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): March 8, 2022

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 2.02 Results of Operations and Financial Condition

On March 8, 2022, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the quarter and fiscal year ended December 31, 2021 and provided an update on recent developments in its business. A copy of the Company's press release and the attached financial schedules are attached as Exhibit 99.1 to this report 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.

Exhibit Number	Description
99.1	Press Release, dated March 8, 2022, announcing the Company's reported financial results for the quarter and fiscal year ended December 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: March 8, 2022

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr
Name: A. Ernest Toth, Jr.
Title: Chief Financial Officer

Exhibit 99.1

Aquestive Therapeutics Reports Full Year 2021 Results Exceeding Revenue and EBITDA Guidance

- Continues to interact with FDA regarding orphan drug review of the NDA for Libervant™ (diazepam) Buccal Film
- Reports start of Part 2 of EPIPHAST crossover study for AQST-109 epinephrine oral film after positive Part 1 data
- Enters license, development and supply agreement for riluzole oral film in China contributing $7 million upfront cash
- Hosts investment community conference call on March 9 at 8:00 am ET

Warren, N.J., March 8, 2022 – Aquestive Therapeutics, Inc. (NASDAQ:AQST), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today reported financial results for the fourth quarter and full year ended December 31, 2021, and provided an update on recent developments in its business.

“2021 was an important year for Aquestive. During the year, we delivered important development, clinical and regulatory milestones as promised, as well as met our financial commitments,” said Keith Kendall, Chief Executive Officer of Aquestive. “The FDA continues to consider the orphan-drug exclusivity implications on the approval of Libervant, as outlined in recent correspondence. We continue to prepare for the launch, if granted market access by the FDA, of this important product for epilepsy patients. We are proud of the progress and clinical performance of our epinephrine oral film AQST-109. We reported positive and exciting topline data in the continuing clinical program for AQST-109. We expect to advance a final commercial configuration of AQST-109 into pivotal studies before the end of 2022. In parallel, our core business continued to contribute new opportunities, cash and a growing Sympazan,” concluded Mr. Kendall.

Libervant™
Libervant™ is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters) that are distinct from a patient’s usual seizure pattern in patients with epilepsy 12 years of age and older. Aquestive developed Libervant as an alternative to the device driven, invasive, inconvenient, and difficult to administer alternatives including a rectal gel and nasal spray products, currently available for patients with refractory epilepsy.

On December 20, 2021, Aquestive received a notification from the FDA that the Agency would not be ready to act by the PDUFA target goal date of December 23, 2021 for the Company’s NDA for Libervant, and was unable to provide an estimate of the timing of an expected action. Subsequently, Aquestive engaged with the Center for Drug Evaluation and Research (CDER) and was informed that CDER had completed its review and no additional information was necessary. Pre-notice requirements, inclusive of labeling negotiations, additional information requests, and the Postmarketing Adverse Drug Experience (PADE) reporting audit, had been completed.

In a correspondence from the FDA on February 15, 2022, the Agency communicated the following regarding Libervant:

- "… the Agency is continuing to consider whether the orphan-drug exclusivity (ODE) identified for another diazepam product in FDA’s publication Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book) affects the approvability of your application."
- "We are continuing to consider the information and arguments submitted by or on behalf of Aquestive, at this time, we cannot provide a specific update regarding timelines or an anticipated action date...."

The Company continues to believe that Libervant provides a major contribution to patient care and it has provided a strong set of facts to the Agency's Office of Orphan Products Development (OOPD) as Libervant has the potential to transform the lives of refractory epilepsy patients seeking a non-invasive and innovative product for the management of seizure clusters.

The Company is actively preparing for a potential favorable outcome. Launch preparations are advancing and Aquestive is building awareness across the epilepsy community inclusive of key opinion leaders, patient advocacy groups and caregivers. Aquestive is prepared to commercially launch Libervant, if approved for U.S. market access, as soon as possible after approval.

Epinephrine
Aquestive is advancing the clinical development of AQST-109, the first and only orally delivered epinephrine product candidate to have shown clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis.

After receiving clearance from Health Canada in December 2021, Aquestive commenced enrollment and dosing in its EPIPHAST study, a randomized, open-label, three-part adaptive design, crossover study. In February 2022, the Company reported topline data from Part 1 of the EPIPHAST study that showed that key pharmacokinetic (PK) measures were aligned with previous favorable results for AQST-109 and that the product was well tolerated with no serious adverse events.

