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 25, 2019

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 7.01 Regulation FD Disclosure.

On November 25, 2019, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing that the Company received FDA approval for Exservan™(riluzole) Oral Film. A copy of such press release is attached as Exhibit 99.1 to this report and incorporated into this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and shall not be deemed to be "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 to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated November 25, 2019, announcing the Company's receipt of FDA approval for Exservan™ (riluzile) Oral Film.

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: November 25, 2019

Aquestive Therapeutics, Inc.

By:/s/ John T. Maxwell
Name: John T. Maxwell
Title: Chief Financial Officer

Exhibit 99.1

Aquestive Therapeutics Receives FDA Approval for Exservan™ (riluzole) Oral Film

WARREN, N.J., November 25, 2019 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products to solve therapeutic problems, today announced that Exservan™ (riluzole) Oral Film received early-action approval from the U.S. Food and Drug Administration (FDA) for the treatment of amyotrophic lateral sclerosis (ALS), an orphan disease.

“We received full FDA approval for Exservan in advance of our PDUFA action date. We appreciate the ongoing feedback from the FDA and its early-action approval. We anticipate that Exservan, via our orally administered PharmFilm® dosage form, will bring meaningful treatment to patients who are diagnosed with ALS and face difficulties swallowing or administering traditional forms of medication,” said Keith J. Kendall, Chief Executive Officer of Aquestive. “In line with our stated objectives, we licensed this product to Zambon S.p.A. for development and commercialization in the EU. We are continuing the dialogue with potential licensees for the US commercial rights.”

Exservan (riluzole) Oral Film is now approved for the treatment of ALS, a debilitating and rare disease affecting as many as 30,000 Americans[1] and 52,000 Europeans[2]. Exservan will now fill a critical need in the armamentarium for ALS patients because it can be administered safely and easily, twice daily, without water where many patients have trouble swallowing. Development initiatives conducted by Aquestive have included studies demonstrating Exservan's pharmacokinetic bioequivalence to the reference listed drug, Rilutek®, as well as additional studies to assess patients' ability to swallow Exservan. Exservan received FDA orphan drug designation in January 2018.

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. Aquestive is advancing a late-stage proprietary product pipeline to treat CNS conditions and 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 may include, but are not limited to, statements regarding therapeutic benefits of Exservan (riluzole) Oral Film and other product candidates; statements about our growth and future financial and operating results and financial position, ability to advance Exservan (riluzole) Oral Film to the EU and US markets, regulatory approvals and pathways, clinical trial timing and plans, short-term and long-term liquidity and cash requirements, cash funding and cash burn, 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 the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; risk of delays in FDA or other governmental approval of our drug candidates or failure to receive approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk that a competitor obtains orphan drug exclusivity and blocks our product for the same indication for seven years; 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; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; risks associated with Indivior's announcement of its intention to cease production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; 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 of our products and product candidates; the success of any competing products, including generics; 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 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 action 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 governmental 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 risks and uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019 and in our quarterly reports on Form 10-Q. Given these 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.

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[1] **Sources**: CDC, "National Amyotrophic Lateral Sclerosis (ALS) Registry FAQ" https://wwwn.cdc.gov/als/alsfaq.aspx (Accessed January 2018), ALS Association, "Quick Facts about ALS" http://www.alsa.org/news/media/quick-facts.html (Accessed January 2018)

[2] **Sources**: European Medicines Agency, https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3192155