UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 4, 2024

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

30 Technology Drive
Warren, NJ 07059
(908) 941-1900
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	AQST	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 4, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the third quarter ended September 30, 2024 and provided an update on recent developments in its business. A copy of the Company's press release and the attached financial schedules are attached as Exhibit 99.1 to this Current Report On Form 8-K and incorporated in this Item 2.02 by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "33 Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 7.01 Regulation FD Disclosure.

The Company is furnishing this Current Report on Form 8-K in connection with the disclosure of information, in the form of a investor presentation, to be given at meetings with institutional investors, analysts and others. This information may be amended or updated at any time and from time to time through another Current Report on Form 8-K, a later Company filing or other means. A copy of the Company's investor presentation is attached hereto as Exhibits 99.2 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The investor presentation is available on the Company's website located at www.aquestive.com, although the Company reserves the right to discontinue that availability at any time.

The information in this Item 7.01 (including Exhibit 99.2) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of Section 18 of the Exchange Act, nor shall it be deemed to be incorporated by reference in any filing under the 33 Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

(d)Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 4, 2024, announcing the Company's reported financial results for the third quarter ended September 30, 2024 and providing an update on recent developments in its business.
99.2	Aquestive Therapeutics Q3 Earnings Supplemental Materials dated November 4, 2024.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: **November 4, 2024**

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.
Title: Chief Financial Officer

Exhibit 99.1

Aquestive Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

- Anaphylm™ (epinephrine) Sublingual Film pre-NDA meeting scheduled for fourth quarter 2024
- AQST-108 (epinephrine) Topical Gel pre-IND meeting scheduled for fourth quarter 2024
- Libervant® (diazepam) Buccal Film for patients aged 2-5 available through retail distribution channels
- Finished third quarter 2024 with approximately $78 million of cash and reaffirms cash runway into 2026
- To host investment community conference call at 8:00 am ET on November 5, 2024

Warren, N.J. November 4, 2024 – 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, reported financial results for the third quarter, which ended September 30, 2024, and provided an update on recent developments in its business.

“Our innovative epinephrine prodrug platform remains the cornerstone of our development strategy," said Daniel Barber, President and Chief Executive Officer of Aquestive. “We've reached a significant milestone with the clinical development program for Anaphylm, our groundbreaking oral epinephrine treatment for severe allergic reactions, including anaphylaxis. With our adult supportive studies now complete, we are preparing for our pre-NDA meeting for Anaphylm with the FDA scheduled for this quarter. Moreover, AQST-108, our promising pipeline candidate, is progressing towards a pre-IND meeting this quarter, setting the stage for a potential Phase 2a study in alopecia areata next year, subject to FDA alignment. On the commercial front, we successfully expanded Libervant's market presence, deploying a dedicated sales force and securing nationwide reimbursement coverage, positioning us for continued growth."

Anaphylm™ (epinephrine) Sublingual Film
Aquestive is advancing the development of Anaphylm™ (epinephrine) Sublingual Film, the first and only orally delivered epinephrine product candidate, as an easy to remember, easy to carry, and easy to use alternative to EpiPen® and other epinephrine medical devices for the treatment of severe life-threatening allergic reactions, including anaphylaxis.

In October 2024, Aquestive reported positive topline data from the oral allergy syndrome challenge study (now referred to as the "OASIS" study), meeting both primary and secondary endpoints. The two-part study demonstrated that Anaphylm maintained its pharmacokinetics (PK) and pharmacodynamics (PD) profile during allergen-induced oral physiological changes. In addition, following allergen exposure where 94% of subjects exhibited moderate to severe symptoms per the pre-defined oral severity score, rapid symptom resolution was observed beginning as early as two minutes after administration of Anaphylm. The median time to complete symptom resolution was twelve minutes compared to seventy-four minutes at screening baseline, with 50% of all symptoms across all subjects resolving by five minutes. The mean time of symptom resolution for edema, which affected approximately 25% of subjects, was five minutes after Anaphylm administration. The PK profile remained consistent, with median time to peak drug concentration (Tmax) maintained at twelve minutes and comparable geometric mean maximum concentration (Cmax) values between allergen-exposed and non-exposed cohorts. The safety profile was favorable, with all adverse events classified as mild to moderate and resolving without medical intervention.

Also in October 2024, at the American College of Allergy Asthma and Immunology (ACAAI) 2024 Annual Meeting in Boston, the Company presented results from a subsequent analysis of its pivotal study data demonstrating Anaphylm's consistent PK and PD profile regardless of variable placement or intraoral movement.