Aquestive has commenced Part 2 of the EPIPHAST study and expects to report topline results in the first half of 2022. Part 2 is a randomized, crossover design comparing AQST-109 12mg to intramuscular injection of epinephrine 0.3mg.

Aquestive received a written response from the FDA in December 2021 to its Pre-Investigational New Drug Application (IND) meeting submission confirming that the development of AQST-109 for the treatment of anaphylaxis under the 505(b)(2) approval pathway is acceptable and AQST-109 has the potential to meet the regulatory criteria for Fast Track designation. Aquestive opened the IND for AQST-109 after receiving FDA clearance in February 2022.

The Company anticipates conducting an end of Phase 2 meeting with the FDA and commencing the pivotal PK study in the second half of 2022.

Licensing, Development and Supply Agreement with Haisco for Exservan ™ (riluzole oral film) for ALS Treatment in China
Effective as of March 3, 2022, Aquestive entered into a License, Development and Supply Agreement with Haisco Pharmaceutical Group Co., Ltd. ("Haisco") for Haisco to develop and exclusively commercialize Exservan™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis (“ALS”) in China. Haisco will lead the regulatory and commercialization activities for Exservan in China. Aquestive will serve as the exclusive sole manufacturer and supplier for the product. Aquestive will receive a $7 million upfront cash payment, regulatory milestone payments, and double-digit royalties on net sales of Exservan in China and will earn manufacturing revenue as the exclusive supplier of Exservan.

Core Business
Aquestive is a commercial stage pharmaceutical company with comprehensive integrated capabilities that enable the advancement of candidates through preclinical and clinical development, and through commercialization. Aquestive has world-class manufacturing capabilities that it has leveraged to produce more than one billion doses of PharmFilm® based products to meet the needs of patients worldwide. The Company's commercialized portfolio consists of five FDA approved products, both proprietary and third party licensed. Aquestive has generated more than ten years of product sales contributing to its cash flow positive business. Aquestive has a valuable intellectual property portfolio with over 200 worldwide patents and more than 75 additional patents pending that offer protection through 2037.

The Company’s proprietary product Sympazan® (clobazam), an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome, has grown for the twelve straight quarters since launch.

Fourth Quarter 2021 Financials
Total revenues were $11.1 million in the fourth quarter 2021, compared to $7.1 million in the fourth quarter 2020, an increase of 55%. Comparing the fourth quarter 2021 to the prior year period, the Company saw a 77% increase in Sympazan net revenue, and a 60% increase in manufacture and supply revenue.

Aquestive’s net loss for the fourth quarter 2021 was $28.9 million, or $0.72 loss per share. The net loss for the fourth quarter 2020 was $20.4 million, or $0.60 loss per share. The change in net loss was primarily driven by a one-time non-cash loss on extinguishment of debt in 2021, partially offset by higher revenue and lower costs and expenses.

During the fourth quarter 2021, Aquestive recognized a one-time, non-cash, accounting loss on the extinguishment of debt of $13.8 million for fees and expenses related to the Fourth Supplemental Indenture that was executed on October 7, 2021. This agreement with the Company's lenders amended the principal amortization schedule to free up over $10 million of capital between the execution and year end 2022, for a $2.7 million fee, payable in four quarterly installments beginning May 15, 2022. This one-time loss on extinguishment of debt had an impact on EPS of $0.34 loss per share in the fourth quarter. Absent this charge, net loss per share would have been $0.38.

Non-GAAP Adjusted EBITDA loss was $9.2 million in the fourth quarter 2021, compared to a $13.0 million loss in the fourth quarter 2020. The change in non-GAAP adjusted EBITDA was primarily driven by a one-time non-cash loss on extinguishment of debt in 2021, a higher net loss, partially offset by a decrease in interest expense due to a lower debt level, a decrease in non-cash interest expense related to the KYNMOBI® royalty monetization transaction, and a decrease in depreciation and amortization.

Full Year 2021 Financials
Total revenues were $50.8 million for the full year 2021, compared to $45.8 million for the full year 2020, an increase of 11%. Total revenue increased 43% year over year after removing the impact of a one-time recognition of royalty and license fee revenue in each year. Comparing the year ended December 31, 2021 to the prior year period, the Company saw a 51% increase

in Sympazan net revenue, despite the continued market access limitations due to COVD-19 and the Omicron variant, and a 42% increase in manufacture and supply revenue.

