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): August 6, 2024

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	**(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 August 6, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the second quarter ended June 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 August 6, 2024, announcing the Company's reported financial results for the second quarter ended June 30, 2024 and providing an update on recent developments in its business.
99.2	Aquestive Therapeutics Q2 Earnings Supplemental Materials dated August 6, 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:August 6**,** 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 Second Quarter 2024 Financial Results and Provides Business Update

- Late-stage pipeline program, Anaphylm™ (epinephrine) Sublingual Film, remains on track for a near-term New Drug Application (NDA) submission to the FDA
- Expanded sales coverage for Libervant™ (diazepam) Buccal Film for patients between ages two to five with national retail distribution anticipated in the fourth quarter 2024
- Anticipates holding epinephrine prodrug technology investor day in the coming months
- Finishes the second quarter 2024 with cash and cash equivalents of approximately $90 million and reaffirms cash runway into 2026
- To host investment community conference call at 8:00 am ET on August 7, 2024

Warren, N.J. August 6, 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 second quarter, which ended June 30, 2024, and provided an update on recent developments in its business.

“We continue to rapidly transform the Company through advancing our epinephrine prodrug platform," said Daniel Barber, President and Chief Executive Officer of Aquestive. “We have utilized this technology platform to drive the development of our product candidate Anaphylm™ as the first and only oral epinephrine product for the treatment of severe allergic reactions, including anaphylaxis. On a global basis, we believe Anaphylm has the potential to be a billion-dollar commercial opportunity. We also believe that our epinephrine prodrug platform branded as Adrenaverse™ is leading the way for potential multiple epinephrine prodrug pipeline opportunities that could produce another billion dollars in opportunities, if new product candidates developed by the Company are approved by the FDA. These opportunities, along with Libervant and our base business, have positioned the Company for continued growth over the next several years.”

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 injectors for the treatment of severe life-threatening allergic reactions, including anaphylaxis.

In June 2024, Aquestive reported positive topline pharmacokinetic (PK) data from the temperature / pH study of Anaphylm™. The single-dose, five-period, randomized crossover study was designed to compare the PK and pharmacodynamics (PD) of Anaphylm just after consuming normal water at different temperatures (hot, cold, and room temperature) as well as water of different pHs (acidic - lemon water, and basic-baking soda water). The most consumed beverages, such as soda, milk, coffee, and juice, have acidity between lemon water and normal water. The primary PK parameters were the maximum amount of epinephrine measured in plasma (Cmax) and exposure, or the area under the curve (AUC), at predefined time points after dosing, in 30 healthy adult subjects. Topline PK and PD data from the study showed no statistically significant difference in PK and PD results between the different groups based on temperature and pH variability in the mouth.

In July 2024, Aquestive reported positive topline data from the self-administration PK study of Anaphylm. The single-dose, three-period, randomized crossover study was designed to compare the PK and PD of Anaphylm self-administered, Anaphylm healthcare provider (HCP)-administered, and Adrenalin manual intramuscular (IM) injection HCP- administered. The primary PK parameters were the maximum amount of epinephrine measured in plasma (Cmax) and exposure, or the area under the curve (AUC), at predefined time points after dosing in 36

healthy adult subjects. The median time to maximum concentration (Tmax) was 15 minutes for both the Anaphylm self-administered and HCP-administered arms, while the median Tmax for the Adrenalin IM HCP administered arm was 50 minutes post administration. Also, there was no statistical difference between the Anaphylm self-administered and HCP-administered arms of the study based on a comparison of epinephrine exposures across the first 60 minutes post-administration. Topline PD data from the study showed no difference in the median increase in systolic blood pressure, diastolic blood pressure, and heart rate whether Anaphylm is self-administered or HCP-administered.

The Company's remaining supportive study, the oral allergy syndrome (OAS) challenge study, is underway, and the study is expected to be completed late in the third quarter or early fourth quarter of 2024. The Company is maintaining its guidance of initiating a full product launch of Anaphylm, if approved by the U.S. Food and Drug Administration (FDA), at the end of 2025 or in the first quarter of 2026. This is based on completing an NDA submission with the FDA in the first quarter of 2025.

AQST-108 (epinephrine) Topical Gel
Aquestive continues to progress its Adrenaverse™ epinephrine prodrug platform with AQST-108, which is an epinephrine prodrug topical gel product candidate for various potential dermatology conditions. The Company completed its first human clinical study for AQST-108 in the first quarter of 2024. The initial study measured the amount of epinephrine that remained on the skin or was found in circulation over time after the application of the gel. The data were positive, and the Company expects to hold a pre-Investigational New Drug (IND) meeting with the FDA in the fourth quarter of 2024 and is planning a phase 2a study in the first half of 2025.

