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 11, 2020

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 11, 2020, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 2019. A copy of such press release and the attached financial schedules are attached as Exhibit 99.1 to this report and incorporated into this Item 2.02 by reference.

The information in this Item 2.02 (including Exhibit 99.1) is being furnished pursuant to Item 2.02 and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, 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 11, 2020, announcing the financial results for the quarter and fiscal year ended December 31, 2019.

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 11, 2020

Aquestive Therapeutics, Inc.

By: /s/ John T. Maxwell
Name: John T. Maxwell
Title: Chief Financial Officer

Exhibit 99.1

Aquestive Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Business Highlights

- Expects to submit IND application for AQST-108 (epinephrine) in second quarter 2020 and commence pharmacokinetics (PK) clinical trials before end of 2020
- FDA sets Libervant™ (diazepam) Buccal Film PDUFA goal date of September 27, 2020
- Reported full year 2019 revenues and adjusted EBITDA that exceeded the top end of guidance range
- Confirms full year 2020 revenue guidance and updates for improved earnings and reduced cash burn
- Hosts investment community conference call at 8:00 am ET on March 12, 2020

Warren, N.J., March 11, 2020 – 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 audited financial results for the fourth quarter and full year ended December 31, 2019 and provided an update on recent developments in its business.

Keith J. Kendall, Chief Executive Officer of Aquestive, stated, "Significant advancements have been made across our portfolio in 2019 and during the first two months of 2020. We had a constructive pre-IND meeting with the FDA in February 2020 for AQST-108, our "first of its kind" oral sublingual PharmFilm® formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis. Preparations are now underway to file the IND for AQST-108 during the second quarter 2020 and commence PK trials by year end. The ability to pursue a 505(b)(2) regulatory approval pathway for this drug candidate will potentially streamline the development and regulatory process from both a timeline and cost standpoint. If approved, AQST-108, as the first highly portable, easy-to-administer and anxiety-free oral sublingual film medication, is positioned to provide an innovative and transformative treatment for the underserved anaphylaxis patient population for whom the current standard of care is an invasive injection."

"Following the FDA's acceptance of our NDA in February, our drug candidate, Libervant™ (diazepam) Buccal Film, the first oral diazepam-based therapy for management of seizure clusters, is advancing through the FDA review process and has been assigned a September 27, 2020 PDUFA goal date. We believe that Libervant, if approved by the FDA, will potentially provide a major contribution to patient care to epilepsy patients who can benefit from another rescue medication. We look forward to working with the FDA in the coming months in seeking to demonstrate that Libervant, as the only orally delivered diazepam-based product for this indication, has one or more of the attributes required by the FDA to be considered a "major contribution to patient care," within the meaning of FDA regulations and guidance, relative to the currently approved products. Although FDA approval of Libervant cannot be assured, we remain committed to helping epilepsy patients affected by seizure clusters by working to bring important innovative products to the market."

Mr. Kendall concluded, "As we focus on these two important programs we also continue to manage our costs and streamline our business operations. We have reflected those efforts on our updated guidance. Based on our planning and expectations, we anticipate that we will have the cash resources to take us through early 2021 and, with the expected monetization of our apomorphine royalty stream, subject to that product being approved by the FDA, the Company expects to extend that horizon further."

Proprietary Pipeline Overview and Business Update

Aquestive is building a portfolio of differentiated medicines that can offer physicians and patients, who have difficulty using currently available treatment options, improved clinical and usability features based on the Company's PharmFilm® technology. The Company's proprietary products and late-stage product candidates are initially focused on CNS conditions and other patient populations with high unmet need.

- At the constructive face-to-face meeting in February 2020 with the U.S. Food and Drug Administration (FDA) prior to filing Aquestive's Investigational New Drug (IND) application for AQST-108, the FDA confirmed that the drug candidate will be reviewed under the 505(b)(2) regulatory approval pathway, and that no additional studies will be necessary prior to opening the proposed IND application. Aquestive is currently preparing the IND application, which is expected to be submitted in the second quarter 2020 and plans to commence PK clinical trials before year end.

- Following the FDA's acceptance of the New Drug Application (NDA) for Aquestive's drug candidate, Libervant™ (diazepam) Buccal Film for the management of seizure clusters, the FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of September 27, 2020. Aquestive believes that Libervant will, if approved by the FDA, represent a "major contribution to patient care", as compared to available treatment options, and further expand patient choice as the first orally delivered diazepam-based product available to manage seizure clusters in epilepsy patients. See an explanation of the FDA's determination of "major contribution to patient care" and its grant of seven-year orphan drug exclusivity for a competing product in the section below in this press release entitled "Additional Information Regarding Orphan Drug Exclusivity".

