diazepam) Buccal Film
Libervant scripts for patients aged two to five years old continued to grow during the first quarter of 2025, reflecting ongoing demand for an oral treatment option for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*,

seizure clusters, acute repetitive seizures) (or ARS). However, following a recent court decision, the FDA revised Libervant's full approval—originally granted in April 2024—to a tentative approval status. This action was not due to any safety or efficacy concerns and was the result of the court's interpretation of the orphan drug statute.

As a result of the change in regulatory status, sales and marketing activities for the product have paused. The Company believes the decision negatively impacts patients and caregivers by restricting access to a differentiated, non-invasive alternative to rectal and intranasal formulations. We plan to provide patient access to Libervant in the U.S. in 2027, upon the expiration of the orphan drug market exclusivity granted by the FDA to an approved intranasal product of another company, or sooner if market access is granted by the FDA. The Company has decided not to pursue an appeal of the court's decision to ensure focus on the launch of Anaphylm.

Commercial Collaborations

Aquestive's manufacturing business remains steady, with the gradual decline of Suboxone ® being offset by growth across newer collaborations, including for the licensed products Ondif®, Sympazan®, and Emylif®. Aquestive's manufacturing facility continues to diversify its operations to support a broader range of products and collaborations. In addition, 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 tariffs, providing continued reliability and stability in production and global distribution for the near term. Aquestive continues to support the manufacturing of Indivior's Suboxone ® Sublingual Film product and its other global collaborations, including Sympazan® (clobazam) Oral Film product for Assertio Holdings, Inc., Ondif® (Ondansetron) Oral Film product for Hypera in Brazil, and Emylif® (Riluzole) Oral Film product for Zambon in Europe.

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 first quarter of 2025.

First Quarter 2025 Financials

Total revenues decreased to $8.7 million in the first quarter 2025 from $12.1 million in the first quarter 2024. This 28% decrease in revenue was primarily driven by decreases in manufacture and supply revenue and license and supply revenue, partially offset by increases in proprietary product revenue, net.

Manufacture and supply revenue decreased to $7.2 million in the first quarter 2025 from $10.5 million in the first quarter 2024, primarily due to decreases in Suboxone revenues, partially offset by an increase in Ondif revenues.

Research and development expenses decreased to $5.4 million in the first quarter 2025 from $5.9 million in the first quarter 2024. The decrease in research and development 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 and preclinical expenses, higher personnel costs and higher share-based compensation.

Selling, general and administrative expenses increased to $19.1 million in the first quarter 2025 from $10.7 million in the first quarter 2024, primarily due to regulatory fees of $4.8 million including the Anaphylm PDUFA fee, higher legal fees of $2.3 million, higher commercial spending of approximately $2.1 million, higher personnel costs of approximately $0.4 million, and higher share-based compensation expenses of $0.3 million, partially offset by decreases in severance costs of approximately $1.1 million and lower insurance expenses of $0.2 million.

Aquestive's net loss for the first quarter 2025 was $22.9 million, or $0.24 for both basic and diluted loss per share, compared to the net loss for the first quarter 2024 of $12.8 million, or $0.17 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 decreases in revenues, partially offset by decreases in manufacture and supply expenses, and research and development expenses and increases in interest income and other income, net.

Non-GAAP adjusted EBITDA loss was $17.6 million in the first quarter 2025, compared to non-GAAP adjusted EBITDA loss of $7.2 million in the first quarter 2024. Non-GAAP adjusted EBITDA loss excluding adjusted research and development expenses was $12.6 million in the first quarter 2025, compared to non-GAAP adjusted EBITDA loss excluding adjusted research and development expenses of $1.4 million in the first quarter 2024.

Cash and cash equivalents were $68.7 million as of March 31, 2025.

2025 Outlook

Aquestive's has revised its full-year 2025 financial guidance as a result of the change in regulatory status of Libervant and pausing sales and marketing activities for the product.

The Company expects:

	Prior Guidance	Current Guidance
Total revenue (in millions)	$47 to $56	$44 to $50
Non-GAAP adjusted EBITDA loss (in millions)	$46 to $53	$47 to $51

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Tuesday, May 13, 2025.

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 2025 Earnings Call**.

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 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 expire in January 2027.