The Company plans to hold an investor day the coming months to communicate the science and intellectual property that is the basis of the Adrenaverse epinephrine prodrug platform. This event will include further information regarding specific potential indications and market opportunities for AQST-108.

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.

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. 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.

Aquestive has launched Libervant for patients between the ages of two and five and expects to expand this launch with up to ten sales representatives in the third quarter 2024. The Company is also expanding its distribution network and expects to have national retail distribution capabilities in place by the fourth quarter 2024 as well as broadening Medicaid and commercial coverage in the coming months. Medicaid accounts for up to fifty percent of all prescriptions among this pediatric patient population.

Commercial Collaborations
Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 34 million doses in the second quarter 2024, compared to approximately 48 million doses in the second quarter 2023. The Company continues to see demand for the manufacturing 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 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 contribute to the Company's revenue in the second quarter 2024.

Second Quarter 2024 Financials

Total revenues increased to $20.1 million in the second quarter 2024 from $13.2 million in the second quarter 2023. This 52% increase in revenue was primarily driven by increases in license and royalty revenue due to the recognition of deferred revenues from the termination of Licensing and Supply agreements, and co-development and research fees, partially offset by decreases in manufacture and supply revenue.

Manufacture and supply revenue decreased to $8.1 million in the second quarter 2024 from $11.6 million in the second quarter 2023, primarily due to timing of Suboxone and Ondif product orders. Manufacture and supply revenue decreased to $18.6 million for the six months ended June 30, 2024 from $21.4 million for the six months ended June 30, 2023. On a June 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 $18.6 million from $19.7 million.

Research and development expenses increased to $4.2 million in the second quarter 2024 from $3.5 million in the second quarter 2023. The increase in research and development expenses was primarily due to the continued advancement of the Anaphylm development program and increases in R&D personnel costs and share-based compensation.

Selling, general and administrative expenses increased to $11.4 million in the second quarter 2024 from $7.4 million in the second quarter 2023. This increase was partially driven by a $1.6 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 second quarter 2024 was $2.7 million, or $0.03 for both basic and diluted loss per share, compared to the net loss for the second quarter 2023 of $5.8 million, or $0.10 for both basic and diluted loss per share. The decrease in net loss was primarily driven by increases in revenues and decreases in manufacture and supply expenses, offset by increases in selling, general and administrative expenses, research and development expenses, and non-cash interest expense related to amortization of the debt and royalty obligation discounts.

Non-GAAP adjusted EBITDA income was $1.8 million in the second quarter 2024, compared to non-GAAP adjusted EBITDA loss of $3.3 million in the second quarter 2023. Non-GAAP adjusted EBITDA income excluding adjusted R&D expenses was $5.6 million in the second quarter 2024, compared to a non-GAAP adjusted EBITDA income excluding adjusted R&D expenses of $0.1 million in the second quarter 2023.

Cash and cash equivalents were $89.9 million as of June 30, 2024.

Outlook

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

Aquestive is updating its full-year 2024 financial guidance based on second quarter 2024 results and updated outlook for the remainder of 2024.

	Updated Guidance	**Previous Guidance**
Total revenue (in millions)	$57 to $60	$48 to $51
Non-GAAP adjusted EBITDA loss (in millions)	$20 to $23	$22 to $26

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Wednesday, August 7, 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: **Second Quarter 2024 Earnings Call.**

About Anaphylm™
Anaphylm™ (epinephrine) Sublingual Film is a polymer matrix-based epinephrine prodrug product candidate. 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 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 an epinephrine prodrug topical gel product candidate. Aquestive completed a first in human study for AQST-108 that measured the amount of epinephrine that remained on the skin or was found in circulation over time after the application of the gel. AQST-108 is based on Aquestive's Adrenaverse™ platform that contains a library of over twenty epinephrine prodrug product candidates intended to control absorption and conversion rates across a variety of possible dosage forms and delivery sites.

Important Safety Information

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

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

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

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

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

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

- Do not allow your child to drive a motor vehicle, operate machinery, or ride a bicycle until you know how Libervant affects your child.
- Do not give other drugs that may make your child sleepy or dizzy while taking Libervant without first talking to your child's healthcare provider. When taken with drugs that cause sleepiness or dizziness, Libervant may make your child's sleepiness or dizziness much worse.

