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): May 7, 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 May 7, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the first quarter ended March 31, 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 May 7, 2024, announcing the Company's reported financial results for the first quarter ended March 31, 2024 and providing an update on recent developments in its business.
99.2	Aquestive Therapeutics Q1 Earnings Supplemental Materials dated May 7, 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: May 7, 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 First Quarter 2024 Financial Results and Provides Business Update

- Met all endpoints in Phase 3 pivotal study for Anaphylm™ (epinephrine) Sublingual Film in first quarter 2024 when compared to EpiPen® and other injectors used for the treatment of anaphylaxis
- On track to complete Anaphylm temperature/pH study in second quarter 2024
- Received positive feedback from FDA on Anaphylm self-administration and allergen exposure protocols; remains on track to complete both studies in third quarter 2024
- Continues to target filing an Anaphylm New Drug Application (NDA) with the FDA by the end of 2024
- Received FDA approval and U.S. market access for Libervant™ (diazepam) Buccal Film in patients between ages two to five
- Extended cash runway into 2026 with completion of $77.5 million underwritten public offering with high quality institutional healthcare investors
- To host investment community conference call at 8:00 am ET on May 8, 2024

Warren, N.J. May 7, 2024 – Aquestive Therapeutics, Inc. (NASDAQ:AQST), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, reported financial results for the first quarter, which ended March 31, 2024, and provided an update on recent developments in its business.

“We continue to successfully execute on our growth strategy as demonstrated by our first quarter results,” said Daniel Barber, Chief Executive Officer of Aquestive. “Over the last several quarters, we have reduced our cash burn, refinanced our debt, significantly strengthened our cash position, attracted high quality institutional healthcare investors, successfully completed our Anaphylm Phase 3 study, and received FDA approval for Libervant in patients between ages 2 to 5. We are focused on continuing our successful track record by executing on the remaining Anaphylm pre-submission studies, developing the commercial infrastructure to support Anaphylm, and efficiently launching Libervant. This approval of Libervant, our fourth FDA approval since 2018, exemplifies our approach to collaborating with the FDA and we plan to continue this with the filing of our Anaphylm application.”

Anaphylm™ (epinephrine) Sublingual Film
Aquestive is advancing the development of Anaphylm (epinephrine) Sublingual Film, the first and only orally delivered epinephrine product candidate, as a more patient friendly alternative to EpiPen® and other injectors for the treatment of severe life-threatening allergic reactions, including anaphylaxis.

In March 2024, Aquestive reported positive topline clinical data for the two-part, Phase 3, single-center, open-label, randomized study, which was designed to compare the pharmacokinetic (PK) and pharmacodynamics (PD) of single and repeat doses of Anaphylm versus single and repeat doses of the epinephrine intramuscular (IM) injection and epinephrine autoinjectors (EpiPen® and Auvi-Q®) in healthy adult subjects. The Company met all predefined primary and secondary PK endpoints in this study.

Aquestive also completed a Type C meeting with the U.S. Food and Drug Administration (FDA) that addressed open items from the November 2022 End-of-Phase 2 meeting, including addressing (1) the impact of any product hold time, (2) the potential for emesis (vomiting), and (3) the impact of potential mouth conditions such as angioedema (swelling). In response to these questions, the FDA indicated that the Company has “adequately addressed” the FDA’s previous concerns by removing product hold time from the administration instructions and providing additional information on how to characterize emesis in the Company’s New Drug Application (NDA)

submission with the FDA. Regarding mouth conditions, the FDA recommended administering Anaphylm after oral exposure to a known allergen and assessing PK performance thereunder. This study will replace the Company's previously planned angioedema study.

Aquestive is conducting the additional studies for Anaphylm in line with its stated timeline. The temperature/pH study is fully enrolled and expected to be completed in the second quarter 2024. FDA feedback on the self-administration study and allergen exposure study was recently received, and the Company remains on track to complete both studies in the third quarter 2024. The pediatric study, in patients from the ages of 7 to 17 (weight greater than or equal to 30kgs), is planned to commence in the second half of 2024 based on feedback from the FDA.

The next anticipated meeting with the FDA is the pre-NDA meeting targeted for the second half of 2024. Aquestive's goal is to file the NDA with the FDA before year end 2024.

