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 25, 2018

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 (17CFR 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))

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 25, 2018, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing the successful completion of a pharmacokinetic epilepsy monitoring unit study relating to its investigational diazepam buccal film, tentatively named Libervant™, with positive topline results. 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 October 25, 2018, announcing the completion of the Diazepam Buccal Film Epilepsy Monitoring Unit Clinical Study with Positive Topline Results

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 30, 2018

Aquestive Therapeutics, Inc.

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

Aquestive Therapeutics Announces Completion of the Diazepam Buccal Film Adult Epilepsy Monitoring Unit (EMU) Clinical Study with Positive Topline Results

Warren, NJ, October 24, 2018 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company, today announced the completion of a pharmacokinetic epilepsy monitoring unit (EMU) study demonstrating that its investigational diazepam buccal film (DBF), tentatively named Libervant™, provides comparable bioavailability whether administered between seizures (interictal) or during and shortly after seizures (ictal/peri-ictal) in adult patients with poorly controlled tonic-clonic seizures or focal seizures with impaired awareness. DBF, a novel formulation of diazepam as a small, thin film strip placed inside the cheek, is under development for the management of selected patients with refractory epilepsy who require intermittent use of diazepam to control episodes of increased seizure activity.

“Often it can be very difficult to administer treatment during periods of increased seizure activity. Currently, the only non-injected formulation of diazepam approved for the acute treatment of seizures is a rectally-applied gel,” said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. “These pharmacokinetic findings, taken together with other DBF studies, will help advance the development of Libervant as an alternative to currently approved therapies. We are very excited to have achieved this critical milestone in the program.”

In this single-dose cross-over study, investigators determined diazepam maximal plasma concentration (C_{max}), time to maximal concentration (T_{max}), and partial area under the diazepam plasma concentration curve (partial AUC) at 2 or 4 hours following administration of 12.5 mg of DBF to the patients while they underwent a clinical epilepsy monitoring unit evaluation. Results from this study have been accepted for late-breaking presentation at the upcoming 2018 meeting of the American Epilepsy Society.

About Aquestive Therapeutics

Aquestive Therapeutics is a specialty pharmaceutical company committed to identifying, developing and commercializing differentiated products to address unmet medical needs. Aquestive Therapeutics has a late-stage proprietary product pipeline focused on the treatment of CNS diseases, and is working to advance orally-administered complex molecules that it believes can be alternatives to invasivelLy-administered standard of care therapies. As the leader in developing and delivering drugs via its PharmFilm® technology, Aquestive Therapeutics also collaborates with pharmaceutical partners to bring new molecules to market in differentiated and highly-marketable dosage forms.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “project,” “will,” “would,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. Such statements include, but are not limited to, statements about regulatory approvals and pathways, clinical trial timing and plans, the achievement of clinical and commercial milestones, future financial and operating results, business strategies, market opportunities, financing, 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; the risks of delays in FDA approval of our drug candidates or failure to receive approval; the risks inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); development of our sales and marketing capabilities; the rate and degree of market acceptance of our product candidates; the success of any competing products; the size and growth of our product markets; the effectiveness and safety of our product candidates; risks associated with intellectual property rights and infringement; unexpected patent developments; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Registration Statement on Form S-1 declared effective by the SEC on July 24, 2018. As with any pharmaceutical product candidate under development, there are significant risks with respect to the development, regulatory approval and commercialization of new products. 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. We assume no obligation to update our forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required under applicable law.

Media inquiries:
Christopher Hippolyte
christopher.hippolyte@syneoshealth.com
212-364-0458

Investor inquiries:
Stephanie Carrington
stephanie.carrington@icrinc.com
646-277-1282