

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): November 6, 2025

Aquestive Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-38599
(Commission File Number)

82-3827296
(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))

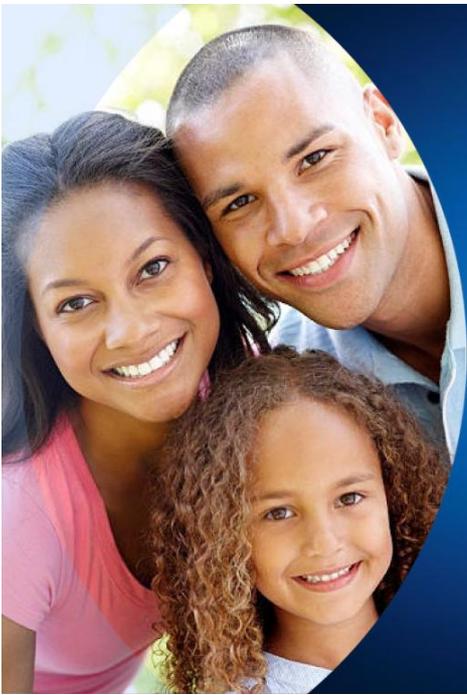
Securities registered pursuant to Section 12(b) of the Act:

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.



Third Quarter 2025 Earnings Supplemental Materials

November 6, 2025

Advancing medicines.
Solving problems.
Improving lives.

Disclaimer

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™ (dibutepinephrine) Sublingual Film through clinical development and approval by the FDA, including whether the clinical data submitted to the FDA will be adequate enough for the FDA to approve Anaphylm, and the following commercial launch of Anaphylm, if approved by the FDA; the advancement and related timing of potential international regulatory filings and market approvals of Anaphylm outside of the U.S.; 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; launch preparedness activities being sufficient to build commercial readiness for Anaphylm and approved patients providing long-term commercial success for Anaphylm, if approved by the FDA; the advancement, growth and related timing of our AdrenaVerse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel for the treatment of alopecia areata, through clinical development and FDA regulatory approval; the timing of international filings for approval of Libervant® (diazepam) Buccal Film; the potential benefits our products and product candidates could bring to patients; that patients will prefer film over available alternative epinephrine delivery products; the potential growth of markets for our product candidates; our future financial and operating results and financial position, including with respect to our 2025 financial outlook, estimated cash runway and sufficiency to support the launch of Anaphylm, if approved by the FDA and achieve other business initiatives; 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 our other product candidates; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including for Anaphylm, Libervant and AQST-108, or failure to receive FDA approval at all of any of these product candidates; risk of government shutdown on the ability of the FDA to act on the approval of our product candidates, including Anaphylm; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our pharmacokinetic and pharmacodynamic (PK/PD) comparability submission for FDA approval of Anaphylm; risks associated with our ability to address the FDA's comments on our NDA, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risks associated with the success of any competing products, including generics; 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 candidates, including Anaphylm, Libervant and AQST-108; risks associated with the potential impact on the value of the Company of the sale or outsourcing of our product and product candidates, including Libervant and Anaphylm and other product candidates; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Senior Secured Notes in 2026, and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, Libervant and AQST-108, should these product candidates be approved by the FDA; risk of the impact of our obligations under the Company's Purchase Agreement and the Royalty Rights Agreement with third parties, each of which agreements requires the Company to make payments to each counterparty thereof, respectively, of a portion of our revenues, on our ability to contribute to the funding of our operations and the payment of principal and interest on our debt; the risk of our obligations under such Purchase Agreement and Royalty Rights Agreement impacting our ability to refinance our 13.5% Senior Secured Notes; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates in the U.S. and abroad, if such product candidates should be approved by the FDA and other regulatory authorities, and our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunsetting product, which accounts for a substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance in the U.S. and abroad of Libervant, Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA and other regulatory authorities, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets; risk associated with our compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm and AQST-108, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office or, if issued, will be sufficient to provide long-term commercial success of these product candidates; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and product candidates and product pricing, reimbursement or access thereof; risk of loss of significant customers; risks related to claims and legal proceedings against us including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and changing interest rates; risks related to the impact of other pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business, including imposition of government tariffs and other trade restrictions; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 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.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

PharmFilm®, Libervant® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. The trade name "Anaphylm" 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.

Q3 2025 earnings key messages

Anaphylm™ (dibutepinephrine) Sublingual Film for severe allergic reactions, including anaphylaxis

- U.S. Food and Drug Administration (FDA) confirms that it will not require an Advisory Committee to review the Company's New Drug Application for Anaphylm
- Preparing for a U.S. launch in Q1 2026, if approved by FDA
 - Continued expansion of commercial and medical infrastructure
 - Expanding awareness of Anaphylm through engagement with Health Care Professionals and advocacy groups
 - Continuing critical work with payers to raise awareness and prepare for launch
- Continue to focus on global expansion
 - Successful meeting with Health Canada occurred in September 2025; progressing towards a New Drug Submission in Canada
 - Initial meeting held with the European Union (EU); preparations underway for an EU submission
- Broadened the patent estate for Anaphylm with the issuance of two new patents
 - Extend patent protection into 2037

