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): January 21, 2021

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 January 21, 2021, Aquestive Therapeutics, Inc. (the "Company") and Mitsubishi Tanabe Pharma America, Inc. issued a joint press release announcing the Company's exclusive license to Mitsubishi Tanabe Pharma Holdings America, Inc. for the commercialization in the United States of Exservan™ (riluzole), an oral film formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS). A copy of such press release is attached as Exhibit 99.1 to this report and incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated January 21, 2021.

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: January 21, 2021

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Mitsubishi Tanabe Pharma America Aquestive Press Release

MITSUBISHI TANABE PHARMA AMERICA AND AQUESTIVE THERAPEUTICS ANNOUNCE U.S. LICENSING AND SUPPLY DEAL FOR RILUZOLE ORAL FILM FOR ALS TREATMENT

JERSEY CITY, N.J. and WARREN, N.J., January 21, 2021 – Mitsubishi Tanabe Pharma America, Inc. (MTPA) and Aquestive Therapeutics, Inc. (NASDAQ: AQST) today announced a licensing and supply deal for the U.S. rights to commercialize EXSERVAN™ (riluzole), an oral film formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS).

“Patients are always the central focus of our work as we try to make a difference in their lives,” said Atsushi Fujimoto, President, MTPA. “This licensing deal will enable us to bring patients a riluzole oral film designed to address the needs of people with ALS, including those who have difficulties swallowing some medications. We are honored to have this opportunity to expand our offerings to the ALS community.”

As a result of the deal, MTPA will commercialize EXSERVAN in the U.S. Aquestive will serve as the exclusive sole manufacturer and supplier for the product.

MTPA plans to make EXSERVAN available to patients in the middle of 2021.

“As a company applying innovative technology to improve medicines for patients, we are delighted to be working with a world-leading innovator in ALS with a deep commitment to the patient community,” said Keith J. Kendall, President and Chief Executive Officer of Aquestive. “Mitsubishi Tanabe Pharma America is the right partner for commercializing EXSERVAN oral film formulation of riluzole in the United States.”

Under the terms of the deal agreement, Aquestive will receive upfront consideration, milestone payments, royalties on net sales of EXSERVAN in the U.S., and will earn revenue pursuant to the exclusive supply agreement.

About EXSERVAN™ (riluzole oral film)
EXSERVAN, an oral film formulation of riluzole, was developed by Aquestive using its PharmFilm® innovative drug delivery technology. The oral film is placed on the patient’s tongue and quickly dissolves without the need for liquids or food. RILUTEK® (riluzole) tablets was the reference product during the oral film development. Oral film riluzole was approved by the U.S. Food and Drug Administration (FDA) in November 2019.

IMPORTANT SAFETY INFORMATION
EXSERVAN™ (riluzole) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Do not use if you are allergic to riluzole or to any of its ingredients.

Before using EXSERVAN, tell your healthcare provider about all the medicines you take and all your health conditions, including if you:

- Have hepatic (liver) impairment.
- Are taking strong or moderate CYP1A2 inhibitors such as ciprofloxacin, enoxacin, fluvoxamine, methoxsalen, mexiletine, oral contraceptives, thiabendazole, vemurafenib, zileuton.
- Are pregnant or intend to become pregnant during EXSERVAN therapy, or if you are breastfeeding or intend to breastfeed during EXSERVAN therapy.

EXSERVAN can cause serious side effects, including:

- **Hepatic Injury:** Cases of drug-induced liver injury, some fatal, have been reported in patients taking riluzole. Consult your healthcare provider promptly if you experience unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine.
- **Neutropenia:** Tell your healthcare provider if you develop a fever while taking EXSERVAN.
- **Interstitial Lung Disease:** Tell your healthcare provider if you have respiratory symptoms such as dry cough and difficult or labored breathing. Discontinue EXSERVAN immediately if interstitial lung disease develops.

The most common side effects include oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain.

These are not all the possible side effects of EXSERVAN. Consult your healthcare provider for medical advice about side effects and if you have any side effect that bothers you or that does not go away. To report SUSPECTED ADVERSE REACTIONS, contact Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Use EXSERVAN as prescribed. The recommended dosage for EXSERVAN is 50 mg taken orally twice daily at least 1 hour before or 2 hours after a meal. Place EXSERVAN oral film strip on the top of the tongue where it will adhere and dissolve. Do not cut or split the film or take liquids with EXSERVAN. Do not chew, spit, or talk while EXSERVAN is dissolving.

About Mitsubishi Tanabe Pharma America, Inc.
Based in Jersey City, N.J., Mitsubishi Tanabe Pharma America, Inc. (MTPA) is a wholly-owned subsidiary of Mitsubishi Tanabe Pharma Corporation's (MTPC) 100 percent owned U.S. holding company, Mitsubishi Tanabe Pharma Holdings America, Inc. It was established by MTPC to commercialize approved pharmaceutical products in North America. For more information, please visit www.mt-pharma-america.com or follow us on Twitter, Facebook and LinkedIn.

Overview of Mitsubishi Tanabe Pharma Corporation
Mitsubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company with one of the longest histories of pharmaceutical companies in Japan.[1] In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 2016-2020. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — immune-inflammation diseases, diabetes and kidney, central nervous system, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world. MTPC is the parent company of MTPA. For more information, go to https://www.mt-pharma.co.jp/e/.

About Aquestive Therapeutics, Inc.
Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, SYMPAZAN® (clobazam), has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven capabilities for drug development and commercialization.

Forward-Looking Statement

This press release includes 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 therapeutic benefits and plans and objectives for advancing EXSERVAN to the market. These forward-looking statements are also 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 Aquestive’s 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 the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans; risk of delays in FDA approval of our other drug candidates or failure to receive approval; 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 inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks and uncertainties concerning royalty and other revenue streams of our licensed products including EXSERVAN, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under license and monetization transactions, and of sufficiency of net proceeds of these monetization and licensing transactions after satisfaction of and compliance with our 12.5% Senior Notes obligations, as applicable, and for funding the Company’s operations; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; 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 cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; 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, including patent infringement, 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 Exchange Commission (SEC). 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. All other registered trademarks referenced herein are the property of their respective owners.

Media inquiries:
Debbie Etchison
908-340-8578
Media_MTPA@mt-pharma-us.com

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

[1] Research by TOKYO SHOKO RESEARCH, LTD.