



## Aquestive Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

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- Initiated Anaphylm™ (epinephrine) Sublingual Film NDA filing process with FDA
- Anaphylm pre-commercial activities underway; launch expected in Q1 2026, if approved by the FDA
- Initial Anaphylm pediatric clinical trial results in subjects 7-17 years of age in line with expectations
- AQST-108 (epinephrine) Topical Gel Phase 2a clinical trial on track to begin in Q2 2025
- Proforma cash and cash equivalents as of December 31, 2024 approximately \$93.0 million
- Company to host investment community conference call on March 6, 2025

WARREN, N.J., March 05, 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 reported financial results for the fourth quarter and full year ended December 31, 2024, and provided a progress update on the key 2025 objectives previously outlined by the Company.

"We are thrilled to announce today the start of our Anaphylm application process with the FDA. We anticipate completion of this process in the first quarter of 2025 and achievement of the FDA acceptance milestone before the end of the second quarter of 2025," said Daniel Barber, President and Chief Executive Officer of Aquestive. "This is a major moment in the Company's history, and we are excited to move significantly closer to the day when patients would benefit from a non-device, non-invasive based treatment option for severe allergic reactions, including anaphylaxis. In parallel, we are also excited to advance our AQST-108 (epinephrine) Topical Gel for patients suffering from alopecia areata into Phase 2a clinical trial development. We believe that we are well-positioned to execute on our strategic priorities and key milestones for 2025."

### **Anaphylm™ (epinephrine) Sublingual Film**

Aquestive is advancing the development of Anaphylm, a non-device based epinephrine product candidate that has demonstrated clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of severe allergic reactions, including anaphylaxis. In the fourth quarter of 2024, the Company successfully completed all adult clinical trials for Anaphylm and received positive feedback in its pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA). The pediatric clinical trial for Anaphylm will be finalized shortly and the initial topline data from this clinical trial is in line with expectations.

With the completion of the Anaphylm clinical program, the Company has started the NDA submission, which will include the necessary pediatric data to support a product label, if approved by the FDA, that would align to the weight and age parameters of the existing 0.3 mg EpiPen® autoinjector. The Company expects to receive acceptance of its NDA for Anaphylm by the FDA in the second quarter of 2025.

In the pre-NDA meeting minutes received from the FDA in the fourth quarter of 2024, the Agency noted that a Pulmonary-Allergy Drugs Advisory Committee may be necessary during the review process for Anaphylm. The advisory committee meeting process would provide Aquestive with the opportunity to further highlight the potential benefits of Anaphylm for patients. Aquestive is actively preparing for this potential Advisory Committee discussion.

Aquestive continues 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 has been optimizing 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 2025. The company remains committed to a successful launch of Anaphylm in the first quarter of 2026, if approved by the FDA.

### **AQST-108 (epinephrine) Topical Gel**

Aquestive is advancing the development of AQST-108 (epinephrine) Topical Gel for the treatment of alopecia areata (AA). The Company successfully completed a pre-Investigational New Drug Application (IND) meeting with the FDA in December 2024. The written response received from the FDA was supportive of continued development of AQST-108. The Company remains on track to begin its Phase 2a clinical trial of AQST-108 in patients with AA in the second quarter of 2025.

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. In the Company's first-in-human Phase 1 clinical trial, AQST-108 demonstrated no serious adverse events or topical adverse events. 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.

### **Libervant® (diazepam) Buccal Film**

Aquestive received FDA approval of Libervant for patients aged between two and five years in April of 2024. Libervant is the first and only FDA approved orally administered rescue product for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) (or ARS) in patients between two and five years of age. This milestone ensured that younger ARS patients in this age group have access to this essential treatment. In December 2024, the Company received Orphan Drug Exclusivity (ODE) for Libervant for ARS patients between two and five years of age until April 2031.

Aquestive launched Libervant for ARS patients aged between two and five years in 2024 with a small, targeted sales force and access for the product has been expanding since its launch. Demand for Libervant in this labeled patient population continues to increase and in the fourth quarter of 2024 it became fully available through national retail distribution.

In February 2025, the U.S. District Court for the District of Columbia ruled that the FDA erred in approving Libervant for ARS patients between the ages of two and five years as a result of the FDA's prior grant of ODE to the previously approved Valtoco nasal spray product for ARS patients aged six years and older. The Company is appealing the Court's ruling. Aquestive intends to continue to take action to keep Libervant on the market for these young patients and to engage with the FDA to protect these young patients.

The NDA for Libervant for ARS patients twelve years of age and older was tentatively approved by the FDA in August 2022 and is currently subject to the ODE block of Valtoco until January 2027.