The analysis showed that 87.5% of subjects maintained consistent film placement during disintegration. In the 12.5% of subjects where movement was noted, there were no significant differences in Cmax and Tmax. These findings further demonstrate that initial placement or subsequent movement of the sublingual film had no impact on epinephrine PK or PD comparability to epinephrine autoinjectors.

The Company recently received positive pre-New Drug Application (NDA) written response feedback from the U.S. Food and Drug Administration (FDA) to the Company's proposed Chemistry, Manufacturing, Controls (CMC) submission for Anaphylm. In addition, a clinically focused pre-NDA meeting with the FDA is scheduled for the fourth quarter of 2024. The Company is maintaining its guidance of initiating a full product launch of Anaphylm, if approved by the FDA, in the first quarter of 2026. This is based on commencing the pediatric study in subjects weighing 30 kgs and above in the fourth quarter of 2024 and completing an NDA submission with the FDA in the first quarter of 2025.

AQST-108 (epinephrine) Topical Gel
Aquestive is advancing the development of AQST-108, a topically delivered adrenergic agonist prodrug. At the Company's virtual investor day in September 2024, Aquestive outlined its development strategy for AQST-108, the second product candidate from the Company's Adrenaverse prodrug platform. The Company outlined the design of its planned Phase 2a study to assess the safety and efficacy of AQST-108 in alopecia areata patients. The Company has scheduled a pre-IND meeting with the FDA in the fourth quarter of 2024 to align on the Phase 2a study design and plans to commence a Phase 2a study in the second quarter of 2025.

An estimated 6.7 million people in the United States have been affected by alopecia areata. 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 estimated market opportunity for JAK inhibitors is over one billion dollars. In the first in human Phase 1 clinical study, 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 severe alopecia areata, has the potential to capture significant market share.

Libervant® (diazepam) Buccal Film
Libervant® (diazepam) Buccal Film is the first and only FDA approved orally administered rescue product for the treatment of seizure clusters in patients between the ages of two and five years.

In April 2024, the FDA approved Libervant 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 between the ages of two to five years.

Aquestive has continued to expand the launch of Libervant for patients between the ages of two and five years and currently has a twelve person national sales team in place. Market access activities have broadened coverage. Libervant for patients between the ages of two and five years is available nationwide with retail distribution capabilities in place, is available for Medicaid patients in this age group in all states, and commercial access for patients in this age group continues to expand based on health plan reviews and Pharmacy Benefit Manager agreements.

The NDA for Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients twelve years of age and older was tentatively approved by the FDA in August 2022 and is currently subject to an orphan drug market exclusivity block until January 2027 based on an FDA approved nasal spray product of another company. The Company expects to file for approval of Libervant for the treatment of these epilepsy patients between six to twelve years of age prior to the expiration of the orphan drug market exclusivity block.

Commercial Collaborations

Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 44 million doses in the third quarter of 2024, compared to approximately 46 million doses in the third quarter of 2023. The Company 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 third quarter of 2024.

Third Quarter 2024 Financials

Total revenues increased to $13.5 million in the third quarter 2024 from $13.0 million in the third quarter 2023. This 4% increase in revenue was primarily driven by increases in license and royalty revenue due to the recognition of deferred revenue from the termination of a licensing and supply agreement, partially offset by decreases in manufacture and supply revenue.

Manufacture and supply revenue decreased to $10.7 million in the third quarter 2024 from $11.4 million in the third quarter 2023, primarily due to decreases in Suboxone and Sympazan revenues, partially offset by an increase in Ondif revenue, which was attributable to an increase in volume. Manufacture and supply revenue decreased to $29.3 million for the nine months ended September 30, 2024 from $32.8 million for the nine months ended September 30, 2023. On a September year-to-date basis and excluding the one-time retroactive price increase of $1.7 million recognized in the three months ended March 31, 2023, manufacture and supply revenue decreased to $29.3 million from $31.1 million.

Research and development expenses increased to $5.3 million in the third quarter 2024 from $3.2 million in the third quarter 2023. The increase in research and development expenses was primarily due to clinical trial costs and product research expenses associated with the continued advancement of the Anaphylm development program.

Selling, general and administrative expenses increased to $12.1 million in the third quarter 2024 from $7.4 million in the third quarter 2023. This increase was partially driven by a $1.5 million year-over-year change in the allocation of expenses of manufacturing and supply costs. Given this year-over-year change, the Company expects to continue to see a positive benefit in gross margin offset by somewhat higher selling, general and administrative expenses. Excluding this item, increases in expenses were driven by increased commercial spending and regulatory fees related to the approval of Libervant and the commercial preparations for Anaphylm.

