

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 4, 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 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 2.02 Results of Operations and Financial Condition**

On May 4, 2021, Aquestive Therapeutics, Inc. (the “Company”) issued a press release announcing its reported financial results for the first quarter ended March 31, 2021 and provided an update on recent developments in its business. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and incorporated by reference.

The information in this Item 2.02 (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.

<u>Exhibit Number</u>	<u>Description</u>
<a href="#">99.1</a>	Press Release, dated May 4, 2021, announcing the Company’s reported financial results for the first quarter ended March 31, 2021 and providing an update on recent developments in its business.

**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 4, 2021

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

Name: A. Ernest Toth, Jr.

Title: Interim Chief Financial Officer

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## Aquestive Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

- On track to refile Libervant™ (diazepam) Buccal Film New Drug Application (NDA) by end of second quarter 2021
- Initiated first-in-human Phase 1 pharmacokinetic (PK) study for AQST-109 epinephrine sublingual film candidate
- Sympazan® (clobazam) continues to meet key performance metrics and gain market share
- Hosts conference call at 8:00 a.m. ET on May 5, 2021

Warren, N.J., May 4, 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 reported financial results for the first quarter ended March 31, 2021 and provided an update on recent developments in its business.

“We are focused on continuing to make progress this year in advancing our proprietary products. In response to feedback from the FDA, we are developing additional analyses of the existing clinical data in the NDA for Libervant and expect to refile by the end of the second quarter of 2021. We recently initiated the first-in-human Phase 1 PK study with our second generation epinephrine candidate AQST-109 and anticipate reporting top-line data in the second half of the year,” said Keith Kendall, President and Chief Executive Officer of Aquestive.

### **Libervant™**

Libervant is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for rapid treatment of acute uncontrolled seizures in selected, refractory patients with epilepsy on stable regimens of AEDs who require intermittent use of diazepam to control bouts of increased seizure activity. The Company is developing Libervant as an alternative to more invasive, inconvenient, and difficult to administer device driven products, including a rectal gel, for patients with refractory epilepsy. As a result of these issues, a large portion of the patient population does not receive adequate treatment or foregoes treatment altogether. The Company believes that Libervant, if approved by the FDA for U.S. market access, will enable a larger share of these patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form.

The Company previously received a Complete Response Letter (CRL) from the FDA in September 2020. Since September, Aquestive has engaged with the FDA and developed a plan to address the deficiencies noted in the CRL. Aquestive continues to believe that no additional clinical studies will be required to resubmit the NDA. The Company anticipates a six month review process and PDUFA action date by the end of 2021.

### **Epinephrine**

Aquestive continues to advance its two product candidates, AQST-108 and AQST-109, for the potential treatment of severe allergic reactions, including anaphylaxis, utilizing Aquestive’s PharmFilm® technologies. In late March 2021, Aquestive began a two part Phase 1 PK trial of AQST-109 in Canada and continues to conduct non-clinical modeling analysis of AQST-108 in anticipation of engaging regulators in the second half of 2021 after the readout from both of these activities.

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## **Sympazan®**

Despite the continued limitations on provider in-person interactions caused by the COVID-19 pandemic, the Company's proprietary product Sympazan® (clobazam), an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome, continues to meet key performance metrics. Shipment volume has grown 13% sequentially quarter over quarter and 40% year over year. Sympazan saw continued growth in the prescriber base, with over 30% penetration into the Company's focused group of prescribers, with approximately 80% of those prescribers writing multiple prescriptions.

### **First Quarter 2021 Financials**

Total revenues were \$11.1 million in the first quarter 2021, compared to \$8.8 million in the first quarter 2020. This year-over-year increase reflected higher license and royalty revenue and growth in Sympazan revenue. Aquestive saw net revenue growth in the first quarter 2021, compared to the prior year period, of 56% for Sympazan, the first of its proprietary products to be launched.

Aquestive's net loss for the first quarter 2021 was \$14.7 million, or \$0.41 loss per share. The net loss for the first quarter 2020 was \$16.5 million, or \$0.49 loss per share. The year-over-year change in net loss was driven by higher revenue and reductions in costs and expenses, partly offset by increased interest expense related to the sale of future revenue. This increase in interest expense was due to the accounting associated with the KYNMOBI® monetization transaction which closed on November 3, 2020 and does not represent a cash output or monetary obligation at any time during the life of the transaction.

Adjusted EBITDA loss was \$6.3 million in the first quarter 2021, compared to \$11.2 million in the first quarter of 2020. The year-over-year change in adjusted EBITDA loss was driven by higher revenue and reductions in costs and expenses.

As of March 31, 2021, cash and cash equivalents were \$27.5 million. During the first quarter 2021, Aquestive accessed capital under its "At-The-Market" (ATM) facility resulting in net proceeds of \$9.9 million.

### **2021 Outlook**

Aquestive is maintaining its full year 2021 financial outlook.