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 ages two to 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. Libervant for patients between the ages of two to five is immediately available in 5mg, 7.5mg, 10mg, 12.5mg, and 15mg, and the Company is currently able to accept and fill non-Medicaid prescriptions for these pediatric patients.

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 remains committed to bringing Libervant to this older patient population and will continue to engage with the FDA on Libervant's approval for U.S. market access in patients twelve years of age and older.

AQST-108 (epinephrine) Topical Gel
Aquestive continues to progress its Adrenaverse™ platform with AQST-108, which is an epinephrine prodrug topical gel for various 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 was positive, and the Company expects to conduct further clinical studies on AQST-108 in the second half of 2024.

Commercial Collaborations
Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 42 million doses in the first quarter 2024, compared to approximately 33 million doses in the first quarter 2023. The Company continues to see consistent order 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 first quarter 2024.

Public Offering

Aquestive closed an underwritten public offering of 16,666,667 shares of its common stock at the public offering price of $4.50 per share on March 22, 2024. The underwriters purchased 559,801 shares of Common Stock to cover over-allotments in that offering on April 22, 2024, bringing the total gross proceeds to the Company from that offering to approximately $77.5 million, before deducting underwriting commissions and other offering expenses payable by the Company. All of the securities sold in that offering were sold by the Company. The Company intends to use the net proceeds received from that offering, together with the Company's existing cash and cash equivalents, primarily to advance the development and commercialization of its product pipeline, including Anaphylm and Libervant in epilepsy patients between the ages of two to five, and for working capital, capital expenditures and general corporate purposes.

First Quarter 2024 Financials

Total revenues increased to $12.1 million in the first quarter 2024 from $11.1 million in the first quarter 2023. This 8% increase in revenue was primarily driven by higher revenue from the Company's out-licensed products.

Excluding the one-time retroactive 2022 price increase of $1.7 million recognized in the three months ended March 31, 2023, manufacture and supply revenue increased by 30%, primarily due to increases in Suboxone and Sympazan manufacturing and supply revenue offset by lower Ondif® revenue from Hypera. In addition, license and royalty revenue increased by 23% primarily due to higher royalty revenue for Azstarys from Zevra and for Sympazan from Assertio. Co-development and research fee decreased by 11%.

Research and development expenses increased to $5.9 million in the first quarter 2024 from $3.5 million in the first quarter 2023. The increase in research and development expenses was primarily due to the continued advancement of the Anaphylm program.

Selling, general and administrative expenses increased to $10.7 million in the first quarter 2024 from $7.5 million in the first quarter 2023. This increase was driven by $1.7 million in one-time expenses related to severance, higher shared-based compensation expenses as well as an increase of $0.9 million due to a year-over-year change in the allocation of expenses of manufacturing and supply costs. Given this year-over-year change, we expect to continue to see a positive benefit in gross margin offset by somewhat higher selling, general and administrative expenses. Excluding these items, personnel costs, consulting costs, and patent costs were higher in the first quarter 2024 when compared to the first quarter 2023 and were offset by lower general legal and insurance costs.

Aquestive's net loss for the first quarter 2024 was $12.8 million, or $0.17 for both basic and diluted loss per share, compared to the net income for the first quarter 2023 of $8.1 million, or $0.15 basic earnings per share and $0.11 diluted earnings per share. The change in net loss was primarily driven by the one-time $14.5 million of other income recognized in the first quarter 2023, and 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 loss was $7.2 million in the first quarter 2024, compared to non-GAAP adjusted EBITDA loss of $3.9 million in the first quarter 2023. Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses was $1.4 million in the first quarter 2024, compared to a non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses of $0.5 million in the first quarter 2023.

Cash and cash equivalents were $95.2 million as of March 31, 2024.

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

The Company expects:

	Guidance
Total revenue (in millions)	$48 to $51
Non-GAAP adjusted EBITDA loss (in millions)	$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, May 8, 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: **First Quarter 2024 Earnings Conference 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 to 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 is an epinephrine prodrug topical gel 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 prodrugs that can control absorption and conversion rates across a variety of dosage forms and delivery sites.