Aquestive's net loss for the third quarter 2024 was $11.5 million, or $0.13 for both basic and diluted loss per share, compared to the net loss for the third quarter 2023 of $2.0 million, or $0.03 for both basic and diluted loss per share. The increase in net loss was primarily driven by increases in selling, general and administrative expenses, research and development expenses, non-cash interest expense related to amortization of the debt and royalty obligation discounts, and decreases in interest income and other income, net partially offset by increases in revenues.

Non-GAAP adjusted EBITDA loss was $6.6 million in the third quarter 2024, compared to non-GAAP adjusted EBITDA loss of $1.3 million in the third quarter 2023. Non-GAAP adjusted EBITDA loss excluding adjusted research and development expenses was $1.6 million in the third quarter 2024, compared to non-GAAP adjusted EBITDA income excluding adjusted research and development expenses of $1.7 million in the third quarter 2023.

Cash and cash equivalents were $77.9 million as of September 30, 2024.

Outlook
Aquestive's full-year 2024 financial guidance is below.

The Company expects:

	Guidance
Total revenue (in millions)	$57 to $60
Non-GAAP adjusted EBITDA loss (in millions)	$20 to $23

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Tuesday, November 5, 2024.

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: **Third Quarter 2024 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 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 approval for U.S. market access received in April 2024 for Libervant is for these epilepsy patients between two and five years of age. The FDA granted tentative approval in August 2022 for Libervant for treatment of these epilepsy 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 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 and without any serious or topical adverse events. 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 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®, 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 dermatology conditions. 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 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 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 2024 and 2023 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 U.S. Food and Drug Administration (FDA), including the timing of submission of supporting and pediatric clinical studies, holding a pre-New Drug Application (NDA) meeting with the FDA and filing the NDA for Anaphylm with the FDA, 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; that Anaphylm will be the first and only oral administration of epinephrine and accepted as an alternative to existing standards of care, if Anaphylm is approved by the FDA; the advancement and related timing of our Adrenaverse pipeline epinephrine prodrug product candidates, including AQST-108, through clinical development and FDA regulatory approval process, including holding a pre-IND meeting with the FDA for AQST-108; the advancement and related timing of our product candidate Libervant® (diazepam) Buccal Film for the indicated epilepsy patient population aged between six and eleven years through clinical development and FDA regulatory approval and the following launch of Libervant for this patient population if approved by the FDA; the approval for U.S. market access of Libervant for this patient population aged six years, and older and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for Libervant for these epilepsy patients six years of age and older; the advancement, growth and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel, through clinical development including design and timing of clinical studies including those necessary to support the targeted indication of alopecia areata for AQST-108, and holding a pre-investigational new drug application meeting (IND) with the FDA; the commercial opportunity of Libervant, Anaphylm, AQST-108 and our other product candidates, including potential revenues (including projected peak annual sales) generated from commercialization of these products and product candidates should these product candidates be approved by the FDA; the potential benefits our products and product candidates could bring to patients; our cash and financial position, including with respect to our 2024 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 the Company's other product candidates; risks associated with the Company’s distribution work for Libervant, including any delays or changes to the timing, cost and success of Company's distribution activities and expansion of market access to patients aged two to five for Libervant; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, including for Anaphylm, AQST-108, Libervant for patients aged between six and eleven 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; risk of the Company’s ability to address the FDA’s comments on the Company’s 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; risk of the success of any competing products; 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 aged six years and older until the expiration of the orphan drug market exclusivity period of the nasal spray product due to expire in January 2027, or for other reasons; risk of loss of U.S. market approval of Libervant for patients aged between two and five resulting from a legal challenge relating to U.S. orphan drug market exclusivity by the owner of the approved nasal spray product with respect to the FDA's approval for U.S. market access of Libervant for this pediatric patient population, 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 sales and marketing capability for commercialization of our product Libervant and other product candidates, including Anaphylm and AQST-108; 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 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 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 six and eleven, should these product candidates be approved by the FDA, and for Libervant patients of six years and older upon expiration of the orphan drug marketing exclusivity period of the nasal spray product; risk that our manufacturing capabilities will be sufficient 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® and risk as a sunsetting product, which accounts for the 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 Libervant for epilepsy patients between two and five years of age, and for older 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 Libervant and 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 of the success of any competing products including generics; risk of the size and growth of our product markets; risk of 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 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 products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive 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 rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases 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. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in the risk factors of the Company's 2023 Annual Report on Form 10-K and our other Quarterly Reports on Form 10-Q and in our Current Reports on Form 8-K and our other filings with the U.S. Securities and Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as 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.