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

- **Call a healthcare provider right away if your child has any of these symptoms, especially if they are new, worse, or worry you:**
    - thoughts about suicide or dying
    - new or worse depression
    - feeling agitated or restless
    - trouble sleeping (insomnia)
    - acting aggressive, being angry or violent
    - other unusual changes in behavior or mood
    - attempts to commit suicide

    - new or worse anxiety or irritability
    - an extreme increase in activity and talking (mania)
    - new or worse panic attacks
    - acting on dangerous impulses
- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your child's healthcare provider as scheduled.
- **Call your child's healthcare provider between visits as needed, especially if you are worried about symptoms.** Suicidal thoughts or actions can be caused by things other than medicines. If your child has suicidal thoughts or actions, your child's healthcare provider may check for other causes.

What are the possible side effects of Libervant?

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

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

About Aquestive Therapeutics, Inc.

Aquestive is pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products marketed by its licensees in the U.S. and around the world and is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product candidate for the treatment of severe allergic reactions, including anaphylaxis and an early-stage epinephrine prodrug topical gel product candidates 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 FDA, including submission of supporting clinical studies and the NDA for Anaphylm in the near term and the following launch of Anaphylm, if approved 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 commercial opportunity of Anaphylm; the advancement and related timing of our Adrenaverse pipeline epinephrine prodrug product candidates, including AQST-108, through clinical development and regulatory approval process, including holding a pre-IND meeting with the FDA for AQST-108; the commercial opportunity of our Adrenaverse epinephrine prodrug platform and its ability to transform the Company; the continued expansion of market access and coverage, commercial and distribution capabilities and future market opportunity for Libervant™ (diazepam) Buccal Film for the indicated epilepsy patient population aged between two and five years; the advancement and related timing of Libervant for these epilepsy patients aged between six and eleven years through the clinical development and regulatory approval process; the approval for U.S. market access of Libervant for this patient population aged twelve 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 focus on continuing to manufacture Suboxone®, Emylif®, Sympazan®, Ondif® and other licensed products and continued growth of these products over several years in the future and our ability to support the manufacture and supply of these products in the U.S. and abroad; the potential benefits our products could bring to patients; our cash requirements, cash funding and cash burn; short-term and longer term liquidity and the ability to fund our business operations; our growth and future financial and operating results and financial position, including with respect to our 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, Libervant for patients aged between six and eleven years, 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 litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product for pediatric epilepsy patients between two to five years of age; risk of delays in advancement of the regulatory approval process through the FDA of Anaphylm, including the filing of the NDA for AQST-108 and our 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 data in its 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 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 between two and five years until the expiration of the exclusivity period in January 2027 or for other reasons; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of our product Libervant and other product candidates including Anaphylm; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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 Anaphylm, should Anaphylm be approved by the FDA; 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; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone; 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 upon approval for U.S. market access of Libervant for these older epilepsy patients after the expiration of the orphan drug 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 products and 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 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 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 cyberattacks; 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; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 2023 Annual Report on Form 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.

Investor inquiries:
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646-277-1282

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 89,870	$ 23,872
Trade and other receivables, net	5,998	8,471
Inventories	6,966	6,769
Prepaid expenses and other current assets	1,177	1,854
Total current assets	104,011	40,966
Property and equipment, net	3,921	4,179
Right-of-use assets, net	5,435	5,557
Intangible assets, net	—	1,278
Other non-current assets	4,238	5,438
Total assets	$ 117,605	$ 57,418
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,696	$ 8,926
Accrued expenses	5,674	6,497
Lease liabilities, current	455	390
Deferred revenue, current	1,046	1,551
Liability related to the sale of future revenue, current	1,000	922
Loans payable, current	24	22
Total current liabilities	13,895	18,308
Notes payable, net	30,006	27,508
Royalty obligations, net	17,477	14,761
Liability related to the sale of future revenue, net	62,684	63,568
Lease liabilities	5,238	5,399
Deferred revenue	21,757	32,345
Other non-current liabilities	2,027	2,016
Total liabilities	153,084	163,905
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 91,059,760 and 68,533,085 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	91	69
Additional paid-in capital	299,080	212,521
Accumulated deficit	(334,650)	(319,077)
Total stockholders' deficit	(35,479)	(106,487)
Total liabilities and stockholders' deficit	$ 117,605	$ 57,418

