

**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): May 3, 2022

Aquestive Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or
Organization)

001-38599
(Commission File Number)

82-3827296
(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.

Aquestive Therapeutics, Inc. (the "Company") entered into a License, Development and Supply Agreement with Haisco Pharmaceutical Group Co., Ltd., a Chinese limited company listed on the Shenzhen Stock Exchange ("Haisco") effective as of March 3, 2022 ("Haisco Agreement") pursuant to which Aquestive granted Haisco an exclusive license to develop and commercialize Exservan™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis, or ALS ("Exservan) in China and Aquestive will serve as the exclusive sole manufacturer and supplier for Exservan in China. Pursuant to the Haisco License Agreement, Haisco has been appointed to serve as Aquestive's agent for matters relating to the commercialization of Exservan in China, including obtaining approval to market and sell (the "Marketing Authorization") Exservan in China. Subsequent to the execution of the Haisco Agreement in March 2022, the Chinese equivalent of the FDA (the "NMPA") raised an issue regarding the named holder of the U.S. New Drug Application (NDA) for Exservan in relation to the application for Marketing Authorization of Exservan in China. It is not clear whether the NMPA will require that Aquestive be the holder of the NDA in order to approve the Marketing Authorization for Exservan in China, or whether the NMPA will find that Aquestive's qualifications as the exclusive licensor, manufacturer and innovator of Exservan will be sufficient for the NMPA to approve Aquestive as the drug sponsor for Exservan in China and grant the Marketing Authorization for Exservan in China. Prior to entering into the Haisco Agreement, the Company had assigned the NDA for Exservan to another third-party in connection with a license agreement in the U.S. for Exservan and is not currently the named holder of the NDA. The Company is collaborating with Haisco to resolve this issue with the NMPA. As a result of this issue, the Company has not received the \$7 million upfront payment due from Haisco under the Haisco Agreement and expects to agree with Haisco to extend the period of time under which Haisco is obligated to make said upfront payment consistent with the decision of the NMPA on this issue, or as otherwise agreed to by the Company and Haisco.

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: May 3, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.

Title: Chief Financial Officer

(Principal Financial Officer)