- Sympazan® (clobazam), an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and launched as a precursor and complement to Libervant, continues to exhibit progress on key performance metrics including prescriber growth, repeat prescribers, quarterly growth in retail shipments, and covered lives.

Fourth Quarter 2019 Financials

Total revenues were $16.4 million in the fourth quarter 2019, compared to $16.8 million in the fourth quarter 2018. This year-over-year decrease reflected lower license fees offset by higher manufacturing and supply revenue from higher volume and price on licensee products.

Aquestive's net loss for the fourth quarter 2019 was $12.6 million, or $0.48 loss per share. The net loss for the fourth quarter 2018 was $13.9 million, or $0.56 loss per share.

Losses before interest, taxes, depreciation and amortization, share-based compensation and other adjustments (adjusted EBITDA losses) were $7.3 million in the fourth quarter of 2019, compared to $10.2 million in the comparable prior period. The year-over-year change in adjusted EBITDA loss was driven primarily by lower research and development and selling, general and administrative expenses, offset partially by higher manufacturing and supply expenses from higher volume on licensee products.

Full Year 2019 Financials
Total revenues were $52.6 million, exceeding the top end of the Company's guidance range, for the full year 2019, compared to $67.4 million for the full year 2018. This year-over-year change came primarily from differences in the magnitude and timing of license and royalty revenue, as well as co-development and research fees.

The Company's net loss for the full year 2019 was $66.2 million, or $2.61 loss per share. The net loss for the full year 2018 was $61.4 million, or $2.96 loss per share.

Adjusted EBITDA losses were $42.7 million in the full year 2019, better than previously guided, compared to $15.8 million in the full year 2018. The change in adjusted EBITDA loss was driven by lower revenues, higher investments in the commercial launch of Sympazan, increased intellectual property expenses in 2019 related to the generic launch and full-year public company costs, partially offset by the timing of research and development expenses.

As of December 31, 2019, cash and cash equivalents were $49.3 million. In December 2019, the Company completed a public offering of 8,050,000 shares of common stock for net proceeds of $37.3 million.

2020 Outlook
Aquestive's full year 2020 financial outlook is as follows. The Company expects:

- Total revenues of approximately $35 million to $45 million
  - Expected revenue from Suboxone® includes branded only, as authorized generic products were discontinued in 2019; branded Suboxone ended 2019 with a 48% film market share and is expected to continue to erode
  - Expected revenues from Sympazan® net sales, co-development programs, and license fees and royalties from licensed products
  - We did not include any Libervant revenues in our 2020 guidance.
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
  - Reflective of the anticipated higher profitability of Suboxone manufacturing revenues and expected greater mix of higher margin proprietary revenue
- Non-GAAP adjusted EBITDA loss of approximately $45 million to $50 million
  - The Company expects to reduce its expenses and to improve adjusted EBITDA losses from previous guidance for 2020 by limiting its near-term focus to Libervant and AQST-108, and managing costs to reflect the declining revenue of Suboxone and the level of contribution of Sympazan
- Cash burn of approximately $45 million to $50 million after considering revised adjusted EBITDA loss guidance, interest, capital spending and working capital effects, but prior to any additional capital transactions

Tomorrow's Conference Call and Webcast Reminder
The management team will host an investment community conference call tomorrow, March 12, 2020, at 8:00 a.m. ET. 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: 3961108.

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. Aquestive is advancing proprietary products and late-stage product candidates to treat CNS conditions and 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 Adjusted EBITDA, non-GAAP gross margins, non-GAAP costs and expenses and other adjusted expense measures, because such measures exclude, as applicable, share-based compensation, interest expense, interest income, depreciation, amortization, income taxes and change in fair value of warrants.

Specifically, the Company adjusts net income (loss) for change in fair value of warrants; loss on the extinguishment of debt; recurring non-cash expenditures, including share-based compensation expenses; depreciation and amortization; and interest expense, interest income and income taxes, with a result of Adjusted EBITDA. Similarly, manufacturing and supply expense, research and development expense, and selling, general and administrative expense were adjusted for the recurring non-cash expenditures of share-based compensation expense and depreciation and amortization. Adjusted EBITDA 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, its future manufacturing 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 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 2018 and 2019 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.

Forward-Looking Statement

This press release includes 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 may include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of AQST-108, Libervant and our other product candidates; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; statements about our growth and future financial and operating results and financial position, regulatory approval and pathways, clinical trial timing and plans, 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, business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company’s development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans; risk of delays in FDA approval of Libervant 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 FDA regulations of our drug candidate Libervant relative to the FDA-approved alternative 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, to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S., and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); 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; 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; risks 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 coronavirus and potential impact on global businesses as well as clinical trials, sourcing, regulatory approval and commercialization of our products and product candidates; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risk 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 action affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company’s products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in governmental 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 risks and uncertainties affecting the Company including those described in the “Risk Factors” section and in other sections included in the Company’s Annual Report on Form 10-K filed with the SEC, in our quarterly reports on Form 10-Q, and in the Form 8-K filed on January 13, 2020. Given these 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.

