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): July 2, 2020

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.

Aquestive Therapeutics, Inc.'s (the "Company's") President and Chief Executive Officer, Keith Kendell, responded to questions posed by *The Fly* (the "Q&A") and published on July 2, 2020. A copy of the Q&A 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) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") 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	The Q&A published in *The Fly* on July 2, 2020.

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: July 2, 2020

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

The Fly Interview Q&A
Keith Kendall, President and CEO of Aquestive Therapeutics

1. **Last month, the company said it plans to advance its strategy to monetize the anticipated royalties associated with Sunovion Pharmaceuticals' apomorphine sublingual film APL-130277, which received FDA approval to treat motor fluctuations experienced by people living with Parkinson's disease. Is the company still pursuing this? How much do you expect to receive from the monetization and can we still expect this royalty stream to extend the capital runway into 2021?**

   As expected, Sunovion's Kynmobi™ product was approved by the FDA on May 21. Sunovion has announced its intention to launch the product in the US in September of 2020. Sunovion licensed Aquestive Therapeutics' technology in order to develop Kynmobi.

   Based on the terms of our license agreement with Sunovion, we expect to receive a regular stream of royalties and license fees over the coming years from Kynmobi. These payments represent a potentially significant source of non-dilutive capital to Aquestive. We have begun the process to monetize the asset, and believe that the market is stabilizing so that we can expect to be in a position in the coming weeks to evaluate the timing and structure of a transaction that is the most advantageous to the Company. Our expectation is that we will raise $50 to $100 million of gross proceeds from this monetization, subject to covenants in our debt agreements.

2. **Aquestive had said that it expects to submit the IND application for AQST-108 this month and to commence PK clinical trials later this year. Does this timeline remain the same? Or has the COVID-19 pandemic impacted the timeline?**

   As we committed, the Company announced on June 29 that we have submitted our IND application to the FDA for AQST-108. We continue to expect to commence PK clinical trials later in 2020. The COVID-19 pandemic has not affected our anticipated timelines on this product. AQST-108 represents a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies.

   We are excited about AQST-108's prospects based on the early proof of concept clinical trials we ran during 2018 and 2019, and the pre-IND meeting we held with the FDA in February 2020. In that meeting, we presented all of our development information to-date, and the FDA indicated no additional clinical work was necessary prior to filing our IND. The FDA also confirmed the application will be reviewed under the 505(b)(2) regulatory pathway. Additionally, the FDA acknowledged that there appears to be an unmet medical need among patients who resist the standard of care use of subcutaneous and intramuscular injection in the treatment of anaphylaxis. We believe that AQST-108 may potentially address some of those unmet needs.

   We plan to announce more about the program after the IND application has been accepted by the FDA, which is expected approximately 30 to 60 days after the filing date.

3. **Can you also provide an update on the NDA for Libervant, which has a September 27 PDUFA goal date? Is everything going as expected?**

As we have indicated previously, the NDA for Libervant was filed in November 2019 and the FDA has assigned a PDUFA goal date of late September 2020. As an organization, we worked closely with the FDA during the development process to do our best to provide the information that the FDA needs to approve our product. However, there can be no assurances with regard to the FDA decision regarding our application. The review to-date has progressed as we would have expected, with a normal exchange of information requests and answers to the requests. We expect that this will continue as we move closer to the September date. At this time, we have no indication or reason to believe that there will be any delay.

4. **Aside from what we discussed and looking out over the remainder of the year, what do you see as the company's most important event or product release?**

There are several things that are important to understand about our business:

- Aquestive has a proven track record of success in developing and manufacturing differentiated therapeutics with PharmFilm technology. We have five FDA approved therapeutics, both licensed and proprietary products.
- We launched our first self-commercialized proprietary product, Sympazan, for the treatment of Lennox-Gastaut Syndrome in December 2018. Sympazan continues to grow and penetrate the market in which many prescribers will also be prescribers of Libervant when it is approved.
- We continue to advance our late-stage pipeline of therapeutics for complex conditions. Libervant is the most advanced candidate in our pipeline, and, while there can be no assurances as to the decision the FDA may make, we hope to see it approved in September.
- AQST-108, which could be the "first of its kind" oral version of epinephrine, will continue on its 505(b)(2) clinical and regulatory pathway following our recent IND filing with the FDA. We expect PK trials to begin later this year.

Through a combination of our revenue, cash on hand and monetizable assets, we believe that we have capital or visibility to capital that will enable us to fund our business well into 2021 and possibly beyond. These, combined with some licensee activities, present a significant number of potential value inflection points for shareholders over the coming 12-24 months.

5. **Is there any misconception about your company that you would like to correct?**

The Company has certainly been negatively impacted by a number of tangential events that are not in our control and, in some cases, not central to the key value drivers of the Company. Aquestive is a fully integrated pharmaceutical company with multiple approved products, and additional pipeline candidates in development. Near term value will be driven by the CNS/Epilepsy franchise comprised of Sympazan, already launched, and Libervant, with its NDA currently pending at the FDA. Additionally, significant value has the potential to be created if we are successful in the development and launch of AQST-108 sublingual epinephrine, a potentially significant disruptive change to the historically injectable therapies currently available. Moreover, we believe that the Company has significant opportunity to continue to provide innovative therapies in complex conditions beyond the programs currently in our pipeline, and we will consider augmenting our PharmFilm technology and know-how with other technologies in order to expand what we do for patients in our targeted therapeutic areas and other disease states. We expect that we will add other products to our pipeline over time, with a focus on under-treated conditions where our innovative drug delivery technology and know-how can create significant value for the patient.