# 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): February 8, 2021

# 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 in	tended to simultaneously satisfy th	ne 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. $\Box$

# Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

- (b) On February 8, 2021, in connection with the events described under Item 5.02(d) below, Douglas K. Bratton notified the Board of Directors (the "Board") of Aquestive Therapeutics, Inc. (the "Company") of his intention to resign from the Board effective as of February 10, 2021. Mr. Bratton's departure is not due to any disagreement with the Company.
- (d) On February 8, 2021, the Board appointed Julie Krop, MD and Marco Taglietti, MD to the Board, effective as of February 10, 2021, to fill the vacancies created by Mr. Bratton's departure and the increase in the size of the Board by one to a total of eight members. Dr. Krop and Dr. Taglietti were each appointed to Class III and will serve until the 2021 Annual Meeting of Stockholders, where they will stand for election. Dr. Krop will serve on the Nominating and Corporate Governance Committee, and Dr. Taglietti will serve on the Audit Committee.

The Board affirmatively determined that each of Drs. Krop and Taglietti will be an "independent director" under applicable rules of the Nasdaq Global Market, and that Dr. Taglietti satisfies the independence requirements for audit committee members set forth in Rule 10A-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the rules of the Nasdaq Global Market.

Drs. Krop and Taglietti will receive compensation consistent with that of the Company's other non-employee directors as described under the heading "Non-Employee Director Compensation" in the Company's definitive proxy statement for the 2020 Annual Meeting of Stockholders, filed with the Securities and Exchange Commission on April 29, 2020. Under our non-employee director compensation program, Drs. Krop and Taglietti will each receive an initial grant of 28,500 stock options, effective on the second full trading date following the Company's release of fourth quarter/fiscal year 2020 earnings in accordance with the Company's equity grant policy. These options will vest over three years in annual one-third increments.

The selection of Drs. Krop and Taglietti to serve as members of the Board was not made pursuant to any arrangement or understanding with any other person. In addition, there are no transactions involving Dr. Krop or Dr. Taglietti requiring disclosure under Item 404(a) of Regulation S-K.

#### Item 7.01 Regulation FD Disclosure.

On February 9, 2021, the Company issued a press release announcing the matters described in Item 5.02 above. 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 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 February 9, 2021.

# **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: February 9, 2021 Aquestive Therapeutics, Inc.

By: /s/ Lori J. Braender

Name: Lori J. Braender

Title: Senior Vice President, General Counsel



# Aquestive Therapeutics Strengthens Board of Directors with Appointments of Julie Krop, M.D., and Marco Taglietti, M.D., and Announces Resignation of Douglas K. Bratton from Board of Directors

Warren, NJ, February 9, 2021 – 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 the appointment of Julie Krop, M.D., Chief Medical Officer of Freeline Therapeutics (NASDAQ: FRLN), and Marco Taglietti, M.D., Director, President and Chief Executive Officer of SCYNEXIS (NASDAQ: SCYX), to the Board of Directors of the Company effective February 10, 2021. Aquestive also announced the resignation of Douglas K. Bratton from the Board of Directors after more than 17 years of service. Aquestive's Board of Directors will now be comprised of eight Directors, seven of whom are independent. Dr. Krop will serve as a member of the Board's Nominating and Corporate Governance Committee and Dr. Taglietti will serve as a member of the Board's Audit Committee.

"We are delighted to welcome Julie and Marco as new independent directors to the Aquestive Board of Directors," said Santo Costa, Aquestive's Chairman of the Board. "Their significant expertise in the pharmaceutical and biotechnology industry and impressive backgrounds complement our Board of Directors' skills and experiences. We are confident they will provide valuable perspectives as we continue to execute our strategy and enhance value for the Company's shareholders."

Dr. Krop stated, "I am thrilled to join the Board of Directors of Aquestive and look forward to working with the Board and the leadership team to advance the Company's mission of providing novel alternatives to invasively administered standard of care therapies. I am particularly excited about helping management guide Aquestive's proprietary orally administered epinephrine through clinical development. This novel formulation of epinephrine has the potential to eliminate the burden of intramuscular or subcutaneous injections for patients at risk of anaphylaxis due to severe allergies."

Dr. Taglietti commented, "Aquestive is at an important stage of its evolution and I am delighted to join the Board of Directors during this exciting time. I look forward to contributing to Aquestive's continued growth and success as the Company advances its Libervant<sup>TM</sup> (diazepam) Buccal Film application through approval and executes on its innovative development activities with the potential to change patients' lives."

"Julie and Marco join Aquestive at an exciting time as we continue to focus on developing and bringing to market valuable products in the CNS and allergy spaces. Julie and Marco's extensive collective experience in leading clinical development, regulatory strategies and commercialization of key value assets is a great addition and complement to the skills already present on our board," remarked Keith Kendall, Director, President and Chief Executive Officer of Aquestive. "We've experienced significant growth and strengthened our capabilities as a commercial pharmaceutical company under Doug's leadership as the original Chairman of the Board and then director. I would like to thank him for his contributions and expert guidance that have well positioned Aquestive for continued momentum and success."