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

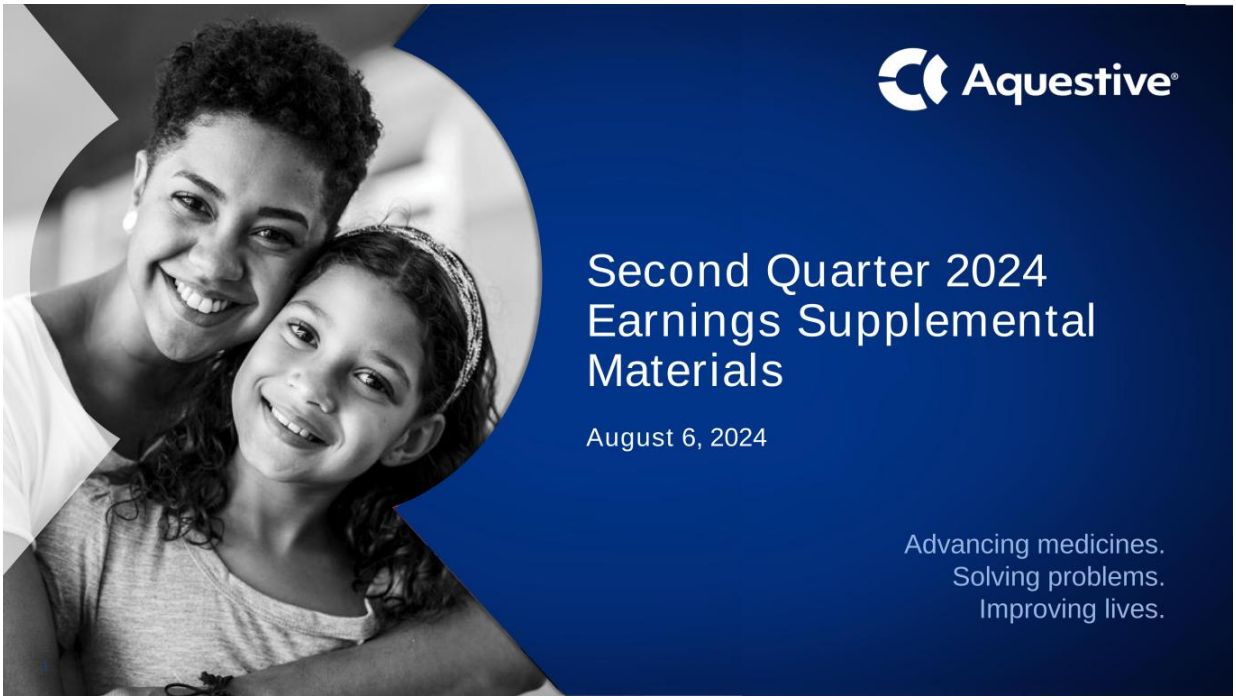
	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenues	$ 20,099	$ 13,241	$ 32,152	$ 24,375
Costs and expenses:				
Manufacture and supply	4,526	6,617	8,915	11,354
Research and development	4,162	3,473	10,094	7,020
Selling, general and administrative	11,356	7,360	22,045	14,815
Total costs and expenses	20,044	17,450	41,054	33,189
Income (Loss) from operations	55	(4,209)	(8,902)	(8,814)
Other income/(expenses):				
Interest expense	(2,779)	(1,373)	(5,563)	(2,808)
Interest expense related to royalty obligations	(1,358)	—	(2,716)	—
Interest expense related to the sale of future revenue	(58)	(55)	(116)	(107)
Interest income and other income, net	1,395	129	1,724	14,642
Loss on extinguishment of debt	—	—	—	(353)
Net (loss) income before income taxes	(2,745)	(5,508)	(15,573)	2,560
Income taxes	—	284	—	284
Net (loss) income	$ (2,745)	$ (5,792)	$ (15,573)	$ 2,276
Comprehensive (loss) income	$ (2,745)	$ (5,792)	$ (15,573)	$ 2,276
Loss) earnings per share attributable to common stockholders:				
Basic (in dollars per share)	$ (0.03)	$ (0.10)	$ (0.19)	$ 0.04
Diluted (in dollars per share)	$ (0.03)	$ (0.10)	$ (0.19)	$ 0.04
Weighted average common shares outstanding:				
Basic (in shares)	90,911,626	57,350,902	82,263,168	56,494,805
Diluted (in shares)	90,911,626	57,350,902	82,263,168	58,938,222

