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 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 99.1 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 99.1) 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	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


Aquestive
First Quarter 2024 Earnings Supplemental Materials
May 7, 2024
Advancing medicines.
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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. Given those uncertainties, readers 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 presentation whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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

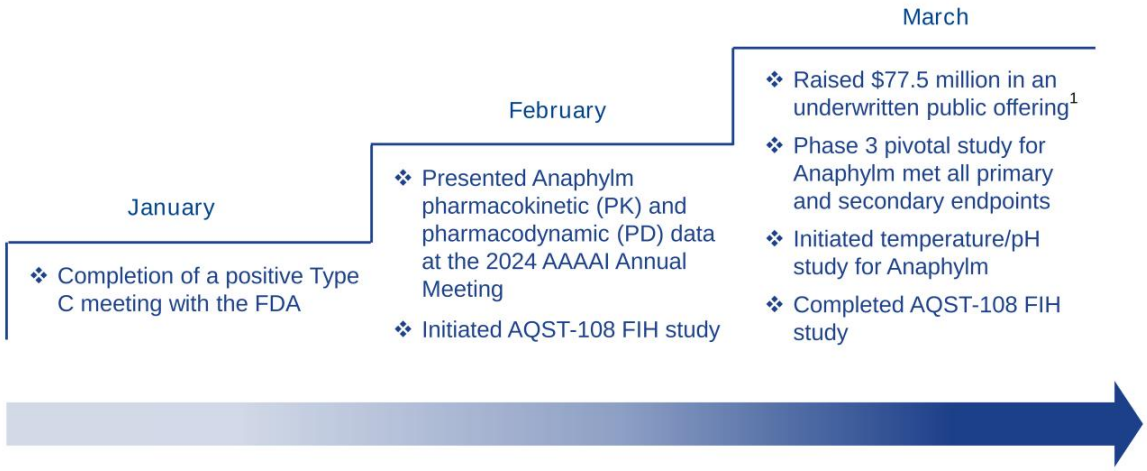
- Positive results from first-in-human (FIH) study

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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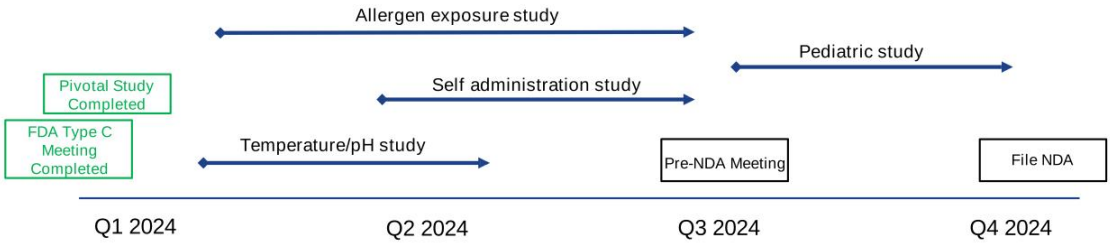
Projected Clinical Timeline



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.

