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): October 24, 2022

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 8.01 Other Events.

On October 24, 2022, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing that the United States District Court for the Eastern District of Pennsylvania entered an order on October 19, 2022 dismissing all claims against the Company in the Suboxone antitrust lawsuit brought by a group of States' Attorneys General against Indivior Inc. (f/k/a Reckitt Benckiser Pharmaceuticals, Inc.) and Aquestive, Case No. 16-cv-5073. A copy of the Company's press release is attached hereto as Exhibit 99.1 and incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Aquestive Therapeutics Press Release dated October 24, 2022.

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: October 24, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.
Title: Chief Financial Officer
(Principal Financial Officer)

Aquestive Therapeutics Announces Positive Decision in States' Suboxone Antitrust Lawsuit on All Claims

WARREN, N.J., Oct. 24, 2022 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing current standards of care to solve patients' problems through simplifying complex delivery methods, announced today that the United States District Court for the Eastern District of Pennsylvania entered an order on October 19, 2022 dismissing all claims against Aquestive in the Suboxone antitrust lawsuit brought by a group of States' Attorneys General against Indivior Inc. (f/k/a Reckitt Benckiser Pharmaceuticals, Inc.) and Aquestive, Case No. 16-cv-5073.

"We are pleased that the Court has granted our summary judgment motion and agreed to dismiss all claims against Aquestive related to the ongoing litigation associated with this case, establishing that the Company should never have been named in the lawsuit. This judgment is another step forward in improving our business," said Daniel Barber, Chief Executive Officer of Aquestive. "With this decision, we will continue to focus our efforts on advancing our pipeline and preparing for our upcoming End-of-Phase 2 meeting with the FDA for our lead program AQST-109 (epinephrine sublingual film) for the treatment of severe allergic reaction, including anaphylaxis."

About Aquestive

Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing current standards of care to solve patients' problems through simplifying complex delivery methods. 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 on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome. Our licensees market their products in the U.S. and around the world. 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, or CNS, 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.

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 are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

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 that the order of the Court of the United States District Court for the Eastern District of Pennsylvania dismissing all claims against the Company in the Suboxone antitrust litigation case could be appealed by the plaintiffs in the case and that, thereafter, the Company could be required to continue its defense of the claims asserted in that case and that said plaintiffs could be entitled to judgment against the Company; risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials for AQST-109 and our other product candidates; risk of delays by the United States Food and Drug Administration (FDA) in approving Libervant® (diazepam) Buccal Film for the U.S. market; risk of our ability to demonstrate to the FDA "clinical superiority" of Libervant within the meaning of the FDA regulations relative to FDA-approved diazepam nasal spray product of a competitor in the U.S., including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products, as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product, and there can be no assurance that we will be successful; risk of delays in FDA approval of AQST-109 and our other drug candidates, or failure to receive FDA approval at all; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk in obtaining market access for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of sufficient capital and cash resources, including access to available debt and equity financing 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; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks 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 the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings and associated costs, including patent infringement, securities, business torts, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the 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 us or any person acting on our

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.

PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc.

Investor Inquiries:
ICR Westwicke
Stephanie Carrington
stephanie.carrington@westwicke.com
646-277-1282