### **Commercial Collaborations**

Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 43 million doses in the fourth quarter 2024, compared to approximately 45 million doses in the fourth quarter 2023. The Company continues to see consistent order demand for the manufacture of Indivior's Suboxone® Sublingual Film product and continues to support its other global collaborations including the recent launch of Emylif® (riluzole) Oral Film product by Zambon S.p.A 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® for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years of age and older, continued to provide a steady stream of revenue in the fourth quarter of 2024.

### **Fourth Quarter 2024 Financials**

Total revenues decreased to \$11.9 million in the fourth quarter 2024, from \$13.2 million in the fourth quarter 2023. This 10% decrease in revenue was primarily driven by decreases in license and royalty revenue due to \$1.0 million of milestone royalty revenue for Azstarys from Zevra Therapeutics recognized in the prior year.

Manufacture and supply revenue decreased to \$10.7 million in the fourth quarter 2024 from \$11.0 million in the fourth quarter 2023, primarily due to a decrease in Suboxone revenues, partially offset by an increase in Ondif® revenues from Hypera Pharma due to timing of orders.

License and royalty revenue decreased to \$0.8 million in the fourth quarter 2024 from \$1.9 million in the fourth quarter 2023, primarily due to \$1.0 million of milestone royalty revenue for Azstarys from Zevra Therapeutics recognized in the prior year.

Research and development (R&D) expenses increased to \$4.9 million in the fourth quarter 2024 from \$2.9 million in the fourth quarter 2023. The increase in R&D expenses was primarily due to an increase in clinical trial costs associated with the continued advancement of the Anaphylm development program.

Selling, general and administrative expenses increased to \$16.0 million in the fourth quarter 2024 from \$9.6 million in the fourth quarter 2023, primarily due to increased commercial spending for both Libervant and Anaphylm, regulatory fees related to the approval of Libervant, severance costs of \$1.8 million, and higher legal expenses of \$1.5 million, partially offset by a decrease in insurance fees.

Aquestive's net loss for the fourth quarter 2024 was \$17.1 million, or (\$0.19) for both basic and diluted loss per share, compared to the net loss for the fourth quarter 2023 of \$8.1 million, or (\$0.12) for both basic and diluted loss per share. The increase in net loss was primarily driven by increases in selling, general and administrative expenses, R&D expenses, non-cash interest expense related to amortization of debt and royalty obligation discounts, and decreases in revenues partially offset by increases in interest income and other income, net, and decreases in manufacture and supply expenses and loss on the extinguishment of debt.

Non-GAAP adjusted EBITDA loss was \$11.0 million in the fourth quarter 2024, compared to Non-GAAP adjusted EBITDA loss of \$2.8 million in the fourth quarter 2023. Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses was \$6.6 million in the fourth quarter 2024, compared to a Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses of \$0.1 million in the fourth quarter 2023.

### **Full Year 2024 Financials**

Total revenues increased to \$57.6 million for the full year 2024, from \$50.6 million for the full year 2023. This 14% increase in

revenue was primarily driven by increases in license and royalty revenue due to the recognition of deferred revenue from the termination of certain licensing and supply agreements, and increases in co-development and research fees, partially offset by decreases in manufacture and supply revenue.

Manufacture and supply revenue decreased to \$40.0 million for the full year 2024 from \$43.8 million for the full year 2023, primarily due to decreases in Suboxone and Sympazan revenues, partially offset by an increase in Emylif® revenues from Zambon and an increase in Ondif revenues. Excluding the one-time retroactive price increase of \$1.7 million recognized in the prior year, manufacture and supply revenue decreased to \$40.0 million for the full year 2024 from \$42.1 million for the full year 2023.

R&D expenses increased to \$20.3 million for the full year 2024 from \$13.1 million in the full year 2023. The increase in R&D expenses was primarily due to clinical trial costs and product research expenses associated with the continued advancement of the Anaphylm and AQST-108 development programs, increases in personnel costs, and an increase in share-based compensation.

Selling, general and administrative expenses increased to \$50.2 million for the full year 2024 from \$31.8 million for the full year 2023. Selling, general and administrative expenses excluding changes to the allocation methodology for manufacture and supply costs increased to \$45.6 million for the full year 2024 from \$31.8 million for the full year 2023. This was primarily driven by higher commercial and regulatory spending for Libervant and Anaphylm of approximately \$6.2 million, one-time severance costs of \$2.9 million, higher shared-based compensation expenses of \$2.3 million, and higher non-commercial personnel costs of approximately \$2.0 million.