Investor inquiries:
ICR Westwicke
Stephanie Carrington
Stephanie.Carrington@icrhealthcare.com
646-277-1282

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 77,893	$ 23,872
Trade and other receivables, net	9,684	8,471
Inventories	7,021	6,769
Prepaid expenses and other current assets	1,972	1,854
Total current assets	96,570	40,966
Property and equipment, net	3,848	4,179
Right-of-use assets, net	5,310	5,557
Intangible assets, net	—	1,278
Other non-current assets	4,230	5,438
Total assets	$ 109,958	$ 57,418
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 7,572	$ 8,926
Accrued expenses	5,025	6,497
Lease liabilities, current	482	390
Deferred revenue, current	1,048	1,551
Liability related to the sale of future revenue, current	1,000	922
Loans payable, current	25	22
Total current liabilities	15,152	18,308
Notes payable, net	31,253	27,508
Royalty obligations, net	18,835	14,761
Liability related to the sale of future revenue, net	62,730	63,568
Lease liabilities	5,109	5,399
Deferred revenue, net of current portion	20,266	32,345
Other non-current liabilities	2,033	2,016
Total liabilities	155,378	163,905
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 91,178,193 and 68,533,085 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	91	69
Additional paid-in capital	300,648	212,521
Accumulated deficit	(346,159)	(319,077)
Total stockholders' deficit	(45,420)	(106,487)
Total liabilities and stockholders' deficit	$ 109,958	$ 57,418

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues	$ 13,542	$ 13,002	$ 45,694	$ 37,377
Costs and expenses:				
Manufacture and supply	4,437	4,798	13,352	16,152
Research and development	5,269	3,196	15,363	10,216
Selling, general and administrative	12,126	7,385	34,171	22,200
Total costs and expenses	21,832	15,379	62,886	48,568
Income (Loss) from operations	(8,290)	(2,377)	(17,192)	(11,191)
Other income/(expenses):				
Interest expense	(2,780)	(1,256)	(8,343)	(4,064)
Interest expense related to royalty obligations	(1,359)	—	(4,075)	—
Interest expense related to the sale of future revenue	(59)	(56)	(175)	(163)
Interest income and other income, net	979	1,514	2,703	16,156
Loss on extinguishment of debt	—	—	—	(353)
Net (loss) income before income taxes	(11,509)	(2,175)	(27,082)	385
Income taxes (benefit) expense	—	(140)	—	144
Net (loss) income	$ (11,509)	$ (2,035)	$ (27,082)	$ 241
Comprehensive (loss) income	$ (11,509)	$ (2,035)	$ (27,082)	$ 241
(Loss) earnings per share attributable to common stockholders:				
Basic (in dollars per share)	$ (0.13)	$ (0.03)	$ (0.32)	$ —
Diluted (in dollars per share)	$ (0.13)	$ (0.03)	$ (0.32)	$ —
Weighted average common shares outstanding:				
Basic (in shares)	91,082,081	64,678,761	85,224,263	59,252,768
Diluted (in shares)	91,082,081	64,678,761	85,224,263	61,513,736

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
GAAP net (loss) income	$ (11,509)	$ (2,035)	$ (27,082)	$ 241
Share-based compensation expense	1,577	774	4,696	1,766
Interest expense	2,780	1,256	8,343	4,064
Interest expense related to royalty obligations	1,359	—	4,075	—
Interest expense related to the sale of future revenue	59	56	175	163
Interest income and other income, net	(979)	(1,514)	(2,703)	(16,156)
Loss on extinguishment of debt	—	—	—	353
Income Taxes	—	(140)	—	144
Depreciation and Amortization	159	264	571	878
Total non-GAAP adjustments	$ 4,955	$ 696	$ 15,157	$ (8,788)
Non-GAAP adjusted EBITDA	$ (6,554)	$ (1,339)	$ (11,925)	$ (8,547)
Excluding Non-GAAP adjusted R&D expenses	(4,943)	(3,069)	(14,521)	(9,869)
Non-GAAP adjusted EBITDA excluding Non-GAAP adjusted R&D expenses	$ (1,611)	$ 1,730	$ 2,596	$ 1,322