Important Safety Information

Do not give Libervant™ to your child 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

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 pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. 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 for Anaphylm; our ability to provide sufficient data in our NDA submission for Anaphylm to address FDA feedback on our clinical trials; the approval for U.S. market access of Libervant for epilepsy patients 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 epilepsy patients six years of age and older; the advancement and related timing of AQST-108 and our other product candidates through clinical development and regulatory process; the focus on continuing to manufacture Suboxone®, Exservan®, Sympazan®, Ondif® and other licensed products; the potential benefits our products could bring to patients; the expansion of our commercial infrastructure to support the launch of Libervant for epilepsy patients between two to five years of age and for Anaphylm should we received FDA approval of Anaphylm; 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, AQST-108 and 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 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 regulatory advancement through the FDA of Anaphylm and our other drug candidates or failure to receive FDA approval at all; 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 twelve years of age and older; 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 future commercialization of our product candidates; 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 have 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 failure to satisfy all financial and other debt covenants and of any default under our debt financings; 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 of Libervant for epilepsy patients between two and five years of age, Anaphylm, AQST-108 and our other products and product candidates and 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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AQUESTIVE THERAPEUTICS, INC.
Condensed Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 95,200	$ 23,872
Trade and other receivables, net	8,324	8,471
Inventories	7,734	6,769
Prepaid expenses and other current assets	2,121	1,854
Total current assets	113,379	40,966
Property and equipment, net	4,046	4,179
Right-of-use assets, net	5,442	5,557
Intangible assets, net	1,239	1,278
Other non-current assets	5,417	5,438
Total assets	$ 129,523	$ 57,418
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 10,523	$ 8,926
Accrued expenses	4,637	6,497
Lease liabilities, current	414	390
Deferred revenue, current	1,551	1,551
Liability related to the sale of future revenue, current	910	922
Loans payable, current	23	22
Total current liabilities	18,058	18,308
Notes payable, net	28,759	27,508
Royalty obligations, net	16,119	14,761
Liability related to the sale of future revenue, net	63,626	63,568
Lease liabilities	5,284	5,399
Deferred revenue	31,957	32,345
Other non-current liabilities	2,021	2,016
Total liabilities	165,824	163,905
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 90,478,731 and 54,827,734 shares issued and outstanding at March 31, 2024 and December 31, 2022, respectively	90	69
Additional paid-in capital	295,514	212,521
Accumulated deficit	(331,905)	(319,077)
Total stockholders' deficit	(36,301)	(106,487)
Total liabilities and stockholders' deficit	$ 129,523	$ 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 March 31,	
	2024	**2023**
Revenues	$ 12,053	$ 11,134
Costs and expenses:		
Manufacture and supply	4,389	4,737
Research and development	5,932	3,547
Selling, general and administrative	10,689	7,455
Total costs and expenses	21,010	15,739
Loss from operations	(8,957)	(4,605)
Other income/ (expenses):		
Interest expense	(2,784)	(1,435)
Interest expense related to royalty obligations	(1,358)	—
Interest expense related to the sale of future revenue	(58)	(52)
Interest income and other income, net	329	14,513
Loss on extinguishment of debt	—	(353)
Net (loss) income before income taxes	(12,828)	8,068
Income taxes	—	—
Net (loss) income	$ (12,828)	$ 8,068
Comprehensive (loss) income	$ (12,828)	$ 8,068
Loss) earnings per share attributable to common stockholders:		
Basic (in dollars per share)	$ (0.17)	$ 0.15
Diluted (in dollars per share)	(0.17)	0.11
Weighted average common shares outstanding:		
Basic (in shares)	73,614,710	55,631,947
Diluted (in shares)	73,614,710	73,792,886

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

	Three Months Ended March 31,	
	2024	**2023**
GAAP net (loss) income	$ (12,828)	$ 8,068
Share-based compensation expense	1,580	344
Interest expense	2,784	1,435
Interest expense related to royalty obligations	1,358	—
Interest expense related to the sale of future revenue	58	52
Interest income and other income, net	(329)	(14,513)
Loss on extinguishment of debt	—	353
Depreciation and Amortization	207	325
Total non-GAAP adjustments	$ 5,658	$ (12,004)
Non-GAAP adjusted EBITDA	$ (7,170)	$ (3,936)
Excluding Non-GAAP adjusted R&D expenses	(5,742)	(3,450)
Non-GAAP adjusted EBITDA excluding Non-GAAP adjusted R&D expenses	$ (1,428)	$ (486)