Q3 2025 earnings key messages - continued

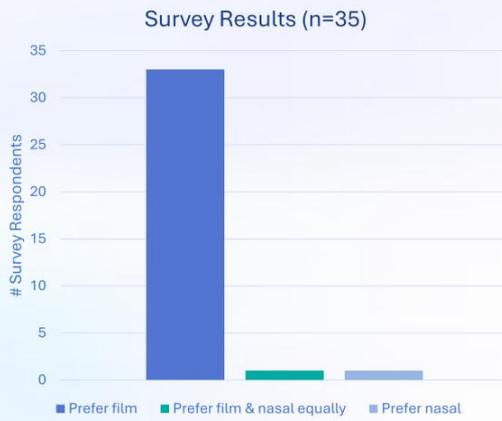
AQST-108 and the expansion of AdrenaVerse™ platform

- Plan to open Investigational New Drug application for AQST-108 with FDA in Q4 2025
- Expect to initiate a clinical study for AQST-108 for Alopecia Areata in 1H 2026
- Strengthened clinical leadership to reiterate commitment to developing new product candidates from this platform

Strengthened balance sheet to support commercial launch execution

- In August 2025, the Company successfully completed an equity raise of \$85MM including participation by several large institutional healthcare investors
- The Company also completed a strategic financing for \$75MM with RTW Investments, LP subject to FDA approval of Anaphylm and refinancing of the Company's existing debt

Recent film strip preference survey completed¹

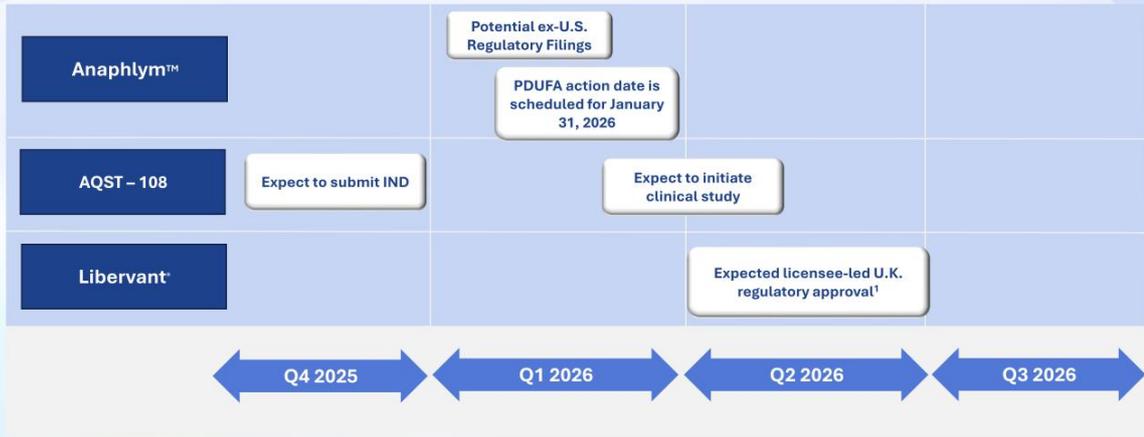


Survey Methodology:

- Double-blinded survey with 17 adult patients and 18 caregivers of pediatric patients at risk for anaphylaxis
- Respondents were mailed an envelope containing one empty, non-labeled nasal spray device and one non-labeled placebo film strip
- Respondents kept envelopes sealed until an on-camera interview video call was conducted and were then instructed to open the envelopes²
- Respondents were asked to assume that, if these products were made available for prescribing by their health care prescriber (HCP), both products would be:
 - Equal in general efficacy and safety to each other and to their current epinephrine auto-injector (EAI)
 - Endorsed by their HCP
 - Equal in out-of-pocket cost to each other

1. Aquestive Therapeutics data on file. 2. Note: Survey sample product envelopes only contained demo nasal spray devices and film strips. Instructions For Use were not provided to respondents.

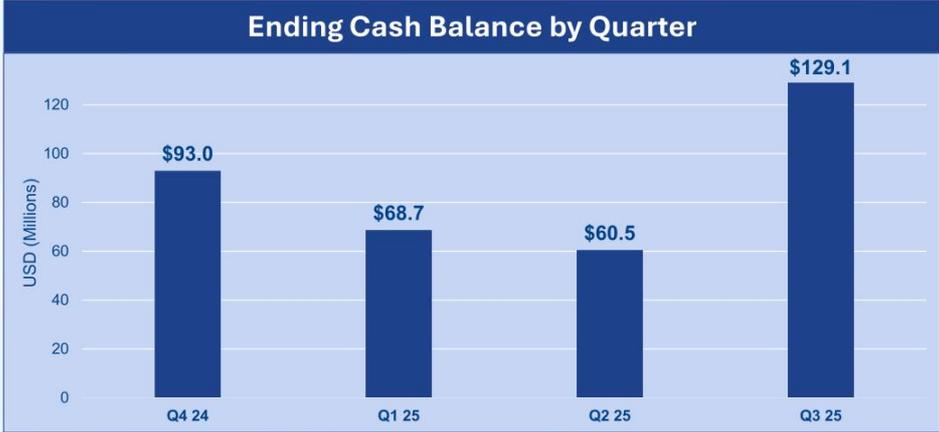
Upcoming expected key milestones



1. Licensee filed for Libervant approval in the EU with the EMA in August 2025.

Third Quarter Results

Expected to meet near-term milestones with projected cash runway into 2027



Manufacturing operations continue to generate cash



2025 guidance as of November 5, 2025

2025 Outlook

- Total revenues of approximately \$44-\$50 million
- Non-GAAP adjusted EBITDA loss of approximately \$47-\$51 million

Thank You