AQUESTIVE THERAPEUTICS, INC.
Reconciliation of Non-GAAP Adjustments - GAAP Expenses to Non-GAAP Adjusted Expenses
(In Thousands, except percentages)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Total costs and expenses	$ 21,832	$ 15,379	$ 62,886	$ 48,568
Non-GAAP adjustments:				
Share-based compensation expense	(1,577)	(774)	(4,696)	(1,766)
Depreciation and amortization	(159)	(264)	(571)	(878)
Non-GAAP adjusted costs and expenses	$ 20,096	$ 14,341	$ 57,619	$ 45,924
Manufacture and Supply Expense	$ 4,437	$ 4,798	$ 13,352	$ 16,152
Gross Margin on total revenue	*67 %*	*63 %*	*71 %*	*57 %*
Non-GAAP adjustments:				
Share-based compensation expense	(102)	(59)	(271)	(155)
Depreciation and amortization	(130)	(214)	(482)	(746)
Non-GAAP adjusted manufacture and supply expense	$ 4,205	$ 4,525	$ 12,599	$ 15,251
Non-GAAP Gross Margin on total revenue	*69 %*	*65 %*	*72 %*	*59 %*
Research and Development Expense	$ 5,269	$ 3,196	$ 15,363	$ 10,216
Non-GAAP adjustments:				
Share-based compensation expense	(310)	(105)	(788)	(277)
Depreciation and amortization	(16)	(22)	(54)	(70)
Non-GAAP adjusted research and development expense	$ 4,943	$ 3,069	$ 14,521	$ 9,869
Selling, General and Administrative Expenses	$ 12,126	$ 7,385	$ 34,171	$ 22,200
Non-GAAP adjustments:				
Share-based compensation expense	(1,165)	(610)	(3,637)	(1,334)
Depreciation and amortization	(13)	(28)	(35)	(62)
Non-GAAP adjusted selling, general and administrative expenses	$ 10,948	$ 6,747	$ 30,499	$ 20,804

Aquestive®

Third Quarter 2024 Earnings Supplemental Materials

November 4, 2024

Advancing medicines.
Solving problems.
Improving lives.

Disclaimer

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and other uncertainties affecting us. 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Aquestive

Q3 2024 earnings key messages

- Anaphylm™ (epinephrine) Sublingual Film
  - Positive topline results - Oral Allergy Syndrome challenge study (referred to as OASIS)
  - Pre-NDA meeting scheduled for Q4 2024
  - Anticipate commencement of the single-dose pediatric study immediately following the pre-NDA meeting
  - Plan to complete the NDA submission in Q1 2025
- Libervant® (diazepam) Buccal Film for patients ages two to five years old
  - Currently have a twelve-person national sales team in place
  - Available through retail distribution as of October 2024
  - For Medicaid patients, Libervant for patients ages two to five years old is reimbursable in all states
  - Commercial patient access to Libervant for patients ages two to five years old continues to improve based on health plan reviews and PBM agreements
- AQST-108 (epinephrine) Topical Gel
  - Target indication is alopecia areata
  - Pre-IND meeting with the FDA scheduled for Q4 2024
  - Planning to initiate a Phase 2a study in Q2 2025 after gaining alignment with the FDA
- Strengthened the Balance Sheet Extending Cash Runway into 2026
  - Finished Q3 2024 with a cash balance of approximately $78 million

Positioned for a strong finish in 2024

July

- Announced positive topline data from Anaphylm self-administration study
- Began enrollment of the OASIS study

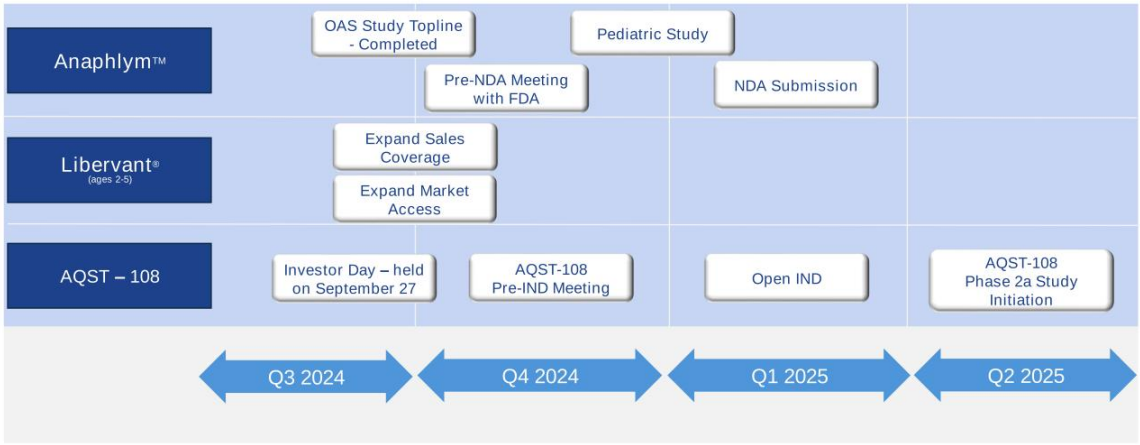
August

- Continued to expand market access for Libervant ages 2-5 for both commercial and CMS patients