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

	Three Months Ended March 31,	
	2024	**2023**
Total costs and expenses	$ 21,010	$ 15,739
Non-GAAP adjustments:		
Share-based compensation expense	(1,580)	(344)
Depreciation and amortization	(207)	(325)
Non-GAAP adjusted costs and expenses	$ 19,223	$ 15,070
Manufacture and Supply Expense	$ 4,389	$ 4,737
Gross Margin on total revenue	*64 %*	*57 %*
Non-GAAP adjustments:		
Share-based compensation expense	(70)	(41)
Depreciation and amortization	(176)	(281)
Non-GAAP adjusted manufacture and supply expense	$ 4,143	$ 4,415
Non-GAAP Gross Margin on total revenue	*66 %*	*60 %*
Research and Development Expense	$ 5,932	$ 3,547
Non-GAAP adjustments:		
Share-based compensation expense	(170)	(72)
Depreciation and amortization	(20)	(25)
Non-GAAP adjusted research and development expense	$ 5,742	$ 3,450
Selling, General and Administrative Expenses	$ 10,689	$ 7,455
Non-GAAP adjustments:		
Share-based compensation expense	(1,340)	(231)
Depreciation and amortization	(11)	(19)
Non-GAAP adjusted selling, general and administrative expenses	$ 9,338	$ 7,205


Aquestive
First Quarter 2024 Earnings Supplemental Materials
May 7, 2024
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Disclaimer

Certain statements in this presentation 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 submission of supporting clinical studies for Anaphylm; our ability to provide sufficient data in our New Drug Application (NDA) submission for Anaphylm with the FDA to address FDA feedback on our clinical trials including as it relates to an Anaphylm pediatric program; our ability to grow our manufacturing operations; 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, AQST-108 and 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 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 2 and 5 years of age; risk of delays in regulatory advancement through the FDA of Anaphylm and our other drug candidates or failure to receive FDA approval at all; risk of the Company's ability to generate sufficient data in its pharmacokinetics and pharmacodynamics 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; 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 future commercialization of our product candidates; 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 pediatric patients between 2 to 5 years of age and to fund future clinical development activities for Anaphylm and AQST-108 and commercial activities should Anaphylm and/or AQST-108 be approved by the FDA; risk that our manufacturing capabilities will be sufficient to support demand for Libervant and 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 any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; 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 of Libervant for epilepsy patients between 2 to 5 years of age, Anaphylm, AQST-108 and our other products and product candidates and 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. 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PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. 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, AQST-109. All other registered trademarks referenced herein are the property of their respective owners.

Q1 2024 Earnings: Key Messages

Anaphylm™ (epinephrine) Sublingual Film

- Pivotal study met all primary and secondary endpoints
- Successful completion of a Type C meeting with the FDA
- On track for goal of submitting a New Drug Application (NDA) before year-end 2024

Libervant™ (diazepam) Buccal Film

- Received FDA approval for Libervant for patients between the ages of two and five years old
- Product is immediately available to non-Medicaid patients

AQST-108 (epinephrine) Topical Gel

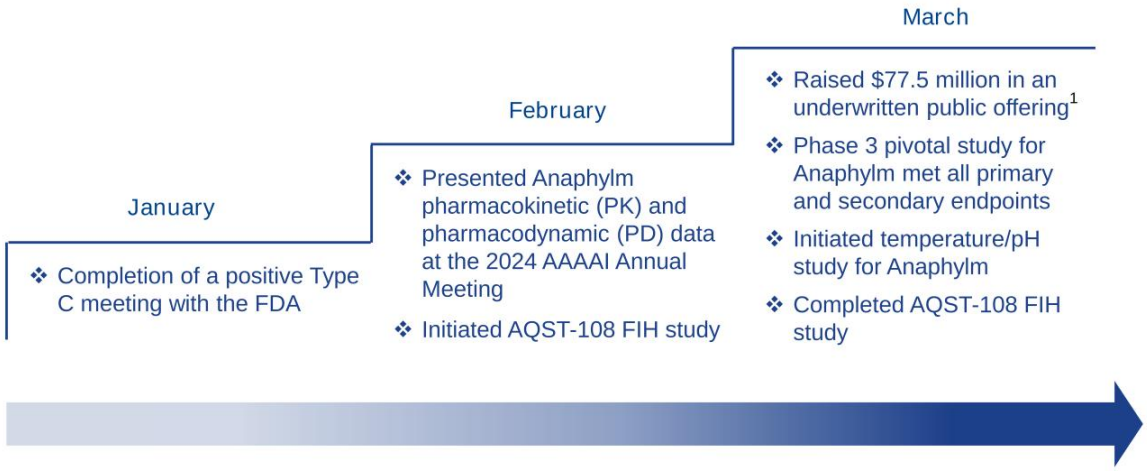
- Positive results from first-in-human (FIH) study