Aquestive's net loss for the full year 2024 was \$44.1 million, or (\$0.51) for both basic and diluted loss per share, compared to the net loss for the full year 2023 of \$7.9 million, or (\$0.13) for both basic and diluted loss per share. The increase in net loss was primarily driven by increases in selling, general and administrative expenses, R&D expenses, non-cash interest expenses related to amortization of debt and royalty obligation discounts, and decreases in interest income and other income, net partially offset by increases in revenues and decreases in manufacture and supply expenses and loss on the extinguishment of debt.

Non-GAAP adjusted EBITDA loss was \$23.0 million for the full year 2024, compared to Non-GAAP adjusted EBITDA loss of \$11.6 million for the full year 2023. Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses was \$4.0 million for the full year 2024, compared to Non-GAAP adjusted EBITDA income excluding adjusted R&D expenses of \$1.0 million for the full year 2023.

As of December 31, 2024, cash and cash equivalents were \$71.5 million. Proforma cash and cash equivalents were approximately \$93.0 million, which includes capital net proceeds of \$21.4 million received on February 14, 2025 through the Company's "At-the-Market" (ATM) facility.

## 2025 Outlook

Aquestive is providing its full year 2025 financial outlook. The Company expects:

	<b>Guidance</b>
Total revenue (in millions)	\$47 to \$56
Non-GAAP adjusted EBITDA loss (in millions)	\$46 to \$53

Our revenue guidance for 2025 includes Libervant for ages two to five and some level of erosion in the demand for Suboxone. As a reminder, our 2024 revenue included one-time recognition of deferred revenue related to the termination of certain licensing and supply agreements.

Our Non-GAAP adjusted EBITDA loss guidance for 2025 includes significant pre-commercial spending for Anaphylm as well as costs associated with the submission of the Anaphylm NDA (and related filing fee), completion of the Anaphylm pediatric clinical trial, preparations for a potential advisory committee if required by the FDA for approval of Anaphylm, commencing the AQST-108 Phase 2a clinical trial in second quarter of 2025, and continued commercialization of Libervant for epilepsy patients aged between two and five years.

## Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. EST on Thursday, March 6, 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 the "Events and Presentations" page of the Investor section of Aquestive's website: [Fourth Quarter 2024 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 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 in the human body over time after the application of the topical gel and 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) (or ARS) that are distinct from a patient's usual seizure pattern, approved by the FDA for ARS patients between two and five years of age. 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 granted tentative approval in August 2022 for Libervant for treatment of ARS patients twelve years of age and older, with U.S. market access for Libervant for this age group of patients subject to the expiration of the existing orphan drug market exclusivity of a previously FDA approved nasal spray drug scheduled to expire in January 2027. In December 2024, the Company received ODE for Libervant for ARS patients between two and five years of age until April 2031. In February 2025, the U.S. District Court for the District of Columbia ruled that the FDA erred in approving Libervant for ARS patients between the ages of two and five years as a result of the FDA's prior grant of ODE to the previously approved Valtoco nasal spray product for ARS patients aged six years and older. The Company is appealing this ruling and has requested an immediate stay of the ruling. The Company intends to continue to take action to keep Libervant on the market for these young patients and to engage with the FDA to protect these young patients. The Company is not able at this time to determine or predict the ultimate outcome of these proceedings or provide a reasonable estimate or range of estimates of the possible outcome in these matters.

### 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. We are developing orally administered and topical gel products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products marketed by the Company and 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<sup>®</sup>, 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 the treatment of possible various dermatology conditions, including alopecia areata. For more information, visit [Aquestive.com](http://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 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 income (loss) for loss on the extinguishment of debt; 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 (expense), 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™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of submission of pediatric clinical studies, and filing and acceptance of the NDA for Anaphylm with the FDA and potential approved label indications, and the following launch of Anaphylm, if approved by the FDA; the results of the Company's clinical studies for Anaphylm and the ability of such results to support submission of the NDA for approval of Anaphylm to the FDA; Anaphylm's potential as a non-device, non-invasive based treatment option for severe allergic reactions, including anaphylaxis, if Anaphylm is approved by the FDA; the advancement, growth and related timing of our Adrenaverse™ pipeline of 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 for AQST-108 and the potential market share that AQST-108 may achieve, if approved by the FDA and launched; the increased market demand for our product Libervant® (diazepam) Buccal Film for the label indicated epilepsy patients between the ages of two and five years; the advancement and related timing of our product candidate Libervant® (diazepam) Buccal Film for the label indicated epilepsy patient population aged between 6 and 11 years through FDA regulatory approval and the following launch of Libervant for this patient population, if approved by the FDA upon the expiration of the orphan drug market exclusivity of an FDA approved nasal spray product of another company scheduled to expire in January 2027; the potential benefits our products and product candidates could bring to patients; the achievement of clinical and commercial milestones; our 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 (including for pediatric patients), AQST-108, and our other product candidates; risks associated with our distribution work for Libervant, including any delays or changes to the timing, cost and success of our distribution activities and expansion of market access for Libervant to ARS patients aged between two and five years; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, for Anaphylm, AQST-108, Libervant for patients aged between 6 and 11 years and other product candidates, or failure to receive FDA approval at all of any of these product candidates; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our PK/PD comparability submission for FDA approval of Anaphylm; risks associated with our ability to address the FDA's comments on our future 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; risks associated with the success of any competing products, including generics; risk that we may not succeed in appealing the ruling of the U.S. District Court of the District of Columbia that the FDA approval of Libervant for the label indicated epilepsy patients between the ages of two and five years was in error as a result of the current orphan drug market exclusivity granted by the FDA for a prior approved nasal spray product of another company for this patient population aged six years and older; risks of not overcome the seven year orphan drug market exclusivity of the FDA approved nasal spray product for these label indicated