September

- Submitted request for pre-NDA meeting for Anaphylm
- Completed enrollment for the OASIS study
- Hosted an Investor Day and announced target indication of alopecia areata for AQST-108 (epinephrine) topical gel

Milestones



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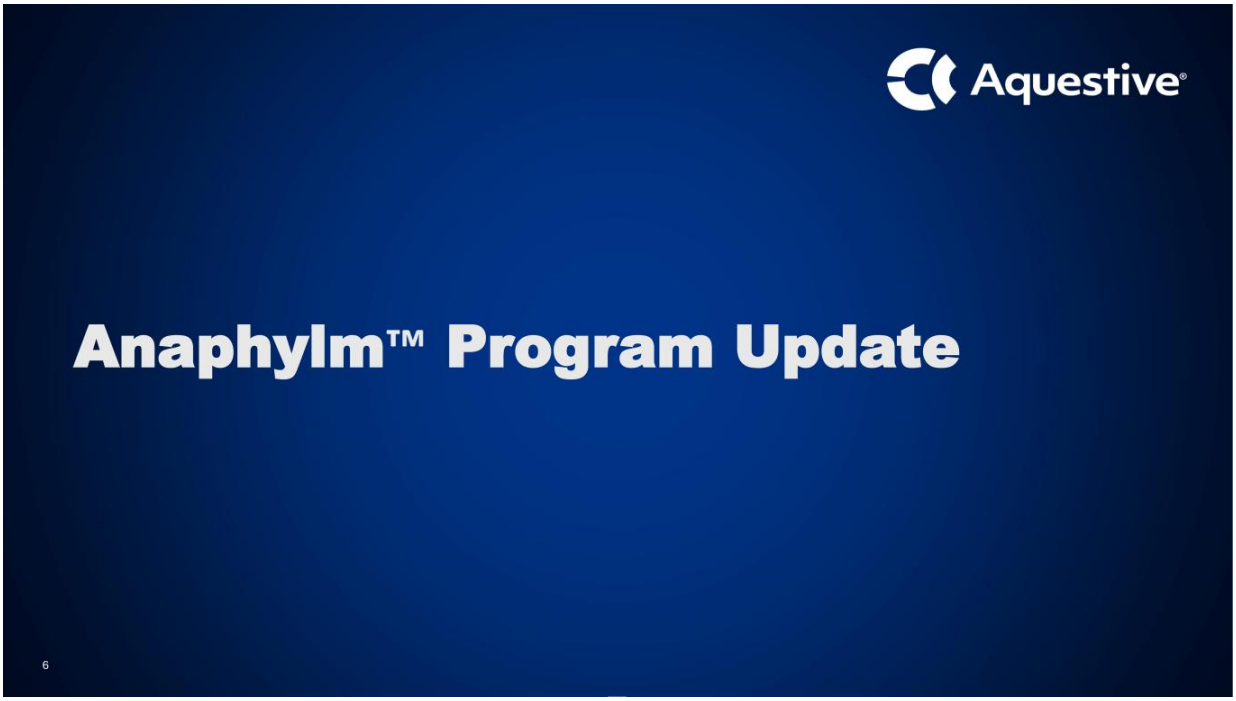
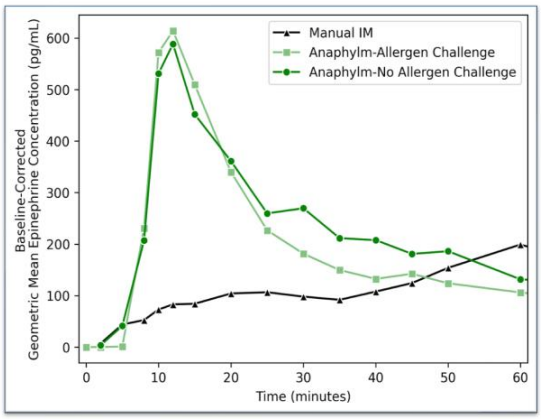

Aquestive
AnaphyIm™ Program Update
6

Anaphylm program update and next steps

- Completed OASIS study
  - Full topline clinical data released and available on the Aquestive website (https://investors.aquestive.com/events-and-presentations)
  - Additional analysis provided on subjects with edema or oral swelling
- All planned adult studies now completed
- Plan to commence pediatric study, pending FDA alignment on protocol, immediately following the pre-NDA meeting with the FDA
- Pre-NDA meeting with FDA scheduled for Q4 2024

OASIS study – symptomatic oral edema has no impact on **Anaphylm's** pharmacokinetics (PK) performance[1]