Strengthened the Balance Sheet

- Finished first quarter 2024 with a cash balance of approximately $95 million
- Raised $77.5 million through an underwritten public offering at a public offering price of $4.50 per share of common stock[1]
  - Provides sufficient cash to fund both the Anaphylm program and Company operations
  - Extends cash runway into 2026

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

Positioned for continued success in 2024



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

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Anaphylm™ Program Update

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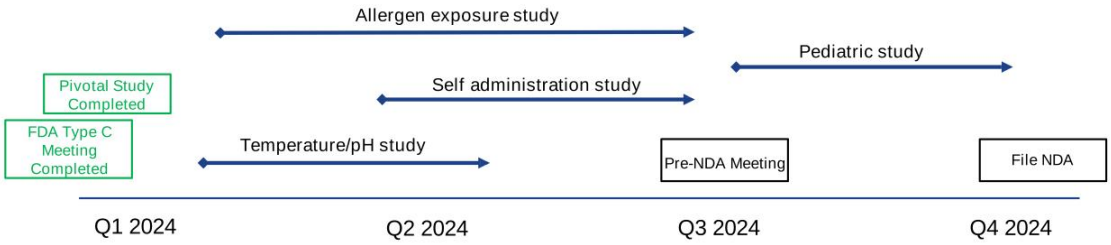
Projected Clinical Timeline



Temperature/pH Study

Study Design

Single dose, five-period, cross-over design using healthy adult volunteers
(n=30)

Endpoints

Comparison of PK/PD from room temperature water arm vs. all other arms

- Room temperature water[1] (25° C)
- Hot water (50° C)
- Cold water (2° C)
- Lemon water (target pH 3)
- Sodium bicarbonate water (target pH 8)

[1] Room temperature water used as reference.

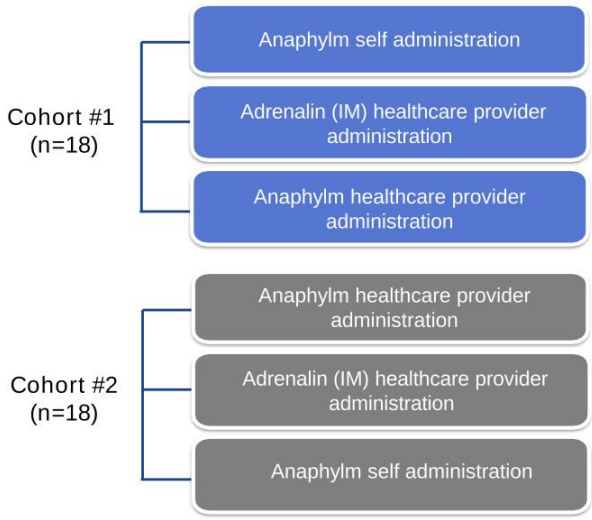
Self-Administration Study

Study Design

Single dose, three-period, cross-over design using healthy adult volunteers (n=36)

Endpoints

Comparison of PK/PD between self-administered, healthcare provider (HCP) administered, and Adrenalin



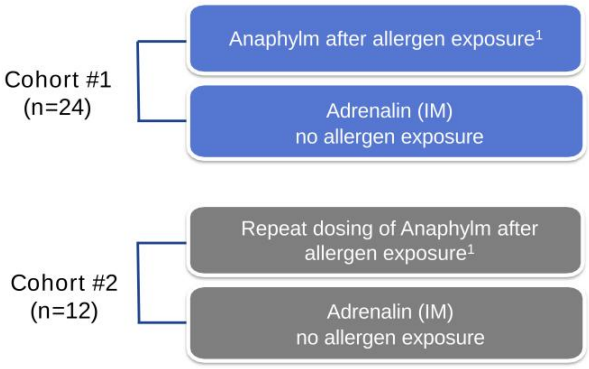
Allergen Exposure Study

Study Design

Single dose, two-period, partially randomized cross-over design using oral allergen syndrome (“OAS”) patients (n=36)

Endpoints

Comparison of PK/PD after allergen exposure to Adrenalin intramuscular(IM) with 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=36)

Anaphylm single dose administration by healthcare provider

Endpoints

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

[1] Study design pending FDA alignment on protocol.