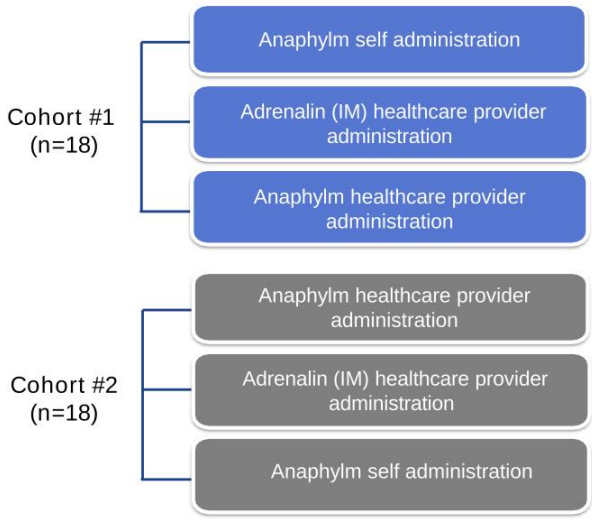
Self-Administration Study

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



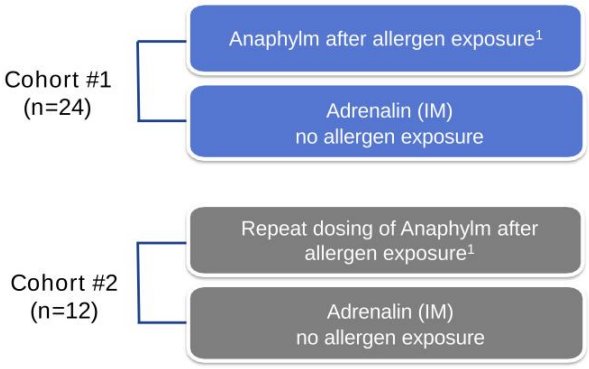
Allergen Exposure Study

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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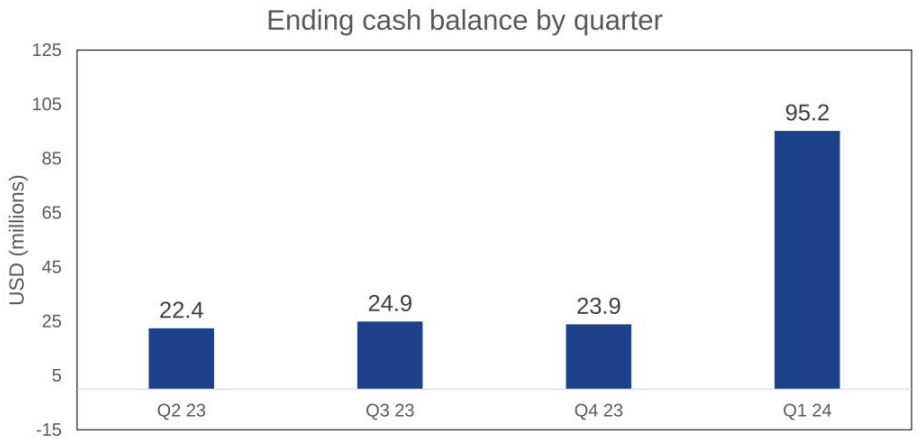
Cash position significantly improved following Q1 equity raise



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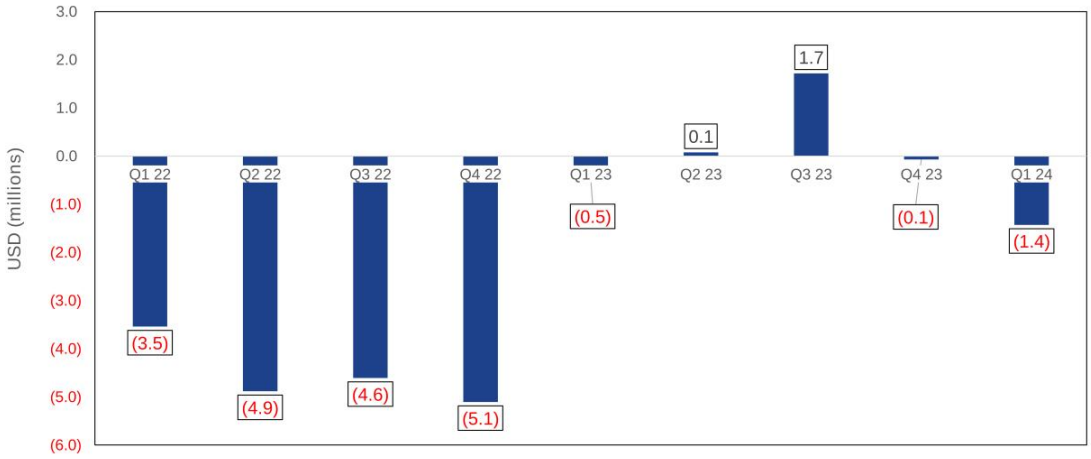
Base business profitability remains a key focus