Single dose (n=7) for subjects with reported oral edema compared to the same subjects without the allergen challenge



Anaphylm administered with and without allergen challenge:

- Remains above the Adrenalin manual intramuscular (Manual IM) out to 45 minutes
- Has similar PK profiles
- Demonstrates consistent median time to peak drug concentration (Tmax)

1. Aquestive Therapeutics data on file.

Aquestive

Planned pediatric study[1]

Study Design

Single dose, single treatment, multi-center, parallel design study in pediatric patients ages 7-17 (weight ≥ 30kg) at heightened risk of anaphylaxis (n=18-24)

Endpoints

Pharmacokinetics (PK), pharmacodynamics (PD), and treatment-emergent adverse events (TEAEs)

Anaphylm single dose administration by healthcare provider

1. Study design pending FDA alignment on protocol.


Aquestive
AQST-108 Program Update
10

AQST-108 planned Phase 2a clinical study for alopecia areata[1]

A Phase 2a, multi-center, double-blind, dose-response, adaptive study to evaluate the safety and efficacy of AQST-108 in mild to moderate alopecia areata patients

Phase 2a Study Design
• 24-48 subjects, 4 doses • 12 – 24 weeks[2] • **Change from baseline ≥10% in Severity of Alopecia Tool (SALT) score at Week 12** • Trichoscopy evaluations and labs at baseline

Phase 2a Study Objectives:

- Assess the safety and efficacy of AQST-108 in alopecia areata patients following 12 weeks of treatment as determined by change from baseline ≥10% in SALT score at week 12

1. Plan on commencing study after alignment with the FDA. 2. Interim data available after 12 weeks and primary endpoint data expected to be available at 24 weeks.


Aquestive
Libervant® Launch Update
12

Libervant prescriptions for patients two to five years of age are increasing as patient access and sales force expands

- Libervant launch continues to expand and remains on target
- Prescriptions average 1.8 cartons per prescription[1]
- Sales force active and sized to cover 2,300 healthcare prescribers (HCPs)
- Full national retail distribution in place since October 1, 2024

1. Aquestive Therapeutics data on file.

Payer coverage and market access continues to expand

Market Access – Payer Coverage

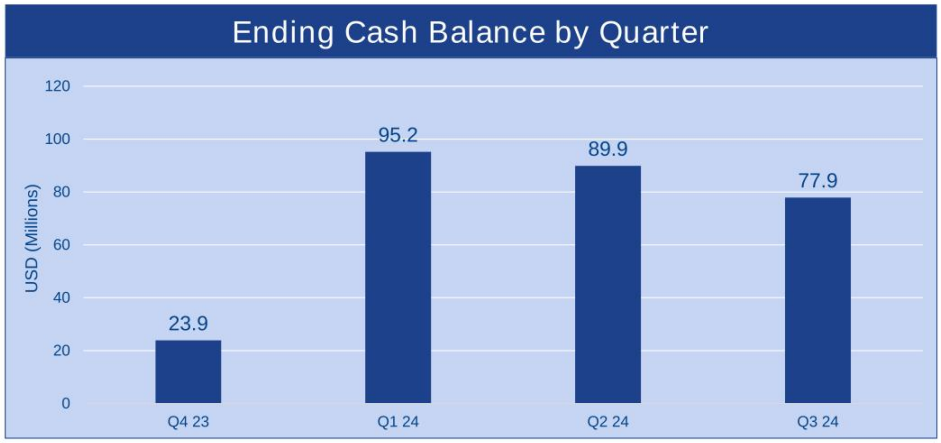
- Medicaid reimbursable in all states with clinically appropriate edits (e.g., age)
- Negotiations continue with commercial pharmacy benefit manager companies (PBMs – agreements completed with 2 of the top 3 PBMs for Libervant patients 2-5
- Commercial health plans have begun adding coverage for Libervant patients 2-5

Market Access – Distribution

- Full retail distribution for Libervant patients 2-5 in place
- Libervant for patients 2-5 stocked at 70 regional wholesaler distribution centers across the U.S. for retail pharmacy access

