

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 9, 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 March 9, 2021, Aquestive Therapeutics, Inc. (the “Company”) issued a press release announcing its reported financial results for the quarter and fiscal year ended December 31, 2020 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
<a href="#">99.1</a>	Press Release, dated March 9, 2021, announcing the Company’s reported financial results for the quarter and fiscal year ended December 31, 2020 and provided 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 9, 2021

Aquestive Therapeutics, Inc.

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

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Name: A. Ernest Toth, Jr.

Title: Interim Chief Financial Officer

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## Aquestive Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

- Libervant™ (diazepam) Buccal Film New Drug Application (NDA) resubmission expected end of second quarter 2021
- Epinephrine program and development strategy to be highlighted at a virtual investor event to be held at 9:00 a.m. ET on March 25, 2021
- Entered U.S. licensing and supply agreement for Riluzole Oral Film for treatment of ALS with Mitsubishi Tanabe Pharma America
- Sympazan® (clobazam) continues to meet key performance metrics
- Management to host conference call and webcast at 8:00 a.m. ET on March 10, 2021

Warren, N.J., March 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 reported financial results for the fourth quarter and full year ended December 31, 2020 and provided an update on recent developments in its business.

“2020 was an important year for Aquestive and we are pleased with the progress we made during the year. We made exciting progress relating to our epinephrine program and most recently we now have a clear path to resubmission of our NDA for Libervant. Additionally, we licensed additional products based on our differentiated PharmFilm® technology. We more than doubled the size of Sympazan and the prescriber base that will be so important to Libervant once approved and launched,” said Keith Kendall, President and Chief Executive Officer of Aquestive.

“We are focused on value creation in 2021 by resubmitting Libervant and, if approved, launching later in the year. Additionally, we will be very focused on advancing our epinephrine program through additional studies and ultimately discussing the program with the FDA,” continued Mr. Kendall.

### **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. We are developing Libervant as an alternative to the device driven, invasive, inconvenient, and difficult to administer alternatives including a rectal gel, currently available for patients with refractory epilepsy. As a result of the issues many patients have regarding the current products in the market, 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 US 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. At a Type A meeting with the FDA held on November 12, 2020, the FDA confirmed that the issues identified in the Complete Response Letter (CRL) received by the Company related to the NDA for Libervant may be addressed by utilizing modeling and simulations based upon the information provided by Aquestive in its FDA meeting package submitted in October 2020. Following the Type A meeting, the Company resubmitted a revised weight-based dosing regimen along with modeling and simulations in December 2020. As recently announced, the FDA provided feedback on the December submission which provided clarity regarding the information that the Agency expected to see in the Company's population pharmacokinetic model and safety data as it relates specifically to the patient population included in the studies. The Company will be working on the NDA to provide a resubmission in a form that the Company believes will be acceptable to the FDA. Based upon the FDA's feedback at the Type A meeting and further guidance from the Agency, the Company continues to believe that no further clinical studies are necessary and that the Company will be able to address the identified issues with additional analytical data that already exists. The Company expects to resubmit its NDA at the end of the second quarter of 2021. Once the NDA is resubmitted, the Company anticipates a six month review process.

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## **Epinephrine**

Aquestive has scheduled a virtual investor event on March 25, 2021 at 9 am ET to review the Company's epinephrine program. At this event, the Company plans to review the data from the two completed Phase 1 PK trials, the breadth of its epinephrine pipeline, and the design of its upcoming Phase 1 PK trial. Utilizing Aquestive's PharmFilm® technologies, AQST-108-Sublingual Film (SF) is a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis. The Company received Fast Track Designation from the FDA for AQST-108-SF, and recently submitted a dossier to Health Canada for a third Phase 1 PK trial. The Company plans on commencing the study, to move towards final formulation and dose, as soon we receive the necessary documentation.

## **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 6% sequentially quarter over quarter and by 59% over the same period last year. Sympazan net revenue grew 132% for the three-month period ended December 31, 2020 versus the same period last year, and 97% for the twelve month period ended December 31, 2020 versus the same period last year.

## **Mitsubishi Tanabe Pharma America Exservan (riluzole) License**

Aquestive entered into a licensing and supply agreement with Mitsubishi Tanabe Pharma America, Inc. (MTPA) for the U.S. rights to commercialize EXSERVAN™ (riluzole), an oral film formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS). Pursuant to the agreement, MTPA will commercialize EXSERVAN in the U.S. Aquestive will serve as the exclusive sole manufacturer and supplier for the product. MTPA plans to make EXSERVAN available to patients in the middle of 2021. The Company now has licensed Exservan in both the U.S. and Europe.

