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): December 15, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) On December 16, 2020, Aquestive Therapeutics, Inc. (the "Company") announced that John T. Maxwell has provided his intent to resign from his role as the Company's Chief Financial Officer. Current plans call for Mr. Maxwell to continue to serve as Chief Financial Officer of the Company until his departure, which currently is anticipated at year end. In connection with his departure, Mr. Maxwell and the Company have entered into a separation and release agreement providing for severance payments and benefits generally consistent with his employment agreement, dated June 26, 2018, including a severance payment equal to the sum of his annual base salary and target annual bonus payable in 12 equal monthly installments, a target bonus for 2020, coverage under group health and life insurance plans for up to 12 months and immediate vesting of all unvested stock options which will remain exercisable for one year following his separation from employment.

(c) On December 16, 2020, the Company announced that, on December 15, 2020, the Board of Directors ("Board") appointed Ernie Toth, 62, to serve as Interim Chief Financial Officer effective upon Mr. Maxwell's departure. Mr. Toth will be a consultant to the Company, providing services pursuant to a Consulting Agreement between the Company and Danforth Advisors, LLC, Mr. Toth's employer (the "Consulting Agreement"). The Consulting Agreement provides for compensation for services provided at a rate of $325 per hour, stock options to purchase 2,500 shares of the Company's common stock under the Company's 2018 Equity Incentive Plan subject to such other terms and conditions as approved by the Compensation Committee of the Board, as well as reimbursement of Mr. Toth's covered commuting expenses to the Company's New Jersey office and any other such necessary business expenses. The term of the Consulting Agreement will continue until such time as either party gives written notice of termination.

Mr. Toth joined Danforth Advisors in November 2020 as a Consultant to provide finance support and strategic consulting services to life science companies and the healthcare technology industry. Prior to that time, Mr. Toth most recently served as Chief Financial Officer of EHE Health from September 2018 to February 2020. Prior to joining EHE Health, he served as Global Chief Financial Officer of ArisGlobal from January 2016 to December 2016, and Global Chief Financial Officer of Synowledge from January 2015 to December 2015. Mr. Toth also serves as Managing Director of Bellair Advisors, LLC, a consulting and advisory firm that provides financial, strategic, operational, and commercial counsel to high growth entrepreneurial businesses.

Other than as described above, the selection of Mr. Toth to serve as the Company's Interim Chief Financial Officer was not made pursuant to any arrangement or understanding with any other person. In addition, there are no family relationships between Mr. Toth and any director or other executive officer of the Company, and there are no transactions involving Mr. Toth requiring disclosure under Item 404(a) of Regulation S-K.

Item 7.01 Regulation FD Disclosure.

On December 16, 2020, the Company issued a press release announcing the matters described in Item 5.02 above and that there is no change to its full year 2020 financial outlook. A copy of the Company's press release is attached hereto as Exhibit 99.1 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, 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	Press Release, dated December 16, 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: December 17, 2020

Aquestive Therapeutics, Inc.

By: /s/ Lori J. Braender
Name: Lori J. Braender
Title: Senior Vice President, General Counsel

Exhibit 99.1

Aquestive Therapeutics Announces Departure of Chief Financial Officer and Appointment of Interim Chief Financial Officer

Warren, NJ, December 16, 2020 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, today announced that John Maxwell, Senior Vice President, Chief Financial Officer (CFO) of the Company, has provided his intent to resign his positions with the Company to pursue other interests. Current plans call for Mr. Maxwell to continue to serve as CFO of the Company until his departure, which currently is anticipated at year end. Mr. Ernie Toth, a seasoned financial executive most recently with EHE Health as Chief Financial Officer, will assume the role of CFO on an interim basis upon Mr. Maxwell's departure.

"We have made meaningful progress in our business since John joined the Company in January 2017," said Keith J. Kendall, President and Chief Executive Officer of Aquestive. "John has been a valuable part of the continued development of the Company. We thank him for his contributions, especially in shepherding our efforts to become a public company and close several critical capital markets transactions. The management team and board of directors of Aquestive joins me in wishing him well in his future business pursuits. We anticipate effecting a very smooth transition over the next few weeks and are pleased to welcome Mr. Toth as the new interim CFO to our team," concluded Mr. Kendall.

"I have enjoyed my time with Aquestive Therapeutics," said Mr. Maxwell. "Upon arrival, my immediate objective was to help evolve the capitalization of the Company. Aquestive was in the midst of its transformation into a commercial proprietary pharmaceutical company. Having accomplished this critical goal, I believe the Company is well positioned for future growth and I believe in the strength of the Aquestive business. I wish the team all the best for its continued success."

The Company also reported that Mr. Maxwell's departure is not related to the Company's operations, financial reporting or controls.

2020 Outlook

The Company also announced that there is no change to its full year 2020 financial outlook.

About Aquestive Therapeutics

Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, Sympazan, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to 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 include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of AQST-108 and Libervant; ability to address the concerns identified in the FDA’s Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant and obtain FDA approval of Libervant for U.S. market access; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; about our growth and future financial and operating results and financial position; regulatory approval and pathway; clinical trial timing and plans; our and our competitors’ orphan drug approval and resulting drug exclusivity for our products or products of our competitors; 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 also 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, 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 and plans; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of our drug candidate Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products 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 of a competitor in the U.S. 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 inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks for consummating the monetization transaction for KYNMOBI and other risks and uncertainties concerning the royalty and other revenue stream of KYNMOBI, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction, and of sufficiency of net proceeds of the monetization transaction after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable, and for funding the Company’s operations; 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; risk associated with Indivior’s cessation of 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 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, including patent infringement, 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 (SEC). 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.

PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

Investor Inquiries:

Westwicke, an ICR Company
Stephanie Carrington
stephanie.carington@westwicke.com
646-277-1282