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 13, 2025

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 1.01 Entry into a Material Definitive Agreement.

On August 13, 2025, Aquestive Therapeutics, Inc. (the "Company") entered into a purchase and sale agreement (the "Purchase Agreement") with funds managed by RTW Investments LP (the "Purchaser"). Under the terms of the Purchase Agreement, in exchange for the Purchaser's payment to the Company of a purchase price of $75 million (the "Purchase Price"), upon approval of Anaphylm by the FDA by a specified date, the refinancing of the Company's existing 13.5% Senior Secured Notes and certain other customary conditions, the Company agreed to a true sale of assigned interests to the Purchaser, including a right for the Purchaser to tiered revenue share payments ranging from 7.5% to 1.0% of Net Sales (as defined in the Purchase Agreement) (and 9.5% for the subsequent calendar year period if Net Sales do not achieve specified level in a calendar year period beginning in 2027) in the United States. Revenue share payments commence in the first fiscal quarter in which the first commercial sale of Anaphylm in the United States after the closing of the transaction. Revenue share payments will cease upon the Purchaser's receipt of $187.5 million by December 31, 2035 or $225 million thereafter. The Purchase Agreement contains customary affirmative and negative covenants, including covenants that limit or restrict the Company's ability to, among other things, incur indebtedness(which restrictions are eliminated after the achievement by the Purchaser of a specified return on its investment), and other provisions customary for transactions of this nature, in each case subject to certain exceptions set forth in the Purchase Agreement.

Item 7.01 Regulation FD Disclosure.

On August 14, 2025, the Company issued a press release announcing the Purchase Agreement described above. A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

The information contained under Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1), shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as may be expressly set forth by specific reference in such filing.

Forward-Looking Statements

Statements contained in this report regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements about the Company's expectations with respect to the description of the Purchase Agreement and the transactions contemplated thereby. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with approval of Anaphylm by the FDA, refinancing the Company's existing debt and the satisfaction of customary closing conditions. Additional factors that could cause actual results to differ materially from those stated or implied by the Company's forward-looking statements are disclosed in the Company's filings with the Securities and Exchange Commission, including in the section captioned "Risk Factors" in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2024. All forward-looking statements contained in this report speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this report.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company issued on August 14, 2025

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 14, 2025

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive Therapeutics Announces $75M Strategic Funding Agreement with RTW to Support the Potential Launch of Anaphylm™ (epinephrine) Sublingual Film

- *Anaphylm launch funding of $75 million committed by RTW, subject to FDA approval of Anaphylm and other conditions*
- *Strategic financing will further strengthen the Company's balance sheet in advance of potential commercialization of Anaphylm for the emergency treatment of allergic reactions, including anaphylaxis*

WARREN, N.J., August 14, 2025 – 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, today announced a $75 million strategic funding agreement with funds managed by RTW Investments, LP ("RTW"), subject to United States Food and Drug Administration (FDA) approval of Anaphylm™ (epinephrine) Sublingual Film and other conditions.

"This financing provides critical capital that will support Aquestive Therapeutics through 2027, enabling us to successfully bring Anaphylm to market, if approved by the FDA, and deliver a new treatment option for patients in need," said Dan Barber, Chief Executive Officer of Aquestive. "We continue to believe Anaphylm, potentially the first and only oral rescue medication for the treatment of severe allergic reactions, including anaphylaxis, can transform how patients carry and access their rescue medication. We are excited to partner with RTW to bring this important medication to patients, if approved by the FDA."

"We are excited to support Aquestive, and today's investment reflects our belief in the commercial prospects of Anaphylm as a rescue treatment for patients experiencing a severe allergic reaction, including anaphylaxis," said Roderick Wong, MD, Managing Partner and Chief Investment Officer of RTW Investments, LP. "We remain committed to helping life science companies bring meaningful innovations, like Anaphylm, to patients, caregivers, and healthcare providers."

The commercial launch financing will become available upon approval of Anaphylm by the FDA, and satisfaction of certain refinancing and other customary conditions related to the Company's existing debt. Under the terms of the agreement, RTW will receive a tiered single digit percentage of annual net sales of Anaphylm in the U.S. for the treatment of type I allergic reactions (including anaphylaxis), subject to a cap.

Cantor Fitzgerald & Co acted as exclusive financial advisor to Aquestive on the royalty financing.

About Anaphylm™ (epinephrine) Sublingual Film
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 Aquestive Therapeutics
Aquestive is a 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 four 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 earlier stage epinephrine prodrug topical gel product candidate for possible various dermatology conditions, including alopecia areata. For more information, visit Aquestive.com and follow us on LinkedIn.

About RTW Investments, LP
RTW Investments, LP is a New York-based, global, full life-cycle investment firm that focuses on identifying transformational and disruptive innovations across the biopharmaceutical and medical technologies sectors. As a leading partner of industry and academia, RTW combines deep scientific expertise with a solution-oriented investment approach to advance emerging medical therapies by building and supporting the companies and/or academics developing them. For further information about RTW, please visit www.rtwfunds.com.

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; the expected plans for regulatory approval and commercialization of Anaphylm in markets outside of the United States, if approved by the applicable regulatory authorities; the potential for Anaphylm to be the first and only orally delivered epinephrine product and its ability change the standard of care; the advancement of the Company's product candidate AQST-108 through clinical development and approval by the FDA for possible various dermatology conditions including alopecia areata; the potential benefits our products and product candidates could bring to patients; 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 and AQST-108; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including with respect to the approval of our filed NDA for Anaphylm, or the failure to receive FDA approval at all for any of our product candidates, including Anaphylm and AQST-108; 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 comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's clinical trials and other concerns identified in the FDA's Type C meeting minutes and filing review letter for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk that the FDA may require that an Advisory Committee be required for the approval of Anaphylm and that the Company is able to address any concerns raised by such Advisory Committee or the FDA after review of the advice from the Advisory Committee; risk of delays in advancement of the regulatory approval process outside the U.S. of our product candidates, including Anaphylm in Canada and the European Union; risk of 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 sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund commercialization activities relating to fund future clinical development and commercial activities for our product candidates, including Anaphylm and AQST-108, should these product candidates be approved by the FDA, Health Canada and EMA; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance in and outside of the U.S. of Anaphylm and our other product candidates, should these product candidates be approved by the FDA, Health Canada and EMA, and for our licensed products in the U.S. and abroad; risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office (USPTO); risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business; 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; risks related to uncertainties about U.S. government initiatives and their impact on our business, including imposition of tariffs and other trade restrictions; 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 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.

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