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



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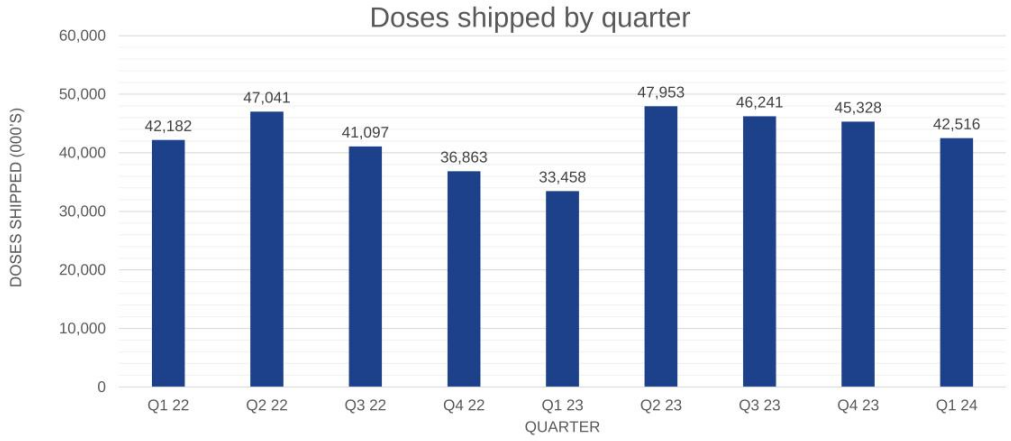
Manufacturing operations continue to generate cash flow



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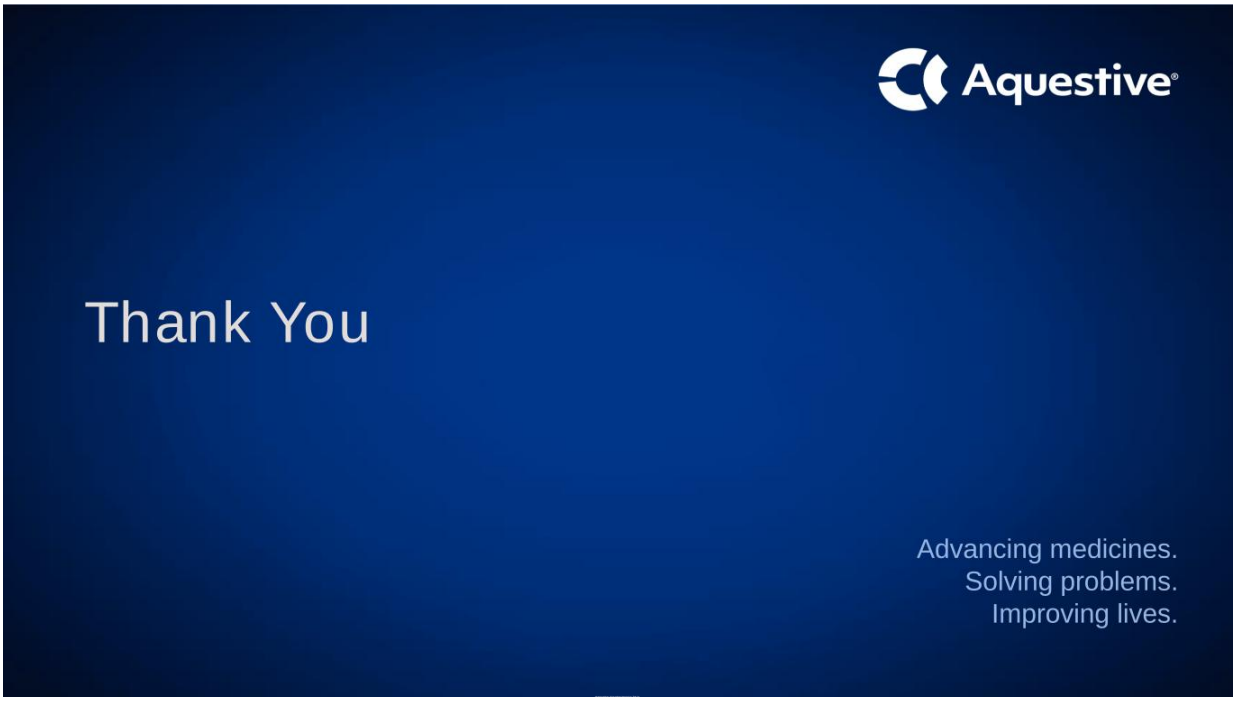
Current full year guidance

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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