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP net (loss) income	$ (2,745)	$ (5,792)	$ (15,573)	$ 2,276
Share-based compensation expense	1,539	648	3,119	992
Interest expense	2,779	1,373	5,563	2,808
Interest expense related to royalty obligations	1,358	—	2,716	—
Interest expense related to the sale of future revenue	58	55	116	107
Interest income and other income, net	(1,395)	(129)	(1,724)	(14,642)
Loss on extinguishment of debt	—	—	—	353
Income Taxes	—	284	—	284
Depreciation and Amortization	205	289	412	614
Total non-GAAP adjustments	$ 4,544	$ 2,520	$ 10,202	$ (9,484)
Non-GAAP adjusted EBITDA	$ 1,799	$ (3,272)	$ (5,371)	$ (7,208)
Excluding Non-GAAP adjusted R&D expenses	(3,836)	(3,350)	(9,578)	(6,800)
Non-GAAP adjusted EBITDA excluding Non-GAAP adjusted R&D expenses	$ 5,635	$ 78	$ 4,207	$ (408)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Total costs and expenses	$ 20,044	$ 17,450	$ 41,054	$ 33,189
Non-GAAP adjustments:				
Share-based compensation expense	(1,539)	(648)	(3,119)	(992)
Depreciation and amortization	(205)	(289)	(412)	(614)
Non-GAAP adjusted costs and expenses	$ 18,300	$ 16,513	$ 37,523	$ 31,583
Manufacture and Supply Expense	$ 4,526	$ 6,617	$ 8,915	$ 11,354
Gross Margin on total revenue	*77 %*	*50 %*	*72 %*	*53 %*
Non-GAAP adjustments:				
Share-based compensation expense	(99)	(55)	(169)	(96)
Depreciation and amortization	(176)	(251)	(352)	(532)
Non-GAAP adjusted manufacture and supply expense	$ 4,251	$ 6,311	$ 8,394	$ 10,726
Non-GAAP Gross Margin on total revenue	*79 %*	*52 %*	*74 %*	*56 %*
Research and Development Expense	$ 4,162	$ 3,473	$ 10,094	$ 7,020
Non-GAAP adjustments:				
Share-based compensation expense	(308)	(100)	(478)	(172)
Depreciation and amortization	(18)	(23)	(38)	(48)
Non-GAAP adjusted research and development expense	$ 3,836	$ 3,350	$ 9,578	$ 6,800
Selling, General and Administrative Expenses	$ 11,356	$ 7,360	$ 22,045	$ 14,815
Non-GAAP adjustments:				
Share-based compensation expense	(1,132)	(493)	(2,472)	(724)
Depreciation and amortization	(11)	(15)	(22)	(34)
Non-GAAP adjusted selling, general and administrative expenses	$ 10,213	$ 6,852	$ 19,551	$ 14,057


Aquestive
Second Quarter 2024 Earnings Supplemental Materials
August 6, 2024
Advancing medicines.
Solving problems.
Improving lives.

Disclaimer

Forward-Looking Statement

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Q2 2024 earnings: key messages

Anaphylm™ (epinephrine) Sublingual Film

- Completed and received positive topline data for temperature/pH and self-administration studies
- Final supportive study, the Oral Allergy Syndrome (OAS) study, is underway and expected to be completed late in the third quarter or early fourth quarter of 2024
- Anticipate submitting a pre-NDA meeting request letter to the FDA in the third quarter 2024
- Anticipate commencement of the single-dose pediatric study immediately following the pre-NDA meeting
- Plan to begin the NDA submission before the end of 2024 and complete in first quarter 2025

Libervant™ (diazepam) Buccal Film

- Received FDA approval for Libervant for patients between the ages of two and five years old
- Anticipate expanding to a national sales team of up to 10 sales reps by fourth quarter 2024
- Anticipate national retail distribution in place by fourth quarter 2024

