UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): March 3, 2022

AQUESTIVE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

30 Technology Drive
Warren, NJ 07059
(Address of Principal Executive Offices) (Zip Code)

(908) 941-1900
(Registrant's telephone number, including area code)

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.

Aquestive Therapeutics, Inc. (the "Company") entered into that certain License, Development and Supply Agreement (the "License and Supply Agreement") with Haisco Pharmaceutical Group Co., Ltd. (SZSE: 002653) ("Haisco"), a pharmaceutical company based in the People's Republic of China ("China"). Pursuant to the License and Supply Agreement, the Company agreed to grant to Haisco an exclusive license to certain of the Company's intellectual property to develop and commercialize Exservan™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis ("ALS") in China during the term of the License and Supply Agreement. Haisco will lead the regulatory and commercialization activities for Exservan in China. The Company will serve as the exclusive sole manufacturer and supplier for the product. The Company will receive a $7 million upfront cash payment, regulatory milestone payments, and double-digit royalties on net sales of EXSERVAN in China, and will earn manufacturing revenue as the exclusive supplier of Exservan pursuant to the terms of the License and Supply agreement. The License and Supply Agreement will expire on the 10 year anniversary of the first commercial sale of the product in China, unless Haisco elects to renew the License and Supply Agreement for additional terms, on written notice to the Company.

The License and Supply Agreement provides that intellectual property developed by a single party pursuant to activities contemplated by the agreement and not based on the practice of certain confidential information or intellectual property of the other party shall be owned by such party. The agreement provides for joint ownership of certain jointly developed intellectual property as well as joint or collaborative prosecution, maintenance, and defense of such intellectual property. Haisco agreed to grant to the Company an exclusive license under jointly developed intellectual property rights, during the term of the License and Supply Agreement, to develop, manufacture and commercialize products outside of China and inside of China for indications other than ALS.

The License and Supply Agreement contains customary termination provisions for each of the Company and Haisco under certain circumstances, including the right to terminate the License and Supply Agreement by either party upon ninety (90) days written notice to the other party if marketing authorization of the product in China has not been granted on the date that is three (3) years after the effective date of the License and Supply Agreement.

The License and Supply Agreement also includes customary representations, warranties and covenants of the Company and Haisco. The representations and warranties made by each party were made solely for the benefit of the other party and (i) were not intended to be treated as categorical statements of fact, but rather as a way of allocating the risk between the parties to the License and Supply Agreement if those statements prove to be inaccurate; (ii) may apply contract standards of "materiality" that are different from "materiality" under the applicable securities laws; and (iii) were made only as of the date of the License and Supply Agreement or such other periods of time as may be specified in the License and Supply Agreement.

The License and Supply Agreement also contains customary insurance provisions and indemnification provisions pursuant to which each of the parties has agreed to indemnify the other party against losses associated with third party claims resulting from certain events, including breaches of representations, warranties, and covenants, and certain other matters.

This summary of the License and Supply Agreement does not purport to be complete and is qualified in its entirety by reference to the provisions of the License and Supply Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2022 and incorporated therein by reference.

Item 8.01. Other Events.

On March 3, 2022, Aquestive Therapeutics, Inc. issued a press release announcing the execution of that certain License, Development and Supply Agreement with Haisco Pharmaceutical Group Co., Ltd. (SZSE: 002653), a pharmaceutical company based in the People's Republic of China ("China"), to develop and commercialize Exservan™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis (ALS) in China. 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	Press Release of Aquestive Therapeutics, Inc. dated March 3, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aquestive Therapeutics, Inc.

Date: March 3, 2022

By: /s/ A. ERNEST TOTH JR.
A. Ernest Toth Jr.
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 99.1

Aquestive Therapeutics and Haisco Pharmaceutical Group Enter Licensing and Supply Agreement for Riluzole Oral Film for ALS Treatment in China

WARREN, N.J., March 03, 2022 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive"), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, announced the execution of a License, Development and Supply Agreement with Haisco Pharmaceutical Group Co., Ltd. (SZSE**:** 002653) ("Haisco"), a pharmaceutical company based in the People's Republic of China ("China"), for Haisco to develop and exclusively commercialize EXSERVAN™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis ("ALS") in China.

Around 85% of ALS patients suffer from a progressive loss of bulbar functionality.[1] Swallowing food and liquids becomes more difficult over time. While most patients initiate on riluzole, some choose to discontinue treatment at various points in the disease progression due to an inability to swallow a tablet. EXSERVAN™ is designed to provide a meaningful treatment option, using Aquestive's orally administered PharmFilm® dosage form, to patients and caregivers. It alleviates the need for swallowing a tablet and water, while having a negligible impact on volume and viscosity of normal saliva.

"This agreement with Haisco will allow ALS patients in China to access EXSERVAN, a riluzole oral film, which will provide a meaningful treatment option to those who have to discontinue their treatment because of difficulties swallowing a tablet. This collaboration perfectly aligns with our mission to design patient-preferred medicines for their safety, efficacy, and ease of use," remarked Keith Kendall, Chief Executive Officer of Aquestive.

Pursuant to the agreement, Haisco will lead the regulatory and commercialization activities for EXSERVAN in China. Aquestive will serve as the exclusive sole manufacturer and supplier for the product. Aquestive will receive a $7million upfront cash payment, regulatory milestone payments, and double-digit royalties on net sales of EXSERVAN in China, and will earn manufacturing revenue as the exclusive supplier of EXSERVAN.

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[1] Difficulty Swallowing - ALS News Today

About Aquestive Therapeutics
Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. 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

About Haisco
Haisco Pharmaceutical Group is a China-based public pharmaceutical company dedicated to providing the best medical products in specialized area to patients and our community. With extensive experience, Haisco is capable of developing, manufacturing and commercializing innovative drug products as well as generic drug products with high technical barrier in our focused areas.

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. Aquestive has entered into separate license and supply agreements for EXSERVAN in Europe with Zambon S.p.A. and in the Unites States with Mitsubishi Tanabe Pharma America.

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.

Forward Looking Statement
This news release contains forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that might cause such a difference include, among others, the review processes and other governmental regulation in China, Haisco's and Aquestive's abilities to successfully develop and commercialize drug candidates, including Exservan, competition from other pharmaceutical companies, the ability to effectively market products, and other factors described in Aquestive's most recent filings with the Securities and Exchange Commission. Aquestive undertakes no duty to update forward looking statements.

Aquestive Contact:
Stephanie Carrington
ICR Westwicke
Stephanie.carrington@westwicke.com
646-277-1282