The Company's net loss for the full year 2021 was $70.5 million, or $1.85 loss per share. The net loss for the full year 2020 was $55.8 million, or $1.66 loss per share. The change in net loss was primarily driven by a one-time non-cash loss on extinguishment of debt in 2021 as previously mentioned, partially offset by higher revenue and lower costs and expenses. Absent this charge, net loss per share would have been $1.49.

Non-GAAP Adjusted EBITDA losses were $24.9 million in the full year 2021, compared to $32.9 million in the full year 2020. The year-over-year change in non-GAAP adjusted EBITDA was primarily driven by a one-time non-cash loss on extinguishment of debt in 2021 and an increase in non-cash interest expense related to the full year impact of the KYNMOBI royalty monetization transaction. This was partially offset by a higher net loss, a decrease in interest expense and a decrease in depreciation and amortization.

The full year impact of the non-cash interest expense related to the sale of future revenue for the KYNMOBI royalty monetization transaction was $12.4 million and the EPS impact was $0.33 loss per share. As a reminder, this accounting does not and will never represent a cash obligation or payment by the Company.

As of December 31, 2021, cash and cash equivalents were $28.0 million. During the fourth quarter 2021, the Company accessed capital net proceeds of $5.2 million under its "At-the-Market" (ATM) facility.

2022 Outlook
Sympazan growth, the continued strong performance of the Company's manufacturing and supply operations, and its other on-going business activities are expected to provide strong operating results during 2022. Spending on R&D is expected to accelerate as the Company continues development of AQST-109 during 2022.

Aquestive is providing its full year 2022 financial outlook.

The Company expects:

- Total revenues of approximately $42 to $47 million
- Non-GAAP adjusted gross margin of approximately 70% to 75%
- Non-GAAP adjusted EBITDA loss of approximately $51 to $58 million

Aquestive expects that its existing cash and cash equivalents, revenue from on-going manufacturing operations and commercialized products, continuing business development activities and prudent expense management actions, combined with ATM activity, will provide adequate funds and meet expected cash requirements for the next twelve months. While the Company has not been accessing the ATM recently, it remains an important tool to support the capital needs of the Company. Separately, the Company expects the potential launch of Libervant, if granted U.S. market access by the FDA, to be funded by the additional $30 million of contingent funds available as part of the existing 12.5% Notes.

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Wednesday, March 9, 2022. 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: 4878955.

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, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome. Our licensees market their products in the U.S. and around the world. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product pipeline focused on treating diseases of the central nervous system, or CNS, and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit Aquestive.com and follow us on LinkedIn.

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 loss 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 loss and non-GAAP gross margin, a description of the 2020 and 2021 adjustments which have been applicable in determining non-GAAP Adjusted EBITDA loss 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.

Forward-Looking Statement
Certain statements in this press release include "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 and related timing of Libervant® (diazepam) Buccal Film and AQST-109 (epinephrine) oral film through the regulatory and development pipeline; the focus on growing the Company's commercial sales of Sympazan® (clobazam) oral film and continuing to manufacture licensed products; ability to obtain FDA approval of Libervant for U.S. market access; clinical trial timing and plans for AQST-109; the 2022 financial outlook; and clinical 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 for AQST-109 and our other product candidates; risk of delays in FDA approval of Libervant, AQST-109, and our other drug candidates or failure to receive FDA 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 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 liquidity and cash requirements and other cash needs, at the times and in the amounts needed; 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 and associated costs, 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. 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.

Investor inquiries:

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

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 28,024	$ 31,807
Trade and other receivables, net	12,120	6,955
Inventories, net	4,038	2,461
Prepaid expenses and other current assets	3,077	3,402
Total current assets	47,259	44,625
Property and equipment, net	5,055	6,873
Right-of-use assets, net	2,725	3,448
Intangible assets, net	51	102
Other non-current assets	6,903	7,836
Total assets	$ 61,993	$ 62,884
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 8,314	$ 7,089
Accrued expenses	8,736	8,569
Lease liabilities, current	899	728
Deferred revenue	765	693
Liability related to the sale of future revenue, current	1,225	1,450
Loans payable, current	2,025	2,575
Total current liabilities	21,964	21,104
Loans payable, net	51,551	34,329
Liability related to the sale of future revenue, net	59,059	47,524
Lease liabilities	1,946	2,846
Deferred revenue, net of current portion	7,122	3,633
Other non-current liabilities	2,485	1,945
Total liabilities	144,127	111,381
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 41,228,736 and 34,569,254 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	41	35
Additional paid-in capital	174,621	137,725
Accumulated deficit	(256,796)	(186,257)
Total stockholders' deficit	(82,134)	(48,497)
Total liabilities and stockholders' deficit	$ 61,993	$ 62,884