patients aged six years and older in order for Libervant to be granted U.S. market access for patients aged two years and older prior to expiration of the orphan drug market exclusivity period of the nasal spray product, which is scheduled to expire in January 2027; 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 Libervant and other 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 fund commercialization activities relating to Libervant for patients between two and five years of age 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 years, should these product candidates be approved by the FDA, and for Libervant patients of 6 years and older upon expiration of the orphan drug marketing exclusivity period of the nasal spray product; risk that our manufacturing capabilities will be insufficient to support demand for Libervant for patients between two and five years of age and for older patients, should Libervant receive U.S. market access for these older patients, and for demand for 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; risks associated with the rate and degree of market acceptance in the U.S. and abroad of Libervant for label indicated epilepsy patients between two and five years of age, and for older label indicated epilepsy patients, 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 Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; 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 and AQST-108, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office; 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 other pandemic diseases, such as COVID-19, on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; 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; 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.**  
**Balance Sheets**  
(In thousands, except share and per share amounts)  
(Unaudited)

	<b>December 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Assets</b>		

Current assets:			
Cash and cash equivalents	\$	71,546	\$ 23,872
Trade and other receivables, net		7,344	8,471
Inventories, net		6,044	6,769
Prepaid expenses and other current assets		3,286	1,854
Total current assets		<u>88,220</u>	<u>40,966</u>
Property and equipment, net		3,799	4,179
Right-of-use assets, net		5,182	5,557
Intangible assets, net		—	1,278
Other non-current assets		4,223	5,438
Total assets	\$	<u>101,424</u>	\$ <u>57,418</u>

#### Liabilities and stockholders' deficit

Current liabilities:			
Accounts payable	\$	10,287	\$ 8,926
Accrued expenses		5,907	6,497
Lease liabilities, current		510	390
Deferred revenue, current		1,048	1,551
Liability related to the sale of future revenue, current		1,000	922
Royalty obligations, current		87	—
Loans payable, current		26	22
Total current liabilities		<u>18,865</u>	<u>18,308</u>
Loans payable, net		32,500	27,508
Royalty obligations, net		20,129	14,761
Liability related to the sale of future revenue, net		62,718	63,568
Lease liabilities		4,968	5,399
Deferred revenue, net of current portion		20,005	32,345
Other non-current liabilities		2,395	2,016
Total liabilities		<u>161,580</u>	<u>163,905</u>
Contingencies			

#### Stockholders' deficit:

Common stock, \$0.001 par value. Authorized 250,000,000 shares; 91,413,742 and 68,533,085 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively

		91	69
Additional paid-in capital		302,967	212,521
Accumulated deficit		(363,214)	(319,077)
Total stockholders' deficit		<u>(60,156)</u>	<u>(106,487)</u>
Total liabilities and stockholders' deficit	\$	<u>101,424</u>	\$ <u>57,418</u>

**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,	
	2024	2023	2024	2023
Revenues	\$ 11,867	\$ 13,206	\$ 57,561	\$ 50,583
Costs and expenses:				
Manufacture and supply	4,520	4,679	17,872	20,831
Research and development	4,917	2,888	20,280	13,104
Selling, general and administrative	16,009	9,550	50,180	31,750
Total costs and expenses	<u>25,446</u>	<u>17,117</u>	<u>88,332</u>	<u>65,685</u>
Loss from operations	(13,579)	(3,911)	(30,771)	(15,102)

