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): August 9, 2021

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))

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. ☐

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

Item 1.01 Entry into a Material Definitive Agreement.

On August 6, 2021, Aquestive Therapeutics, Inc. (the "Company") entered into the Third Supplemental Indenture (the "Third Supplemental Indenture"), by and among the Company and U.S. Bank National Association, as Trustee (the "Trustee") and collateral agent thereunder, to the Indenture, dated as of July 15, 2019 (the "Base Indenture" and, as supplemented by the First Supplemental Indenture and Second Supplemental Indenture, the "Indenture"), by and between the Company and the Trustee. Pursuant to the Third Supplemental Indenture, the Company has the option to issue (i) an additional $10.0 million aggregate principal amount of the Notes if the Company has received approval from the U.S. Food and Drug Administration (the "FDA") for the Company's drug candidate Libervant™ on or prior to June 30, 2022 (the "First Additional Notes"); provided, however, that such approval shall not require any market access or a waiver of orphan drug exclusivity, and (ii) up to an additional $30.0 million (less the amount of any First Additional Notes issued by the Company) if the Company obtains full approval from the FDA of its product candidate Libervant™, which full approval shall include market access on or prior to June 30, 2022; in each case, subject to certain conditions, including that no event of default under the Indenture has occurred and is continuing. The Third Supplemental Indenture extended out the foregoing dates in the Indenture from December 31, 2021.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of the Registrant.

The information required by this Item 2.03 relating to the First Additional Notes and the Indenture is set forth under Item 1.01 of this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
4.1	Third Supplemental Indenture, dated August 6, 2021, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank, National Association, as Trustee and Collateral Agent
99.1	Press Release dated August 9, 2021, announcing Aquestive Therapeutics, Inc. Negotiates Six Month Extension to June 30, 2022 for Additional Libervant™ Related Capital Under Current Debt Agreement

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: August 9, 2021

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr.

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

THIRD SUPPLEMENTAL INDENTURE

This Third Supplemental Indenture, made as of August 6, 2021 (the "Supplemental Indenture"), to that certain Indenture (as such indenture has been supplemented and amended by the First Supplemental Indenture, dated November 3, 2020 and by the Second Supplemental Indenture, dated as of November 19, 2020, the "Existing Indenture" and the Existing Indenture, as it may from time to time be supplemented or amended by one or more additional indentures supplemental thereto entered into pursuant to the applicable provisions thereof, being hereinafter called the "Indenture") dated as of July 15, 2019 among Aquestive Therapeutics, Inc., a Delaware corporation with an address at 30 Technology Drive, Warren, New Jersey 07059 (the "Issuer"), any Guarantor that becomes party thereto pursuant to Section 4.10 of the Existing Indenture, and U.S. Bank National Association, as trustee (the "Trustee") and as collateral agent (the "Collateral Agent").

WHEREAS, the Issuer has heretofore executed and delivered to the Trustee the Existing Indenture, providing for the issuance of an aggregate principal amount of up to $104.0 million of 12.5% Senior Secured Notes due 2025;

WHEREAS, the Issuer proposes to amend the Existing Indenture (the "Proposed Amendments"), which amendments, pursuant to Section 9.02 of the Indenture, must be approved with the written consent of Holders of a majority in principal amount of the outstanding Notes voting as a single class (the "Required Holders");

WHEREAS, the Issuer has received and delivered to the Trustee and to the Collateral Agent the consent of the Required Holders to the Proposed Amendments (the "Holder Consent");

WHEREAS, the Issuer has been authorized by a resolution of its board of directors to enter into this Supplemental Indenture;

WHEREAS, all other acts and proceedings required by law, by the Existing Indenture and by the certificate of incorporation and bylaws of the Issuer to make this Supplemental Indenture a valid and binding agreement for the purposes expressed herein, in accordance with its terms, have been duly done and performed;

WHEREAS, pursuant to Section 9.02, the Trustee and the Collateral Agent are authorized to execute and deliver this Supplemental Indenture; and

WHEREAS, following the execution of this Supplemental Indenture, the terms hereof will become operative on the date hereof.

NOW, THEREFORE, THIS SUPPLEMENTAL INDENTURE WITNESSETH:

That, for and in consideration of the premises herein contained and in order to effect the Proposed Amendments contained herein, pursuant to Section 9.02 of the Existing Indenture, the Issuer agrees with the Trustee and the Collateral Agent as follows:

ARTICLE 1

Amendment of Existing Indenture

Section 1.01. Amendment of Existing Indenture. This Supplemental Indenture amends the Existing Indenture as provided for herein.