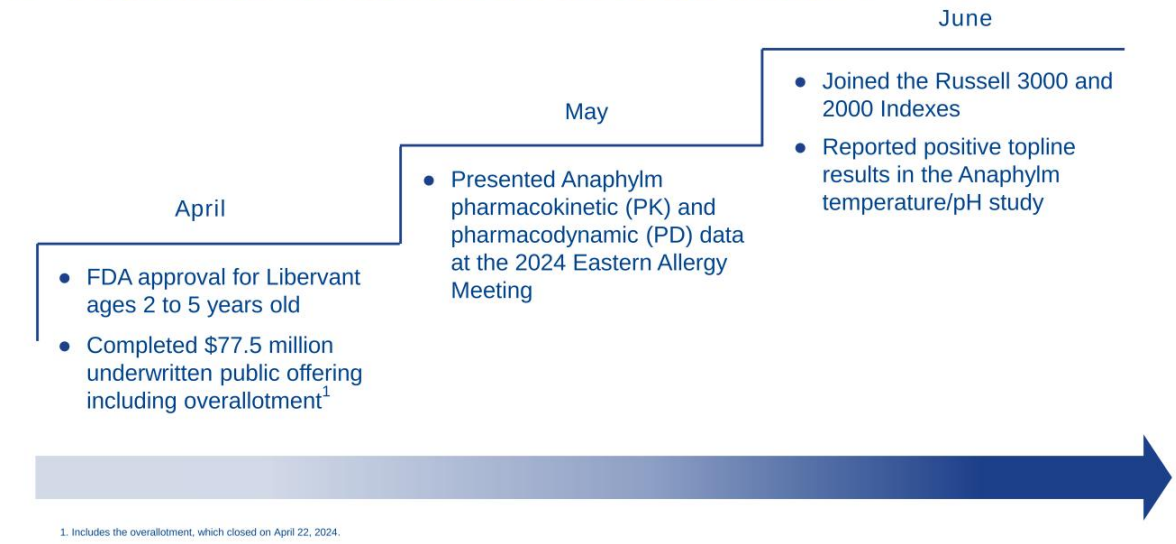
AQST-108 (epinephrine) Topical Gel

- Expect to hold a pre-IND meeting with the FDA in fourth quarter 2024
- Planning a phase 2a study in the first half of 2025

Strengthened the Balance Sheet Extending Cash Runway into 2026

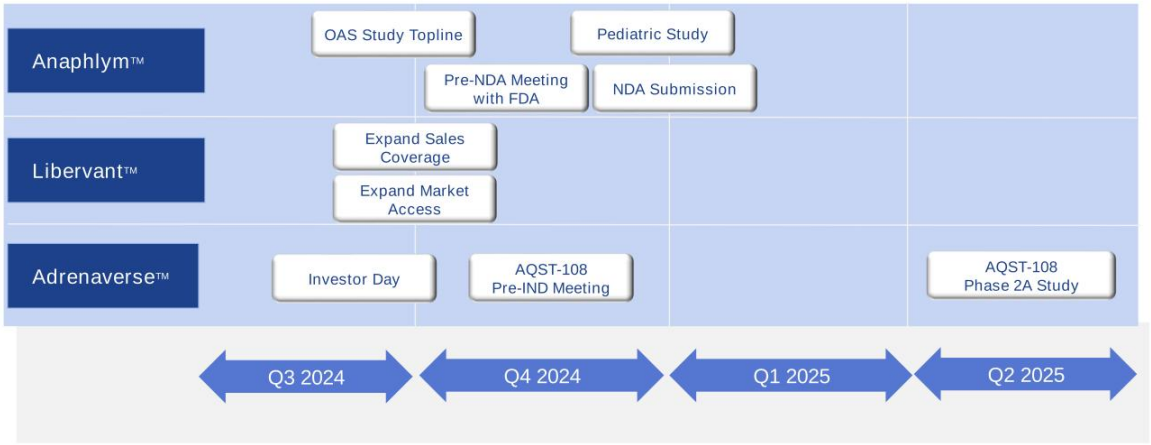
- Finished the second quarter 2024 with a cash balance of approximately $90 million

Positioned for continued success in 2024



1. Includes the overallotment, which closed on April 22, 2024.

Upcoming milestones



Anaphylm™ Program Update

Advancing medicines.
Solving problems.
Improving lives.

Temperature/pH study pharmacokinetic (PK) results[1]

Test Condition	Maximum Plasma Concentration (Cmax) (Test Condition/Room Temperature Water)	Area under the curve (AUC) 0-60min (Test Condition/Room Temperature Water)
Cold water	106%	98%
Hot water	104%	107%
Lemon water (target pH: 3)	98%	99%
Baking soda water (target pH:8)	123%	132%

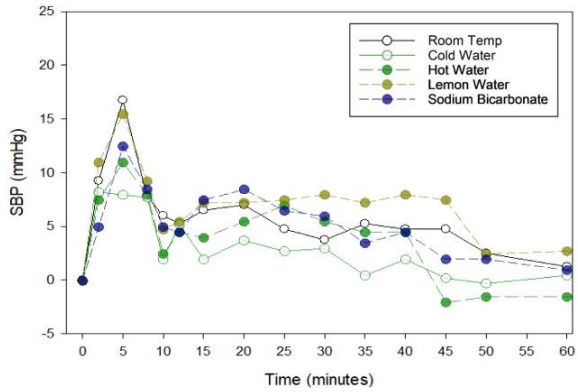
Key Takeaways:

- No significant difference in PK results based on changes in temperature and pH

1. Aquestive Therapeutics data on file.

Temperature/pH study pharmacodynamic (PD) results[1]

Median Change in Systolic Blood Pressure Over 60 Minutes Following Administration of Anaphylm (epinephrine) Sublingual Film