Financial Results

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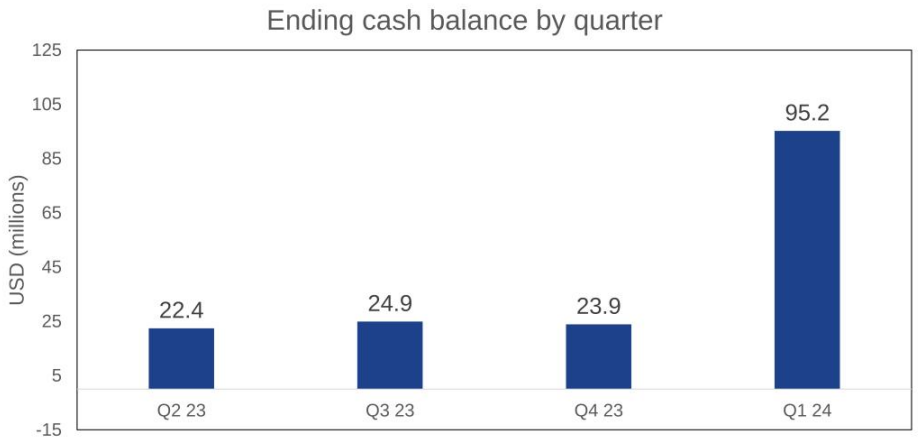
Cash position significantly improved following Q1 equity raise



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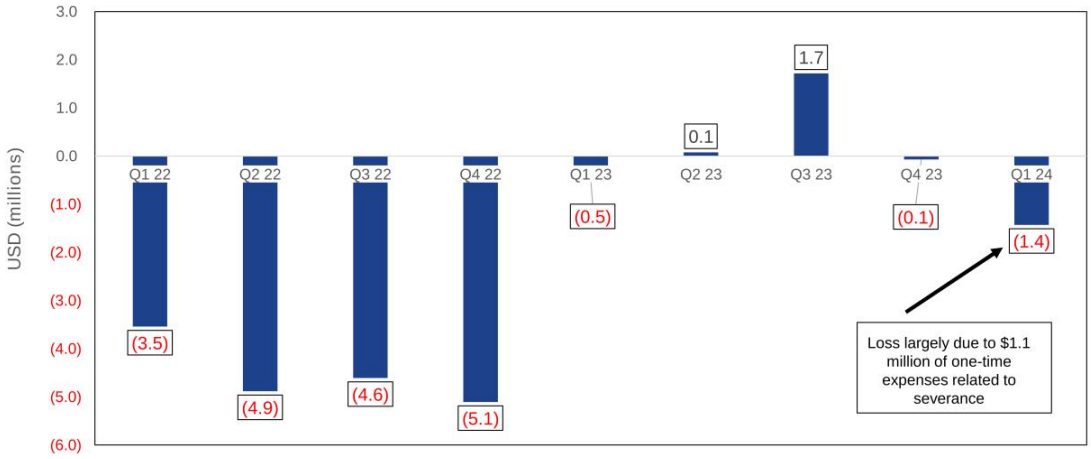
Base business profitability remains a key focus