Section 1.02. Amendment of Section 2.01. Pursuant to Section 9.02 of the Existing Indenture:

Section 2.01(c) and (d) of the Existing Indenture are hereby amended and restated in their entirety as follows:

"(c) On any Business Day on or prior to June 30, 2022 that does not fall between a Record Date and its related Payment Date (but, for the avoidance of doubt, only one Business Day, but not more than one Business Day), the Issuer may issue and deliver, in accordance with this Article 2, and pursuant to and in accordance with the terms and conditions of the October 2020 Purchase Agreements, without the consent of any Holder of or any holder of beneficial interests in the Securities, upon five Business Days' written notice to the Trustee, First Additional Securities in an aggregate principal amount of $10,000,000; provided, that, as of such Business Day, as conditions to the issuance of such First Additional Securities, (i) no Event of Default has occurred and is continuing, (ii) the First Additional Securities Triggering Event has occurred and (iii) the Issuer shall deliver to the Trustee, in addition to the written order of the Issuer pursuant to Section 2.03, Officers' Certificates of the Issuer (A) certifying as to the satisfaction of the foregoing clause (i) and clause (ii) and (B) stating that the representations and warranties of the Issuer in the October 2020 Purchase Agreements are true and correct in all material respects on and as of such Business Day with the same force and effect as if expressly made on and as of such Business Day (except for such representations and warranties qualified by materiality or material adverse effect, which are true and correct in all respects). Such First Additional Securities shall have the same terms as the Original Securities and any 2020 Additional Securities, except that the issue date, the issue price, the initial Payment Date and the initial date from which interest shall accrue may vary. If the Issuer determines that such First Additional Securities are issued as part of a "qualified reopening" for U.S. federal income tax purposes, such First Additional Securities will have the same CUSIP number as the Original Securities or any 2020 Additional Securities, as the case may be, and for U.S. federal income tax purposes will have the same issue date and issue price as the Original Securities or such 2020 Additional Securities, as the case may be. If the Issuer determines that such First Additional Securities are not issued as part of a "qualified reopening" for U.S. federal income tax purposes, such First Additional Securities will be required to have a CUSIP number that is different than the CUSIP number of the Original Securities and any 2020 Additional Securities.

(d) On any Business Day on or prior to June 30, 2022 that does not fall between a Record Date and its related Payment Date (but, for the avoidance of doubt, only one Business Day, but not more than one Business Day), the Issuer may issue and deliver, in accordance with this Article 2, without the consent of any Holder of or any holder of beneficial interests in the Securities, upon five Business Days' written notice to the Trustee, Second Additional Securities in an aggregate principal amount of up to $30,000,000; provided, that, as of such Business Day, if

the Issuer has issued the First Additional Securities, the Issuer may only issue and deliver such Second Additional Securities in an aggregate principal amount of up to $20,000,000; provided, further, that, as of such Business Day, as conditions to the issuance of such Second Additional Securities, (i) no Event of Default has occurred and is continuing, (ii) the Second Additional Securities Triggering Event has occurred and (iii) the Issuer shall deliver to the Trustee, in addition to the written order of the Issuer pursuant to Section 2.03, Officers' Certificates of the Issuer (A) certifying as to the satisfaction of the foregoing clause (i) and clause (ii) (the "Second Additional Securities Triggering Event Officers' Certificate") and (B) stating that the representations and warranties of the Issuer in the October 2020 Purchase Agreements are true and correct in all material respects on and as of such Business Day with the same force and effect as if expressly made on and as of such Business Day (except for such representations and warranties qualified by materiality or material adverse effect, which are true and correct in all respects). Such Second Additional Securities shall have the same terms as the Original Securities and any First Additional Securities, 2020 Additional Securities, except that the issue date, the issue price, the initial Payment Date and the initial date from which interest shall accrue may vary. If the Issuer determines that such Second Additional Securities are issued as part of a "qualified reopening" for U.S. federal income tax purposes, such Second Additional Securities will have the same CUSIP number as the Original Securities or any First Additional Securities or 2020 Additional Securities, as the case may be, and for U.S. federal income tax purposes will have the same issue date and issue price as the Original Securities or such First Additional Securities, 2020 Additional Securities, as the case may be. If the Issuer determines that such Second Additional Securities are not issued as part of a "qualified reopening" for U.S. federal income tax purposes, such Second Additional Securities will be required to have a CUSIP number that is different than the CUSIP number of the Original Securities and any First Additional Securities, 2020 Additional Securities."

