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 26, 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 1.01 Entry into a Material Definitive Agreement.

Effective October 26, 2022, Aquestive Therapeutics, Inc. ("Aquestive" or the "Company") entered into a License Agreement with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. (NASDAQ: ASRT) ("Assertio"), a specialty pharmaceutical company offering differentiated products to patients, to license Sympazan® (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients aged two years of age or older (the "Assertio License Agreement"). Under the terms of the Assertio License Agreement, the Company granted an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of the Assertio License Areement for an upfront payment of $9.0 million. Under the terms of the Assertio License Agreement, Aquestive will receive a $6.0 million milestone payment within thirty (30) days after Aquestive's receipt of a notice of allowance from the United States Patent and Trademark Office (PTO) of the Company's patent application U.S. Serial No. 16/561,573, and payment by the Company of the related allowance fee. The Company received the notice of allowance from the PTO and paid the related allowance fee on October 27, 2022. In addition, under the Assertio License Agreement, the Company will receive royalties from Assertio for the sale of the product through the expiration of the Assertio License Agreement. The Company also entered into a long-term supply agreement with Assertio for Sympazan pursuant to which the Company is the exclusive sole worldwide manufacturer and supplier of the product and will receive manufacturing fees from Assertio for the product through the expiration of such supply agreement.

The Assertio License Agreement contains customary termination provisions for each of the Company and Assertio under certain circumstances, including that Assertio may terminate the Assertio License Agreeement upon twenty-four (24) months' written notice to the Company, with or without cause.

The Assertio License Agreement also includes customary representations, warranties and covenants of the Company and Assertio. 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 Assertio License 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 Assertio License Agreement or such other periods of time as may be specified in the Assertio License Agreement.

The Assertio License 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 Assertio License Agreement does not purport to be complete and is qualified in its entirety by reference to the provisions of the Assertio License 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 September 30, 2022 and incorporated therein by reference.

Item 8.01 Other Events.

On October 27, 2022, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing the execution of that certain License Agreement, effective as of October 26, 2022, with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. (NASDAQ: ASRT) ("Assertio") to license Sympazan® (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients aged two years or older, throughout the world. 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 27, 2022 Announcing License Agreement for Sympazan® (clobazam) oral film throughout the world.

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 27, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Aquestive Therapeutics Licenses Sympazan® (clobazam) Oral Film to Assertio Holdings, Inc.

WARREN, N.J., Oct. 27, 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 a transaction to license Sympazan® (clobazam) oral film to Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. ("Assertio") (NASDAQ: ASRT), a specialty pharmaceutical company offering differentiated products to patients. Sympazan (clobazam) oral film is for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients aged two years of age or older.

"The completion of this transaction marks the beginning of a new chapter for Aquestive, and we are thrilled that Assertio recognizes Sympazan's significant growth opportunities," remarked Daniel Barber, Chief Executive Officer of Aquestive. "This agreement for Sympazan is another example of a non-dilutive financing option that allows us to continue focusing our efforts on the development of AQST-109 (epinephrine sublingual film), to meet the needs of patients who need an alternative emergency treatment of severe allergic reactions, including anaphylaxis. Our commercial expertise will now be able to focus on the potential launch of AQST-109, if approved by the FDA."

Under the terms of the definitive agreement, Aquestive exclusively licensed the product's intellectual property to Assertio for an upfront payment of $9.0 million. Aquestive also entered into a long-term supply agreement with Assertio for Sympazan. Under the terms of the agreement, Aquestive will continue to prosecute an existing patent application that could extend patent coverage for Sympazan to as late as 2039. Upon the patent allowance for Sympazan, Aquestive will receive a $6.0 million milestone payment and royalties from Assertio.

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 include, but are not limited to, statements regarding the potential allowance of a patent application that would extend patent coverage of Sympazan to as late as 2039, and related milestone payments, the advancement of AQST-109 through the regulatory and development pipeline and clinical and business strategies, market opportunities, and other statements that 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, risk that the additional patent application filed for Sympazan will not be allowed by the U.S. Patent and Trademark Office, and there can be no assurance that we will be successful in obtaining such allowance, and risk of delays related to the allowance of such patent application; 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 in FDA approval of Libervant® (diazepam) Buccal Film, AQST-109, and our other drug candidates or failure to receive FDA approval; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of Libervant relative to a FDA-approved 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 product, 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 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 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.

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