Financial Results

Cash position significantly improved following equity raise in Q1 2024



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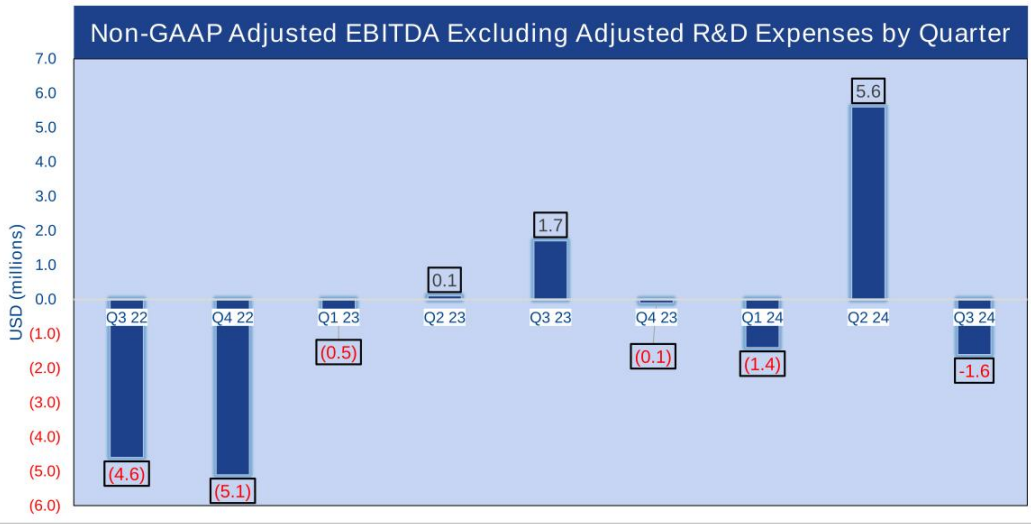
EBITDA excluding research and development expenses[1]



1. Excludes R&D pipeline investments in Anaphylm and AQST-108; includes commercial investments in Anaphylm and Libervant.

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Manufacturing operations continue to generate cash flow

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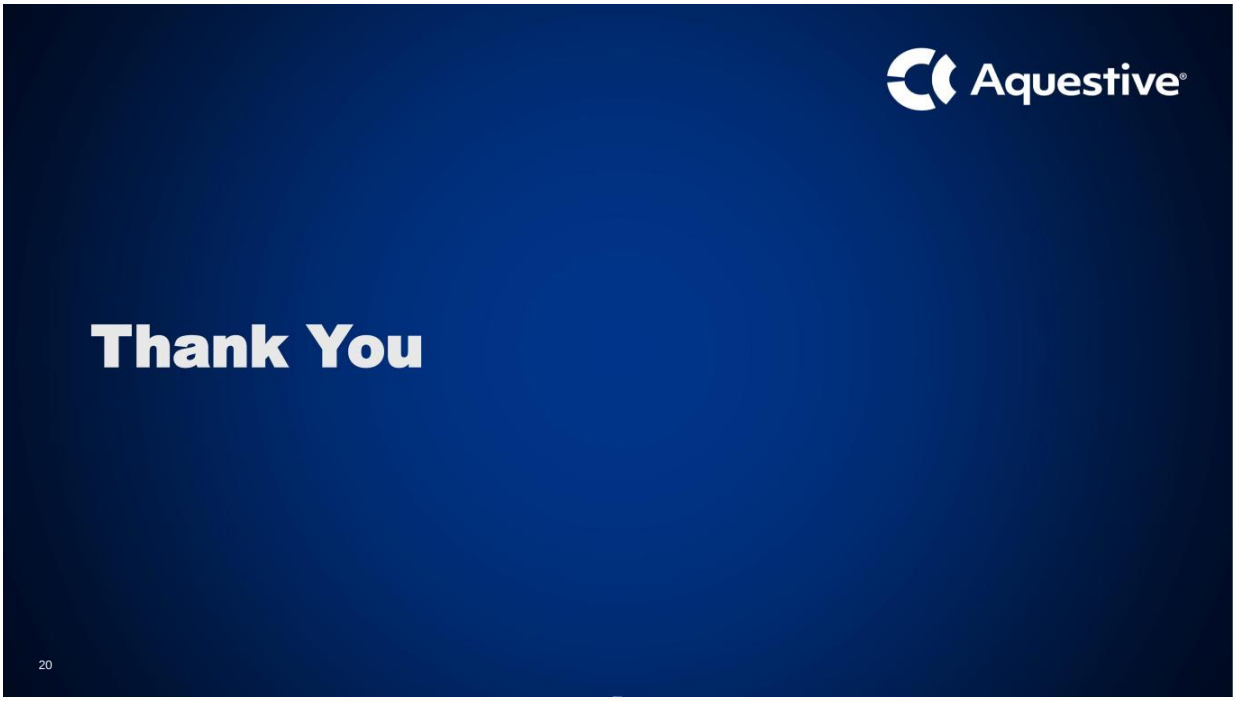
Current full year guidance

2024 Outlook

- Total revenues of approximately $57 to $60 million
- Non-GAAP adjusted EBITDA loss of approximately $20 to $23 million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Thank You
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