The Company expects:

- Total revenues of approximately \$38 million to \$42 million
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
- Non-GAAP adjusted EBITDA loss of approximately \$42 million to \$45 million

### **Tomorrow's Conference Call and Webcast Reminder**

The Company will host a conference call at 8:00 a.m. ET on Wednesday, May 5, 2021. Investors and analysts may participate in the conference call by dialing (866) 417-5886 from the U.S. and (409) 217-8235 internationally, followed by the conference ID: 4455107.

There will also be a simultaneous, live webcast available on the Investors section of the Company's website at <https://investors.aquestive.com/events-and-presentations>. The webcast will be archived for 30 days.

### **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.

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**Non-GAAP Financial Information**

This press release and our webcast earnings call regarding our quarterly financial results contains financial measures that do not comply with U.S. generally accepted accounting principles (GAAP), such as non-GAAP adjusted EBITDA loss, non-GAAP adjusted gross margins, non-GAAP adjusted costs and expenses and other adjusted expense measures, because such measures exclude, as applicable, share-based compensation expense, interest expense, interest expense related to the sale of future revenue, interest income, depreciation, amortization, and income taxes.

Specifically, the Company adjusts net income (loss) for loss on the extinguishment of debt; certain non-cash expenses, including share-based compensation expenses; depreciation and amortization; and interest expense related to the sale of future revenue, interest income and other income (expense), net and income taxes, with a result of adjusted EBITDA loss. Similarly, manufacture and supply expense, research and development expense, and selling, general and administrative expense were adjusted for certain non-cash expenses of share-based compensation expense and depreciation and amortization. Adjusted EBITDA loss and these non-GAAP expense categories are used as a supplement to the corresponding GAAP measures to provide additional insight regarding the Company's ongoing operating performance.

These measures supplement the Company's financial results prepared in accordance with GAAP. Aquestive management uses these measures to analyze its financial results, and its future manufacture and supply expenses, gross margins, research and development expense and selling, general and administrative expense and to help make managerial decisions. In management's opinion, these non-GAAP measures provide added transparency into the operating performance of Aquestive and added insight into the effectiveness of our operating strategies and actions. We may provide one or more revenue measures adjusted for certain discrete items, such as fees collected on certain licensed products, in order to provide investors added insight into our revenue stream and breakdown, along with providing our GAAP revenue. Such measures are intended to supplement, not act as substitutes for, comparable GAAP measures and should not be read as a measure of liquidity for Aquestive. Adjusted EBITDA loss and the other non-GAAP measures are also likely calculated in a way that is not comparable to similarly titled measures reported by other companies.

**Non-GAAP Outlook**

In providing outlook for non-GAAP adjusted EBITDA and non-GAAP gross margin, we exclude certain items which are otherwise included in determining the comparable GAAP financial measures. In order to inform our outlook measures of non-GAAP adjusted EBITDA and non-GAAP gross margin, a description of the 2021 and 2020 adjustments which have been applicable in determining non-GAAP Adjusted EBITDA and non-GAAP gross margin for these periods are reflected in the tables below. In providing outlook for non-GAAP gross margin, we adjust for non-cash share-based compensation expense and depreciation and amortization. We are providing such outlook only on a non-GAAP basis because the Company is unable to predict with reasonable certainty the totality or ultimate outcome or occurrence of these adjustments for the forward-looking period such as share-based compensation expense, income tax, amortization, and certain other adjusted items, which can be dependent on future events that may not be reliably predicted. Based on past reported results, where one or more of these items have been applicable, such excluded items could be material, individually or in the aggregate, to reported results.

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## Forward-Looking Statement

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 clinical advancement and related timing of Libervant, AQST-108 and AQST-109 through the regulatory and development pipeline; the focus on growing the Company’s commercial sales of Sympazan®; 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; the 2021 financial outlook; 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 also 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, AQST-109 and our other drug candidates; risk of delays in regulatory advancement through the FDA of Libervant, AQST-108, AQST-109 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 that a competitor will obtain other market exclusivity with respect to our products; 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 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; risks and uncertainties concerning the royalty and other revenue stream of the KYNMOBI® monetization, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction; risk of failure to satisfy all financial and other debt covenants and of any default; 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 of eroding market share for Suboxone and risk of a sunset 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, securities, 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.carrington@westwicke.com

646-277-1282



**AQUESTIVE THERAPEUTICS, INC.**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share and per share amounts)  
(Unaudited)