## **Additions to Management Team and Board of Directors**

Aquestive has strengthened its management team and Board of Directors. Ernie Toth was appointed interim Chief Financial Officer in December 2020. Mr. Toth is a seasoned financial executive with over two decades of senior financial leadership at ArisGlobal, Synowledge, and JHP Pharmaceuticals, and most recently with EHE Health. Mark Lepore, M.D., was appointed as the Chief Medical Officer for Allergy in January 2021. Dr. Lepore is a board-certified allergist and pediatrician and has over fourteen years of drug development experience with prior roles at Lupin Pharmaceuticals and Teva Pharmaceuticals. Julie Krop, M.D., Chief Medical Officer of Freeline Therapeutics, and Marco Taglietti, M.D., Director, President and Chief Executive Officer of SCYNEXIS, were appointed as independent directors to the Board in February 2021.

## **Fourth Quarter 2020 Financials**

Total revenues were \$7.1 million in the fourth quarter 2020, compared to \$16.4 million in the fourth quarter 2019. This year-over-year decrease reflected lower Suboxone manufacture and supply revenue, as well as lower license and royalty revenue, offset partially by growth in Sympazan revenue.

Aquestive's net loss for the fourth quarter 2020 was \$20.4 million, or \$0.60 loss per share. The net loss for the fourth quarter 2019 was \$12.6 million, or \$0.48 loss per share. The change in net loss was driven by lower revenue and offset by reductions in costs and expenses, primarily in manufacture and supply expense reflecting the lower volume of production in the fourth quarter 2020, compared to the fourth quarter 2019.

Adjusted EBITDA loss was \$13.0 million in the fourth quarter 2020, compared to \$7.3 million of losses in the comparable prior period. The year-over-year change in adjusted EBITDA loss was driven primarily by lower revenue partially offset by reductions in costs and expenses, primarily in manufacture and supply expenses, in the fourth quarter 2020, compared to the fourth quarter 2019.

## **Full Year 2020 Financials**

Total revenues were \$45.8 million for the full year 2020, compared to \$52.6 million for the full year 2019. This year-over-year change came primarily from lower Suboxone manufacture and supply revenue and co-development and research fees offset in part by higher license and royalty revenue and proprietary product revenue, net.

The Company's net loss for the full year 2020 was \$55.8 million, or \$1.66 loss per share. The net loss for the full year 2019 was \$66.2 million, or \$2.61 loss per share.

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Adjusted EBITDA losses were \$32.9 million in the full year 2020, compared to \$42.7 million in the full year 2019. The change in adjusted EBITDA loss was driven by lower revenues and a reduction in manufacture and supply costs attributable to lower volumes of Suboxone production in 2020, higher investments in the commercial launch of Sympazan, and increased intellectual property expenses in 2019 related to the launches of multiple generic products in competition with Suboxone, partially offset by the timing of research and development expenses.

As of December 31, 2020, cash and cash equivalents were \$31.8 million. During the fourth quarter 2020, the Company accessed capital net proceeds of \$6.1 million under its "At-the Market" (ATM) facility.

## **2021 Outlook**

Aquestive is providing 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

Aquestive anticipates that the net cash provided by the KYNMOBI® monetization, the cash position, ATM activity to date, and expense management efforts will provide the Company with 12 months or more of capital, with additional options for capital, when needed. As previously stated, those options include up to \$30 million of additional capital available, subject to FDA approval of Libervant and U.S. market access, under its existing senior debt facility.

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

The Company will host a conference call at 8:00 a.m. ET on Wednesday, March 10, 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: 7828506.

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.

## **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.

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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 2019 and 2020 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 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 and related timing of Libervant and AQST-108-SF through the regulatory and development pipeline; the focus on growing the Company's commercial sales of Sympazan® and continuing to manufacture Suboxone® and other licensed products; 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; clinical trial timing and plans for AQST-108-SF; 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-SF and our other drug candidates; risk of delays in regulatory advancement through the FDA of Libervant and AQST-108-SF 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); 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 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, 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.

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PharmFilm<sup>®</sup>, Sympazan<sup>®</sup>, 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:

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

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 31,807	\$ 49,326
Trade and other receivables, net	6,955	13,130
Inventories, net	2,461	2,859
Prepaid expenses and other current assets	3,402	2,999
<b>Total current assets</b>	<b>44,625</b>	<b>68,314</b>
Property and equipment, net	6,873	9,726
Right-of-use assets, net	3,448	—
Intangible assets, net	102	153
Other non-current assets	7,836	286
<b>Total assets</b>	<b>\$ 62,884</b>	<b>\$ 78,479</b>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 7,089	\$ 12,274
Accrued expenses	8,569	5,475
Lease liabilities, current	728	—
Deferred revenue	693	806
Liability related to the sale of future revenue, current	1,450	—
Loans payable, current	2,575	—
<b>Total current liabilities</b>	<b>21,104</b>	<b>18,555</b>
Loans payable, net	34,329	60,338
Liability related to the sale of future revenue, net	47,524	—
Lease liabilities	2,846	—
Deferred revenue, net of current portion	3,633	4,348
Other non-current liabilities	1,945	1,360
<b>Total liabilities</b>	<b>111,381</b>	<b>84,601</b>
Contingencies (note 20)		
Stockholders' deficit:		
Common stock, \$0.001 par value. Authorized 250,000,000 shares; 34,569,254 and 33,562,885 shares issued and outstanding at December 31 2020 and 2019, respectively	35	34
Additional paid-in capital	137,725	124,318
Accumulated deficit	(186,257)	(130,474)
<b>Total stockholders' deficit</b>	<b>(48,497)</b>	<b>(6,122)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 62,884</b>	<b>\$ 78,479</b>