About AQST-108
AQST-108 (epinephrine) Topical Gel is a topically delivered adrenergic agonist prodrug gel product candidate. Aquestive completed a first in human study for AQST-108 that measured the amount of epinephrine that remained on the skin or was found in circulation over time after the application of the gel. AQST-108 is based on Aquestive's Adrenaverse™ platform that 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.

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 pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has four licensed commercialized products marketed by its licensees in the U.S. and around the world and is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product candidate for the treatment of severe allergic reactions, including anaphylaxis, and an early-stage epinephrine prodrug topical gel product candidate for various possible 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 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 non-GAAP adjusted EBITDA loss. Similarly, manufacture and supply expense, research and development expense, and selling, general and administrative expense were adjusted for certain non-cash expenses of share-based compensation expense and depreciation and amortization. Non-GAAP 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, research and development 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. Non-GAAP 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 2025 and 2024 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™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of acceptance of the NDA for Anaphylm by the FDA, potential approved label indications, and potential for an advisory committee meeting, and the following launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; Anaphylm's potential to be the first and only oral administration of epinephrine and to be accepted as an alternative to existing standards of care and best-in-class epineprhine therapy, if approved by the FDA; the expected growth of the epinephrine market including in value and the opportunity such growth presents to the Company should Anaphylm be approved by the FDA; the expected commercialization of Anaphylm in markets outside of the United States; the advancement and related timing of our product candidate 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 for AQST-108 and the following launch of AQST-108, if approved by the FDA; the launch of Libervant® (diazepam) Buccal Film for the indicated epilepsy patient population following approval for U.S. market access upon the expiration of the orphan drug market exclusivity of an FDA approved intranasal spray product of another company extending to January 2027, or earlier approval for U.S. market access of Libervant by the FDA, if any; the potential impact of tariffs on our supply chain; the focus on continuing to manufacture Suboxone®, Emylif®, Sympazan®, Ondif® and other licensed products and innovative therapies; the potential benefits our products and product candidates could bring to patients; the achievement of clinical and commercial milestones, product orders and fulfillment; 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 2025 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, including those relating to Anaphylm, AQST-108, and our other product candidates, or failure to receive FDA approval at all for these and other product candidates; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the acceptance of the NDA for Anaphylm; the risk of whether the Company's clinical data is sufficient for approval of Anaphylm,

including with respect to our PK and pharmacodynamic (PD) comparability submission for FDA approval of Anaphylm; risks associated our ability to address the FDA's comments on our clinical trials and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in advancement of the regulatory approval process through the FDA of Libervant for patients aged between 6 and 11; risks associated with the success of any competing products, including generics; risk that we may not overcome the seven year orphan drug market exclusivity granted by the FDA for the approved nasal spray product of another company in the U.S. in order for Libervant to be granted U.S. market access for patients prior to expiration of the orphan drug market exclusivity period of the nasal spray product, which is due to occur in January 2027, or for other reasons; 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 market access, sales and marketing capability for commercialization of our product candidates, including Anaphylm and AQST-108; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product and product candidates, including Libervant and Anaphylm and other product candidates; risk of insufficient capital and cash resources, including insufficient 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 and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Notes in 2026 and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, AQST-108 and Libervant for patients aged between 6 and 11, should these product candidates be approved by the FDA, and for the launch of Libervant upon expiration of the orphan drug marketing exclusivity period of the nasal spray product, if granted by the FDA; risk that our manufacturing capabilities will be insufficient to support demand for Libervant should Libervant receive U.S. market access, and for demand for 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; risks associated with the rate and degree of market acceptance in the U.S. and abroad of our product candidates, including Anaphylm, if approved by the FDA, and Libervant, if approved for U.S. market access and after the expiration of the orphan drug market exclusivity period in January 2027; risk of the rate and degree of market acceptance in the U.S. and abroad of our licensed products; risk associated with the size and growth of our product markets; 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 United States Patent and Trademark Office (PTO); 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, including a potential recession; risks related to uncertainty about U.S. government initiatives and their impact on our business, including imposition of tariffs and other trade restrictions; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 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.
Condensed Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2025	December 31, 2024