ARTICLE 2

Miscellaneous Provisions

Section 2.01. Ratification of Indenture; Supplemental Indentures Part of Indenture. Except as expressly amended and supplemented hereby, the Indenture is in all respects ratified and confirmed and all the terms, conditions and provisions thereof shall remain in full force and effect. This Supplemental Indenture shall form a part of the Indenture for all purposes, and every Holder shall be bound hereby.

Section 2.02. Defined Terms. As used in this Supplemental Indenture, terms defined in the Indenture or in the preamble or recitals hereto are used herein as therein defined, except that the term "Holders" in this Supplemental Indenture shall refer to the term "Holders" as defined in the Indenture and the Trustee and the Collateral Agent acting on behalf of and for the benefit of such Holders. The words "herein", "hereof" and "hereby" and other words of similar import used in this Supplemental Indenture refer to this Supplemental Indenture as a whole and not to any particular section hereof.

Section 2.03. Counterparts. The parties may sign any number of copies of this Supplemental Indenture. Each signed copy shall be an original, but all of them together represent the same agreement. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or PDF transmission shall constitute effective execution and delivery of this

Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

Section 2.04. Effect of Headings. The Section headings herein are for convenience of reference only and shall not affect the construction thereof.

Section 2.05. Effectiveness. The provisions of this Supplemental Indenture will take effect immediately upon execution thereof by the parties hereto.

Section 2.06. Governing Law. THIS SUPPLEMENTAL INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAW (OTHER THAN SECTIONS 5-1401 AND 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS LAW).

Section 2.07. No Representation; Recitals. Neither the Trustee nor the Collateral Agent makes any representation as to the validity or sufficiency of this Supplemental Indenture. The recitals to this Supplemental Indenture are made solely by the Issuer and shall not be attributable to the Trustee or the Collateral Agent.

{Remainder of page intentionally left blank}

IN WITNESS WHEREOF, the parties have caused this Supplemental Indenture to be duly executed as of the date first written above.

AQUESTIVE THERAPEUTICS, INC.

By: _____
Name: Keith Kendall
Title: Chief Executive Officer

U.S. BANK NATIONAL ASSOCIATION,
as Trustee

By: _____
Name: Alison D.B. Nadeau
Title: Vice President

U.S. BANK NATIONAL ASSOCIATION,
as Collateral Agent

By: _____
Name: Alison D.B. Nadeau
Title: Vice President

Aquestive Therapeutics Negotiates Six Month Extension to June 30, 2022 for Additional Libervant™ Related Capital Under Current Debt Agreement

- Provides access to $30 million in capital contingent on FDA approval and U.S. market access for Libervant

WARREN, N.J., August 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, announced today that it has reached an agreement with its lenders to amend the base indenture providing an extension of the term by six months to June 30, 2022 to provide additional debt in the aggregate of up to $30.0 million. In line with the extension to June 30, 2022, Aquestive is entitled, at its option, to draw up to $10 million following FDA approval for Libervant, the first orally delivered diazepam product for the management of seizure clusters, and up to an additional $20 million following the FDA grant of U.S. market access for Libervant.

"We continue to believe that our non-invasive and innovative product for refractory epilepsy represents a meaningful improvement in the treatment options available to this patient population and a significant commercial opportunity. We appreciate the continued support from our lenders and their flexibility given the current PDUFA date for Libervant. With this six month extension, we maintain the capital optionality and may access to up to $30 million under our existing debt facility that we can potentially utilize to fund the launch of Libervant, if approved for market access," said Keith Kendall, Chief Executive Officer of Aquestive.

The FDA has accepted for filing the resubmission of the New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") target goal date of December 23, 2021. Aquestive received a Complete Response Letter (CRL) from the FDA in September 2020, completed a Type A meeting with the FDA in November 2020 and received further guidance from the FDA in February 2021. Based upon the Agency's guidance, the submission included additional statistical modeling and supporting analyses of the existing clinical data. The Company continues to believe that no additional clinical studies will be required for FDA approval of Libervant for U.S. market access.

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 Statement

This press release includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, 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™, including our belief that the resubmitted NDA addresses all of the issues raised in the CRL, 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; risk of delays in FDA approval of Libervant 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 in obtaining such approval; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug product candidates 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 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; 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.

Investor Inquiries
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