Non-GAAP adjusted EBITDA excluding adjusted R&D expenses by quarter



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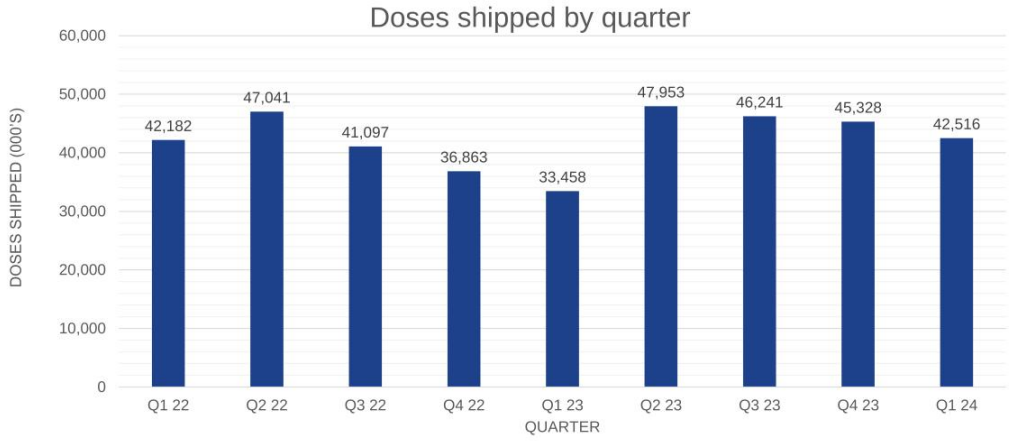
Manufacturing operations continue to generate cash flow



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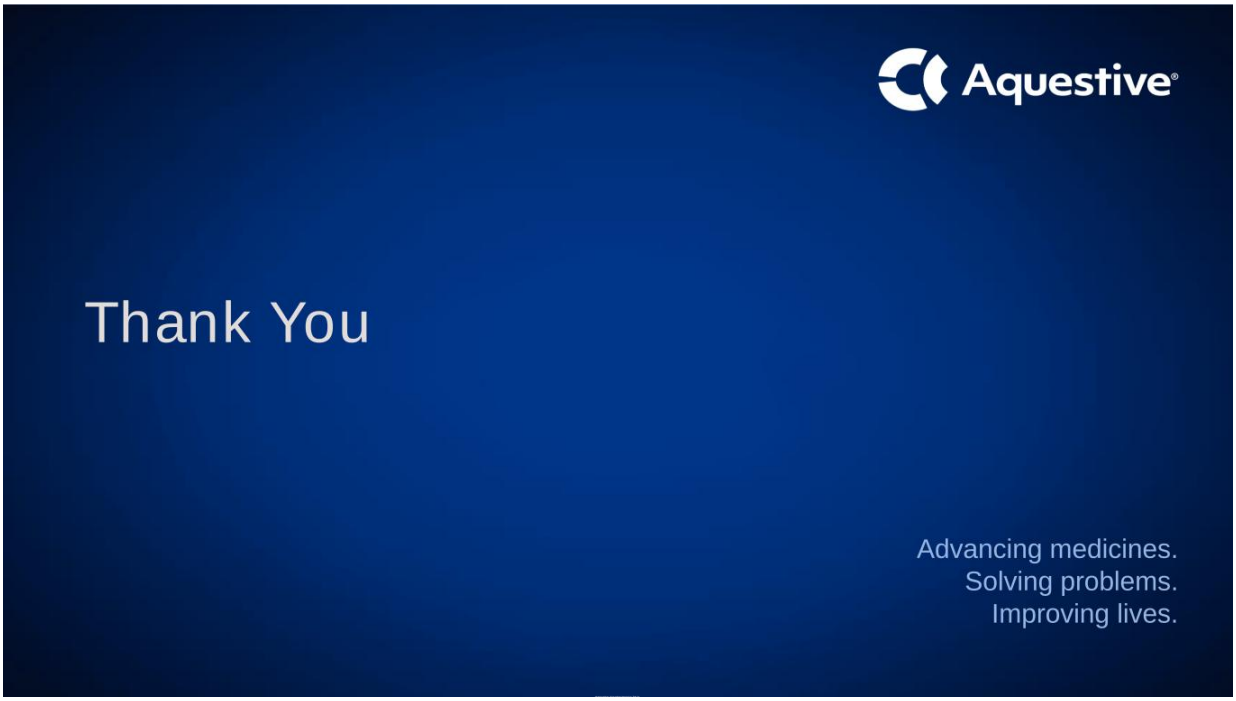
Current full year guidance

2024 Outlook

- Total revenues of approximately $48 to $51 million
- Non-GAAP adjusted EBITDA loss of approximately $22 to $26 million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