Assets		
Current assets:		
Cash and cash equivalents	$ 68,657	$ 71,546
Trade and other receivables, net	10,444	7,344
Inventories	7,198	6,044
Prepaid expenses and other current assets	2,870	3,286
Total current assets	89,169	88,220
Property and equipment, net	3,801	3,799
Right-of-use assets, net	5,049	5,182
Other non-current assets	4,215	4,223
Total assets	$ 102,234	$ 101,424
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 12,280	$ 10,287
Accrued expenses	3,314	5,907
Lease liabilities, current	540	510
Deferred revenue, current	1,048	1,048
Liability related to the sale of future revenue, current	1,000	1,000
Royalty obligations, current	89	87
Loans payable, current	27	26
Total current liabilities	18,298	18,865
Notes payable, net	33,746	32,500
Royalty obligations, net	21,559	20,129
Liability related to the sale of future revenue, net	62,777	62,718
Lease liabilities	4,822	4,968
Deferred revenue, net of current portion	19,744	20,005
Other non-current liabilities	2,218	2,395
Total liabilities	163,164	161,580
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 99,317,153 and 91,413,742 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	99	91
Additional paid-in capital	325,115	302,967
Accumulated deficit	(386,144)	(363,214)
Total stockholders' deficit	(60,930)	(60,156)
Total liabilities and stockholders' deficit	$ 102,234	$ 101,424

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,	
	2025	**2024**
Revenues	$ 8,720	$ 12,053
Costs and expenses:		
Manufacture and supply	3,652	4,389
Research and development	5,361	5,932
Selling, general and administrative	19,072	10,689
Total costs and expenses	28,085	21,010
Loss from operations	(19,365)	(8,957)
Other income/(expenses):		
Interest expense	(2,782)	(2,784)

Interest expense related to royalty obligations	(1,437)	(1,358)
Interest expense related to the sale of future revenue	(59)	(58)
Interest income and other income, net	713	329
Net loss before income taxes	(22,930)	(12,828)
Net loss	$ (22,930)	$ (12,828)
Comprehensive loss	$ (22,930)	$ (12,828)
Loss per share attributable to common stockholders:		
Basic and diluted (in dollars per share)	$ (0.24)	$ (0.17)
Weighted average common shares outstanding:		
Basic and diluted (in shares)	95,497,056	73,614,710

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

	Three Months Ended March 31,	
	2025	**2024**
GAAP net loss	$ (22,930)	$ (12,828)
Share-based compensation expense	1,587	1,580
Interest expense	2,782	2,784
Interest expense related to royalty obligations	1,437	1,358
Interest expense related to the sale of future revenue	59	58
Interest income and other income, net	(713)	(329)
Depreciation and Amortization	139	207
Total non-GAAP adjustments	$ 5,291	$ 5,658
Non-GAAP adjusted EBITDA	$ (17,639)	$ (7,170)
Excluding Non-GAAP adjusted R&D expenses	(5,016)	(5,742)
Non-GAAP adjusted EBITDA excluding Non-GAAP adjusted R&D expenses	$ (12,623)	$ (1,428)

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,	
	2025	**2024**
Total costs and expenses	$ 28,085	$ 21,010
Non-GAAP adjustments:		
Share-based compensation expense	(1,587)	(1,580)
Depreciation and amortization	(139)	(207)
Non-GAAP adjusted costs and expenses	$ 26,359	$ 19,223
Manufacture and Supply Expense	$ 3,652	$ 4,389
Gross Margin on total revenue	*58%*	*64%*
Non-GAAP adjustments:		
Share-based compensation expense	(100)	(70)
Depreciation and amortization	(115)	(176)
Non-GAAP adjusted manufacture and supply expense	$ 3,437	$ 4,143
Non-GAAP Gross Margin on total revenue	*61%*	*66%*

Research and Development Expense	$ 5,361	$ 5,932
Non-GAAP adjustments:		
Share-based compensation expense	(330)	(170)
Depreciation and amortization	(15)	(20)
Non-GAAP adjusted research and development expense	$ 5,016	$ 5,742

Selling, General and Administrative Expenses	$ 19,072	$ 10,689
Non-GAAP adjustments:		
Share-based compensation expense	(1,157)	(1,340)
Depreciation and amortization	(9)	(11)
Non-GAAP adjusted selling, general and administrative expenses	$ 17,906	$ 9,338