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenues	$ 11,078	$ 7,149	$ 50,832	$ 45,849
Costs and expenses:				
Manufacture and supply	3,366	2,788	14,989	12,964
Research and development	4,400	4,425	17,047	19,886
Selling, general and administrative	14,981	15,582	53,475	55,892
Total costs and expenses	22,747	22,795	85,511	88,742
Loss from operations	(11,669)	(15,646)	(34,679)	(42,893)
Other income (expenses):				
Interest expense	(1,744)	(2,768)	(10,049)	(11,064)
Interest expense related to the sale of future revenue	(1,845)	(1,958)	(12,412)	(1,958)
Interest income and other income, net	135	4	423	132
Loss on the extinguishment of debt	(13,822)	—	(13,822)	—
Net loss before income taxes	(28,945)	(20,368)	(70,539)	(55,783)
Income taxes	—	—	—	—
Net loss	$ (28,945)	$ (20,368)	$ (70,539)	$ (55,783)
Comprehensive loss	$ (28,945)	$ (20,368)	$ (70,539)	$ (55,783)
Net loss per share – basic and diluted	$ (0.72)	$ (0.60)	$ (1.85)	$ (1.66)
Weighted-average number of common shares outstanding - basic and diluted	40,391,538	33,821,508	38,077,660	33,651,127

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Net loss	$ (28,945)	$ (20,368)	$ (70,539)	$ (55,783)
Share-based compensation expense	1,691	1,529	6,819	6,581
Interest expense	1,744	2,768	10,049	11,064
Interest expense related to the sale of future revenue	1,845	1,958	12,412	1,958
Interest income and other income (expense), net	(135)	(4)	(423)	(132)
Income taxes	—	—	—	—
Depreciation, amortization, and impairment	731	1,157	2,964	3,443
Loss on extinguishment of debt	13,822	—	13,822	—
Total non-GAAP adjustments	$ 19,698	$ 7,408	$ 45,643	$ 22,914
Adjusted EBITDA	$ (9,247)	$ (12,960)	$ (24,896)	$ (32,869)

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Total costs and expenses	$ 22,747	$ 22,795	$ 85,511	$ 88,742
Non-GAAP adjustments:				
Share-based compensation expense	(1,691)	(1,529)	(6,819)	(6,581)
Depreciation, amortization, and impairment	(731)	(1,157)	(2,964)	(3,443)
Adjusted costs and expenses	$ 20,325	$ 20,109	$ 75,728	$ 78,718

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Manufacture and supply expense	$ 3,366	$ 2,788	$ 14,989	$ 12,964
Gross Margin on total revenue	*70 %*	*61 %*	*71 %*	*72 %*
Non-GAAP adjustments:				
Share-based compensation expense	(72)	(67)	(313)	(275)
Depreciation, amortization, and impairment	(580)	(503)	(2,324)	(2,374)
Adjusted manufacture and supply expense	$ 2,714	$ 2,218	$ 12,352	$ 10,315
Non-GAAP Gross Margin on total revenue	*76 %*	*69 %*	*76 %*	*78 %*

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Research and development expense	$ 4,400	$ 4,425	$ 17,047	$ 19,886
Non-GAAP adjustments:				
Share-based compensation expense	(211)	(186)	(881)	(729)
Depreciation, amortization, and impairment	(48)	(46)	(208)	(225)
Adjusted research and development expense	$ 4,141	$ 4,193	$ 15,958	$ 18,932

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Selling, general and administrative expenses	$ 14,981	$ 15,582	$ 53,475	$ 55,892
Non-GAAP adjustments:				
Share-based compensation expense	(1,408)	(1,276)	(5,625)	(5,577)
Depreciation, amortization, and impairment	(103)	(607)	(432)	(843)
Adjusted selling, general and administrative expenses	$ 13,470	$ 13,699	$ 47,418	$ 49,472