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,498	\$ 31,807
Trade and other receivables, net	10,209	6,955
Inventories, net	2,799	2,461
Prepaid expenses and other current assets	3,937	3,402
<b>Total current assets</b>	<b>44,443</b>	<b>44,625</b>
Property and equipment, net	6,279	6,873
Right-of-use assets, net	3,277	3,448
Intangible assets, net	89	102
Other non-current assets	7,835	7,836
<b>Total assets</b>	<b>\$ 61,923</b>	<b>\$ 62,884</b>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 6,687	\$ 7,089
Accrued expenses	6,371	8,569
Lease liabilities, current	787	728
Deferred revenue, current	437	693
Liability related to the sale of future revenue, current	1,905	1,450
Loans payable, current	3,863	2,575
<b>Total current liabilities</b>	<b>20,050</b>	<b>21,104</b>
Loans payable, net	34,193	34,329
Liability related to the sale of future revenue, net	50,383	47,524
Lease liabilities	2,635	2,846
Deferred revenue, net of current portion	4,699	3,633
Other non-current liabilities	1,761	1,945
<b>Total liabilities</b>	<b>113,721</b>	<b>111,381</b>
Stockholders' deficit:		
Common stock, \$.001 par value. Authorized 250,000,000 shares; 36,241,358 and 34,569,254 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	36	35
Additional paid-in capital	149,095	137,725
Accumulated deficit	(200,929)	(186,257)
<b>Total stockholders' deficit</b>	<b>(51,798)</b>	<b>(48,497)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 61,923</b>	<b>\$ 62,884</b>



**AQUESTIVE THERAPEUTICS, INC.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share data amounts)  
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Revenues	\$ 11,122	\$ 8,765
Costs and expenses:		
Manufacture and supply	2,757	3,659
Research and development	3,659	4,354
Selling, general and administrative	13,231	14,613
Total costs and expenses	19,647	22,626
Loss from operations	(8,525)	(13,861)
Other income/(expenses):		
Interest expense	(2,761)	(2,771)
Interest expense related to the sale of future revenue, net	(3,334)	—
Interest income and other income (expense), net	(52)	102
Net loss before income taxes	(14,672)	(16,530)
Income taxes	—	—
Net loss	\$ (14,672)	\$ (16,530)
Comprehensive loss	\$ (14,672)	\$ (16,530)
Net loss per share - basic and diluted	\$ (0.41)	\$ (0.49)
Weighted-average number of common shares outstanding - basic and diluted	35,563,275	33,569,694

**AQUESTIVE THERAPEUTICS, INC.**  
**Reconciliation of Non-GAAP Adjustments - Net Loss to Adjusted EBITDA**  
**(In Thousands)**  
**(Unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2021</b>	<b>2020</b>
GAAP net loss	\$ (14,672)	\$ (16,530)
Share-based Compensation Expense	1,507	1,860
Interest expense	2,761	2,771
Interest expense related to the sale of future revenue, net	3,334	—
Interest income and other income (expense), net	52	(102)
Depreciation and Amortization	755	766
Income Taxes	—	—
Total non-GAAP adjustments	\$ 8,409	\$ 5,295
Adjusted EBITDA	\$ (6,263)	\$ (11,235)

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**AQUESTIVE THERAPEUTICS, INC.**  
**Reconciliation of Non-GAAP Adjustments - GAAP Expenses to Adjusted Expenses**  
(In Thousands)  
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Total costs and expenses	\$ 19,647	\$ 22,626
Non-GAAP adjustments:		
Share-based compensation expense	(1,507)	(1,860)
Depreciation and amortization	(755)	(766)
Adjusted costs and expenses	\$ 17,385	\$ 20,000

**AQUESTIVE THERAPEUTICS, INC.**  
**Reconciliation of Non-GAAP Adjustments - GAAP Manufacture & Supply Expense to Adjusted Manufacture and Supply Expense**  
(In Thousands, except percentages)  
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Manufacture and Supply Expense	\$ 2,757	\$ 3,659
<i>Gross Margin on total revenue</i>	75%	58%
Non-GAAP adjustments:		
Share-based compensation expense	(82)	(63)
Depreciation and amortization	(585)	(627)
Adjusted manufacture and supply expense	\$ 2,090	\$ 2,969
<i>Non-GAAP Gross Margin on total revenue</i>	81%	66%

**AQUESTIVE THERAPEUTICS, INC.****Reconciliation of Non-GAAP Adjustments - GAAP Research and Development Expense to Adjusted Research and Development Expense  
(In Thousands)  
(Unaudited)**

	Three Months Ended March 31,	
	2021	2020
Research and Development Expense	\$ 3,659	\$ 4,354
Non-GAAP adjustments:		
Share-based compensation expense	(232)	(182)
Depreciation and amortization	(57)	(60)
Adjusted research and development expense	<u>\$ 3,370</u>	<u>\$ 4,112</u>

**AQUESTIVE THERAPEUTICS, INC.****Reconciliation of Non-GAAP Adjustments - GAAP Selling, General and Administrative Expenses to Adjusted Selling, General and Administrative Expenses  
(In Thousands)  
(Unaudited)**

	Three Months Ended March 31,	
	2021	2020
Selling, General and Administrative Expenses	\$ 13,231	\$ 14,613
Non-GAAP adjustments:		
Share-based compensation expense	(1,193)	(1,615)
Depreciation and amortization	(113)	(79)
Adjusted selling, general and administrative expenses	<u>\$ 11,925</u>	<u>\$ 12,919</u>

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