"On behalf of the Board of Directors and the Company, I would like to thank Doug for his more than 17 years of service to our Board, including as former Chairman, in guiding the Company from its start-up phase to a public commercial pharmaceutical company and leader in the film-based therapeutics industry," said Mr. Costa.

"It has been a great privilege to serve as a director and former Chairman of Aquestive's Board of Directors, the members of which I hold in very high regard. I'd like to thank Keith, his team, and the Board for many exciting and satisfying years, and look forward to watching them accomplish even more great things for Aquestive in the months and years to come," stated Mr. Bratton.

## **About Douglas K. Bratton**

Mr. Bratton has served as a member of the Company's Board of Directors since January 2004 and was the Chairman of the Board from January 2004 until August 2018. Mr. Bratton is the Founder, President and Chief Investment Officer of Crestline Investors, an institutional alternative investment management firm. He has been an investment professional specializing in alternative asset strategies since 1983 and has managed assets on behalf of the Bass family of Fort Worth, Texas since 1988.

### About Julie Krop, M.D.

Dr. Krop is a seasoned biotech executive with more than two decades of experience successfully designing and executing clinical development programs from early stage development all the way through FDA approval. She has held senior leadership roles across clinical development, regulatory affairs, clinical operations, pharmacovigilance, medical affairs and program management during her career in the pharmaceutical and biotechnology industry. She currently serves as the Chief Medical Officer of Freeline Therapeutics (NASDAQ: FRLN). Prior to assuming her position with Freeline Therapeutics, Dr. Krop was the Chief Medical Officer and Executive Vice President, Development, at AMAG Pharmaceuticals (NASDAQ: AMAG) from 2015 to 2020. From 2012 to 2015, Dr. Krop served as the Vice President, Clinical Development for Vertex Pharmaceuticals (NASDAQ: VRTX). In addition, Dr. Krop was Vice President, Clinical Development and Regulatory Affairs for Stryker Biotech (NYSE: SYK) from 2006 to 2012. Dr. Krop received a B.A. from Brown University and her M.D. from Brown University School of Medicine. She completed her fellowship in the Department of Endocrinology at the Johns Hopkins University School of Medicine where she was also a Robert Wood Johnson Foundation Clinical Scholar.

## About Marco Taglietti, M.D.

Dr. Taglietti has more than three decades of experience in the pharmaceutical and biotechnology industry. He currently serves as a Director and President and Chief Executive Officer of SCYNEXIS Inc. (NASDAQ: SCYX). Prior to joining SCYNEXIS, Dr. Taglietti held various executive positions with Forest Laboratories (now AbbVie (NYSE: ABBV)) from 2007 until 2014, including President, Forest Research Institute, Chief Medical Officer and Executive Corporate Vice President, Research & Development. Dr. Taglietti was also the Senior Vice President, Head of Global Research and Development for Stiefel Laboratories, Inc. (now a GlaxoSmithKline company) from 2004 until 2007 and served in a number of executive positions from 1992 to 2004 with Schering-Plough Research Institute, including Vice President, Clinical Research Anti-Infectives, CNS, Dermatology and Endocrinology. From 1987 until 1992, Dr. Taglietti served in a number of executive positions with Marion Merrell Dow Research Institute, including as the European Product Team Leader - Anti-Infectives. Dr. Taglietti previously served on the boards of directors of Delcath (NASDAQ: DCTH) from 2014 to 2020 and NephroGenex (NASDAQ: NRX) from 2014 to 2017. Dr. Taglietti also served as a director of Stiefel International, Ltd., a private company, from 2004 to 2007 and a director of TransCelerate BioPharma, a non-profit pharma coalition dedicated to streamlining and accelerating the research and development of innovative new therapies, from 2013 to 2014. Since 2011, Dr. Taglietti has served on the board of directors of BioNJ, a life sciences trade association in New Jersey. In addition, Dr. Taglietti served on the board of directors of HINJ, Health Institute of New Jersey, a trade association for the leading research-based biopharmaceutical and medical technology companies in New Jersey, from 2011 to 2014, and is currently on the boards of directors of Orchestra of St. Luke, a New York City based orchestra, and American Foundation for Suicide Prevention, the largest non-profit organization dedicated to saving lives and bringing hope to those affected by suicide. Dr. Taglietti received his Degree in Medicine from the University of Pavia, Italy.

#### **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® (clobazam) oral film, 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 Statements**

Certain statements in this press release are "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 advancement of Libervant and other product candidates through the regulatory and development pipeline; 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, 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 for AQST-108 and our other drug candidates: risk of delays in FDA approval of our drug candidate Libervant and AOST-108 and our other drug candidates or failure to receive approval; ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of 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 and uncertainties concerning the royalty and other revenue stream of the KYNMOBI<sup>TM</sup> monetization transaction, 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; 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; 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 forwardlooking 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