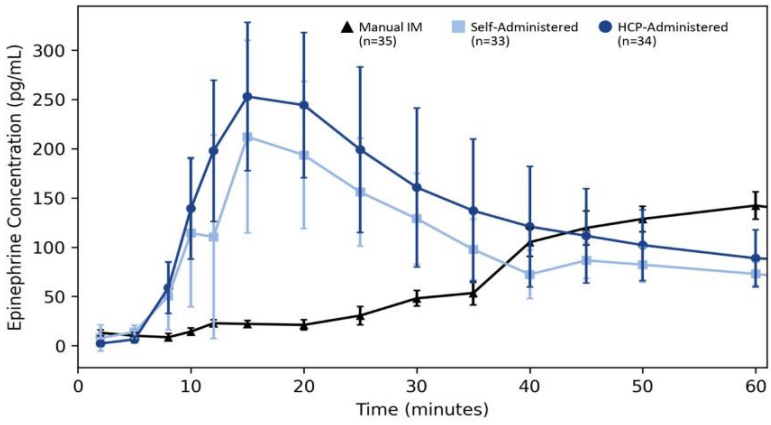


Key Takeaways:

- Topline results demonstrate no statistically significant difference in the maximum increase in systolic blood pressure due to temperature/pH conditions
- PD results for this study are in alignment with prior study results

1. Aquestive Therapeutics data on file.

Self-administration study PK results[1]

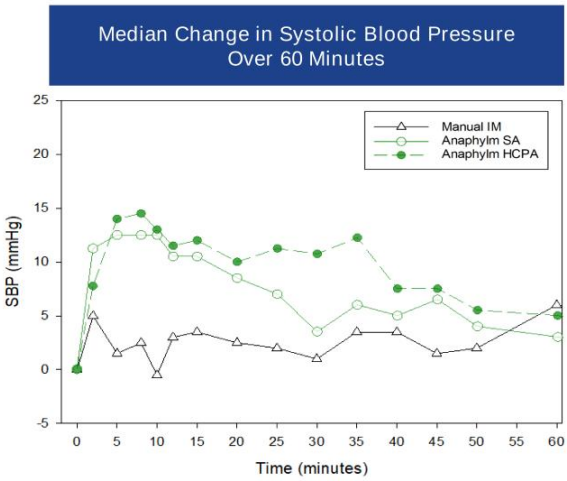


Key Takeaways:

- Cmax was not statistically different whether Anaphylm was self-administered or administered by an HCP
- Median time to maximum concentration (Tmax) was 15 minutes for Anaphylm whether self-administered or administered by a healthcare provider (HCP)
- Median Tmax for the Adrenalin intramuscular (IM) injection was 50 minutes after dosing

1. Aquestive Therapeutics data on file.

Self-administration study PD results[1]



Key Takeaways:

- Topline PD results demonstrate no difference in the median increase in systolic blood pressure whether Anaphylm is self-administered or HCP-administered
- PD results for this study are in alignment with prior study results

1. Aquestive Therapeutics data on file.

Oral allergy syndrome (OAS) study

Study Design

Single dose, three-period, randomized, fixed sequence, stratified study using oral allergen syndrome ("OAS") patients (n=24-36)

Cohort #1 (n=12-18)

- Anaphylm after allergen exposure[1]
- Adrenalin (IM) no allergen exposure
- Anaphylm no allergen exposure

Endpoints

Comparison of PK/PD after allergen exposure to Adrenalin intramuscular(IM) with no allergen exposure

Cohort #2 (n=12-18)

- Repeat dosing of Anaphylm after allergen exposure[1]
- Repeat dosing of Adrenalin (IM) no allergen exposure
- Repeat dosing of Anaphylm no allergen exposure

1. Volunteers with OAS will be challenged by exposure to the allergen known to trigger their reaction (e.g., apple, cherry, mango, melon, kiwi, celery, banana or carrot).

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)

Anaphylm single dose administration by healthcare provider

Endpoints

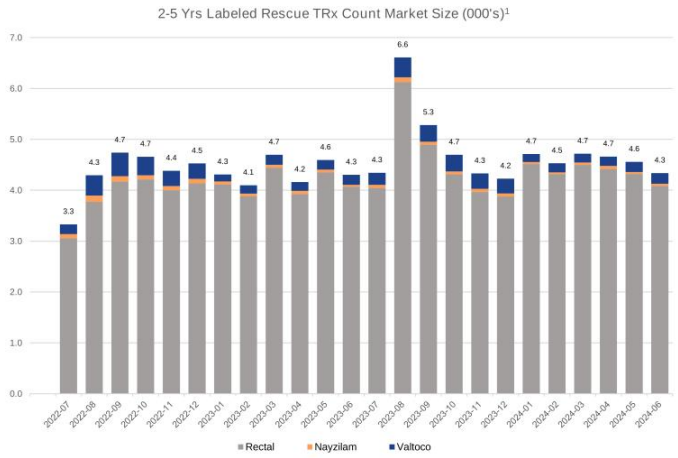
PK, PD, and treatment-emergent adverse events (TEAEs)

1. Study design pending FDA alignment on protocol.

Libervant™ Launch Update

Advancing medicines.
Solving problems.
Improving lives.