Other income (expenses):				
Interest expense	(2,779)	(2,273)	(11,122)	(6,337)
Interest expense related to royalty obligations	(1,384)	(905)	(5,459)	(905)
Interest expense related to the sale of future revenue	(61)	(57)	(236)	(220)
Interest income and other income, net	734	165	3,437	16,321
Loss on the extinguishment of debt	—	(1,029)	—	(1,382)
Net loss before income taxes	(17,069)	(8,010)	(44,151)	(7,625)
Income taxes benefit (expense)	14	(101)	14	(245)
Net loss	<u>\$ (17,055)</u>	<u>\$ (8,111)</u>	<u>\$ (44,137)</u>	<u>\$ (7,870)</u>
Comprehensive loss	<u>\$ (17,055)</u>	<u>\$ (8,111)</u>	<u>\$ (44,137)</u>	<u>\$ (7,870)</u>

**Loss per share attributable to common stockholders:**

Net loss per share – basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.12)</u>	<u>\$ (0.51)</u>	<u>\$ (0.13)</u>
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**Weighted average common shares outstanding:**

Weighted-average number of common shares outstanding - basic and diluted	<u>91,199,407</u>	<u>67,199,645</u>	<u>86,726,211</u>	<u>61,255,864</u>
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**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,	
	2024	2023	2024	2023
GAAP net loss	\$ (17,055)	\$ (8,111)	\$ (44,137)	\$ (7,870)
Share-based compensation expense	2,403	923	7,099	2,689
Interest expense	2,779	2,273	11,122	6,337
Interest expense related to the sale of future revenue	61	57	236	220
Interest expense related to royalty obligations	1,384	905	5,459	905
Interest income and other income (expense), net	(734)	(165)	(3,437)	(16,321)
Income taxes	(14)	(101)	(14)	(245)
Depreciation, amortization, and impairment	147	433	718	1,345
Loss on extinguishment of debt	—	1,029	—	1,382
Total non-GAAP adjustments	<u>\$ 6,026</u>	<u>\$ 5,354</u>	<u>\$ 21,183</u>	<u>\$ (3,688)</u>
Adjusted EBITDA	<u>\$ (11,029)</u>	<u>\$ (2,757)</u>	<u>\$ (22,954)</u>	<u>\$ (11,558)</u>
Excluding adjusted R&D expenses	<u>\$ (4,474)</u>	<u>\$ (2,688)</u>	<u>\$ (18,995)</u>	<u>\$ (12,557)</u>
Adjusted EBITDA excluding adjusted R&D expenses	<u>\$ (6,555)</u>	<u>\$ (69)</u>	<u>\$ (3,959)</u>	<u>\$ 999</u>

**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,	
	2024	2023	2024	2023
<b>Total costs and expenses</b>	\$ 25,446	\$ 17,117	\$ 88,332	\$ 65,685
Non-GAAP adjustments:				
Share-based compensation expense	(2,403)	(923)	(7,099)	(2,689)
Depreciation, amortization, and impairment	(147)	(433)	(718)	(1,345)
<b>Adjusted costs and expenses</b>	<u>\$ 22,896</u>	<u>\$ 15,761</u>	<u>\$ 80,515</u>	<u>\$ 61,651</u>

<b>Manufacture and supply expense</b>	\$	4,520	\$	4,679	\$	17,872	\$	20,831
<i>Gross Margin on total revenue</i>		62%		65%		69%		59%
Non-GAAP adjustments:								
Share-based compensation expense		(103)		(36)		(374)		(191)
Depreciation, amortization, and impairment		(124)		(395)		(606)		(1,140)
<b>Non-GAAP adjusted manufacture and supply expense</b>	\$	4,293	\$	4,248	\$	16,892	\$	19,500
<i>Non-GAAP Gross Margin on total revenue</i>		64%		68%		71%		61%
<b>Research and development expense</b>	\$	4,917	\$	2,888	\$	20,280	\$	13,104
Non-GAAP adjustments:								
Share-based compensation expense		(427)		(179)		(1,215)		(456)
Depreciation, amortization, and impairment		(16)		(21)		(70)		(91)
<b>Non-GAAP adjusted research and development expense</b>	\$	4,474	\$	2,688	\$	18,995	\$	12,557
<b>Selling, general and administrative expenses</b>	\$	16,009	\$	9,550	\$	50,180	\$	31,750
Non-GAAP adjustments:								
Share-based compensation expense		(1,873)		(708)		(5,510)		(2,042)
Depreciation, amortization, and impairment		(7)		(17)		(42)		(79)
<b>Non-GAAP adjusted selling, general and administrative expenses</b>	\$	14,129	\$	8,825	\$	44,628	\$	29,629