**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,	
	2020	2019	2020	2019
Revenues	\$ 7,149	\$ 16,419	\$ 45,849	\$ 52,609
Costs and expenses:				
Manufacture and supply	2,788	6,792	12,964	20,361
Research and development	4,425	3,057	19,886	20,574
Selling, general and administrative	15,582	16,474	55,892	64,342
Total costs and expenses	22,795	26,323	88,742	105,277
Loss from operations	(15,646)	(9,904)	(42,893)	(52,668)
Other income (expenses):				
Interest expense	(2,768)	(2,803)	(11,064)	(9,318)
Interest expense related to the sale of future revenue	(1,958)	—	(1,958)	—
Interest income and other income (expense), net	4	71	132	636
Loss on the extinguishment of debt	—	—	—	(4,896)
Net loss before income taxes	(20,368)	(12,636)	(55,783)	(66,246)
Income taxes	—	—	—	—
Net loss	\$ (20,368)	\$ (12,636)	\$ (55,783)	\$ (66,246)
Comprehensive loss	\$ (20,368)	\$ (12,636)	\$ (55,783)	\$ (66,246)
Net loss per share – basic and diluted	\$ (0.60)	\$ (0.48)	\$ (1.66)	\$ (2.61)
Weighted-average number of common shares outstanding - basic and diluted	33,821,508	26,435,840	33,651,127	25,356,098

**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,	
	2020	2019	2020	2019
Net loss	\$ (20,368)	\$ (12,636)	\$ (55,783)	\$ (66,246)
Share-based compensation expense	1,529	1,873	6,581	7,071
Interest expense	2,768	2,803	11,064	9,318
Interest expense related to the sale of future revenue	1,958	—	1,958	—
Interest income and other income (expense), net	(4)	(71)	(132)	(636)
Income taxes	—	—	—	—
Depreciation and amortization	1,157	723	3,443	2,905
Loss on extinguishment of debt	—	—	—	4,896
Total non-GAAP adjustments	<u>\$ 7,408</u>	<u>\$ 5,328</u>	<u>\$ 22,914</u>	<u>\$ 23,554</u>
Adjusted EBITDA	<u>\$ (12,960)</u>	<u>\$ (7,308)</u>	<u>\$ (32,869)</u>	<u>\$ (42,692)</u>

**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,	
	2020	2019	2020	2019
Total costs and expenses	\$ 22,795	\$ 26,323	\$ 88,742	\$ 105,277
Non-GAAP adjustments:				
Share-based compensation expense	(1,529)	(1,873)	(6,581)	(7,071)
Depreciation and amortization	(1,157)	(723)	(3,443)	(2,905)
Adjusted costs and expenses	<u>\$ 20,109</u>	<u>\$ 23,727</u>	<u>\$ 78,718</u>	<u>\$ 95,301</u>

**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,	
	2020	2019	2020	2019
Manufacture and supply expense	\$ 2,788	\$ 6,792	\$ 12,964	\$ 20,361
<i>Gross Margin on total revenue</i>	61%	59%	72%	61%
Non-GAAP adjustments:				
Share-based compensation expense	(67)	(50)	(275)	(231)
Depreciation and amortization	(503)	(585)	(2,374)	(2,350)
Adjusted manufacture and supply expense	<u>\$ 2,218</u>	<u>\$ 6,157</u>	<u>\$ 10,315</u>	<u>\$ 17,780</u>
<i>Non-GAAP Gross Margin on total revenue</i>	<u>69%</u>	<u>63%</u>	<u>78%</u>	<u>66%</u>

**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,	
	2020	2019	2020	2019
Research and development expense	\$ 4,425	\$ 3,057	\$ 19,886	\$ 20,574
Non-GAAP adjustments:				
Share-based compensation expense	(186)	(185)	(729)	(720)
Depreciation and amortization	(46)	(65)	(225)	(265)
Adjusted research and development expense	<u>\$ 4,193</u>	<u>\$ 2,807</u>	<u>\$ 18,932</u>	<u>\$ 19,589</u>

**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,	
	2020	2019	2020	2019
Selling, general and administrative expenses	\$ 15,582	\$ 16,474	\$ 55,892	\$ 64,342
Non-GAAP adjustments:				
Share-based compensation expense	(1,276)	(1,632)	(5,577)	(6,120)
Depreciation and amortization	(607)	(73)	(843)	(290)
Adjusted selling, general and administrative expenses	<u>\$ 13,699</u>	<u>\$ 14,769</u>	<u>\$ 49,472</u>	<u>\$ 57,932</u>

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