Libervant prescriptions remain limited while the Company expands distribution, payer coverage and sales coverage for patients 2-5



- Prescriptions average 1.5 cartons per prescription
- Our sales force is sized to initially cover up to 2,300 HCPs
- Full national retail distribution through the top three wholesalers is expected by early fourth quarter 2024 for patients 2-5

1. Aquestive Therapeutics data on file.

Payer coverage/market access for Libervant patients aged 2-5

Market Access – Payer Coverage

- Key states have added Libervant patients 2-5 to their Medicaid Drug formularies, e.g., NY, MI, FL, PA, NC, SC, GA, IN, and OH
- Commercial PBM negotiations continue
- Health Plans have begun adding coverage for Libervant patients 2-5

Market Access – Distribution

- Access for Libervant patients 2-5 continues to expand
- Full retail distribution for Libervant patients 2-5 is on track for fourth quarter 2024
- Will be available for all pharmacies in the U.S. for Libervant patients 2-5 by October 2024

Financial Results

Advancing medicines.
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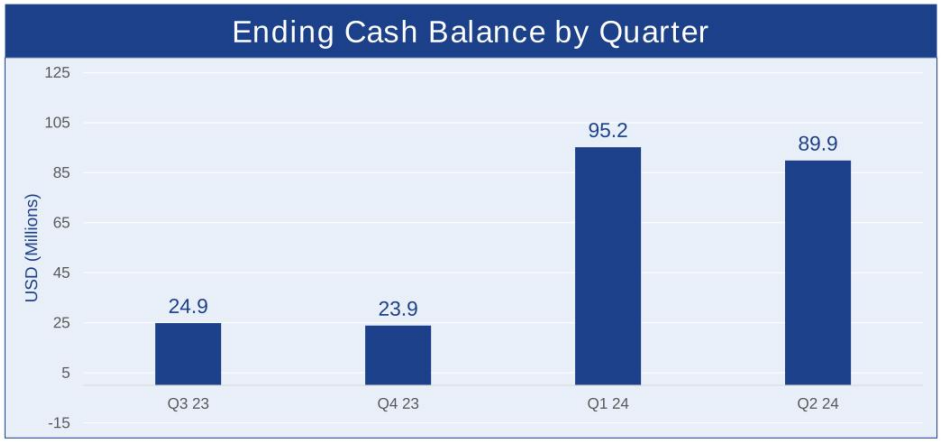
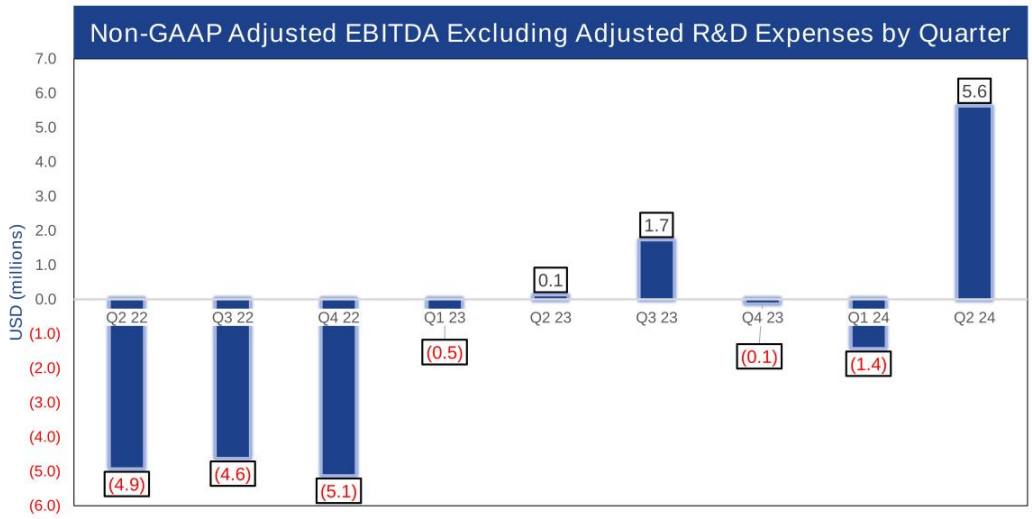
Cash position significantly improved following equity raise in Q1 2024



Base business profitability remains a key focus



Manufacturing operations continue to generate cash flow

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

Thank You

Advancing medicines.
Solving problems.
Improving lives.