Additional Information Regarding Orphan Drug Exclusivity

In a recent decision, the FDA's Center for Drug Evaluation and Research granted marketing exclusivity for seven years to Valtoco®, a drug approved for the labeled indication of acute treatment of intermittent stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy six years of age and older. Although we cannot be assured of the FDA's approval of Libervant or finding that Libervant represents a "major contribution to patient care" to overcome this market exclusivity, Aquestive remains committed to helping people affected by seizure clusters and acute repetitive seizures by looking to bring important innovative products to the market that will improve the lives of patients. In the FDA's response to the Company's Citizen's Petition dated November 1, 2019, the FDA outlined the pertinent factors that may be considered by the FDA, under appropriate circumstances, in making a determination of "major contribution to patient care" for "clinical superiority" as: convenient treatment location; duration of treatment; patient comfort; reduced treatment burden; advances in ease and comfort of drug administration; longer periods between doses; and potential for self-administration. The FDA also discussed in the Citizen's Petition the relevant law regarding a determination of "clinically superior" as follows:

"Section 527 of the [Federal Food, Drug, and Cosmetic Act] defines "clinically superior" to mean "the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care." The orphan-drug regulations elaborate on the definition of "clinically superior" as follows:

Clinically superior means that a drug is shown to provide a significant therapeutic advantage over and above that provided by an approved drug (that is otherwise the same drug) in one or more of the following ways:

> Greater effectiveness than an approved drug (as assessed by effect on a clinically meaningful endpoint in adequate and well controlled clinical trials). Generally, this would represent the same kind of evidence needed to support a comparative effectiveness claim for two different drugs; in most cases, direct comparative clinical trials would be necessary; or
>
> Greater safety in a substantial portion of the target populations, for example, by the elimination of an ingredient or contaminant that is associated with relatively frequent adverse effects. In some cases, direct comparative clinical trials will be necessary; or
>
> In unusual cases, where neither greater safety nor greater effectiveness has been shown, a demonstration that the drug otherwise makes a major contribution to patient care.

Because of the diverse ways in which drugs may qualify as clinically superior under these criteria, FDA evaluates clinical superiority on a case by case basis. Specifically, with respect to the major contribution to patient care prong of the clinical superiority definition, the FDA has further stated:

> There is no way to quantify such superiority in a general way. The amount and kind of superiority needed would vary depending on many factors, including the nature and severity of the disease or condition, the quality of the evidence presented, and diverse other factors;
>
> and
>
> The following factors, when applicable to severe or life-threatening diseases, may in appropriate cases be taken into consideration when determining whether a drug makes a major contribution to patient care: convenient treatment location; duration of treatment; patient comfort; reduced treatment burden; advances in ease and comfort of drug administration; longer periods between doses; and potential for self-administration."

SYMPAZAN IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

CONTRAINDICATIONS

SYMPAZAN is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions.

WARNINGS AND PRECAUTIONS

Potentiation of Sedation from Concomitant Use with Central Nervous System (CNS) Depressants

SYMPAZAN has a CNS depressant effect. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol as the effects of other CNS depressants or alcohol may be potentiated.

Somnolence or Sedation
SYMPAZAN causes dose-related somnolence and sedation, which generally begins within the first month of treatment and may diminish with continued treatment. Monitor patients for somnolence and sedation, particularly with concomitant use of other CNS depressants. Caution patients against engaging in hazardous activities requiring mental alertness, i.e., operating dangerous machinery or motor vehicles, until the effect of SYMPAZAN is known.

Withdrawal Symptoms
Abrupt discontinuation of SYMPAZAN should be avoided. The risk of withdrawal symptoms is greater with higher doses. Withdraw SYMPAZAN gradually to minimize the risk of precipitating seizures, seizure exacerbation, or status epilepticus.

Serious Dermatological Reactions
Serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with clobazam in both children and adults. Discontinue SYMPAZAN at the first sign of rash, unless the rash is clearly not drug-related.

Physical and Psychological Dependence
Patients with a history of substance abuse should be under careful surveillance when receiving SYMPAZAN.

Suicidal Behavior and Ideation
AEDs, including SYMPAZAN, increase the risk of suicidal thoughts or behavior in patients. Patients treated with SYMPAZAN should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Inform patients, their caregivers, and families of the increased risk of suicidal thoughts and behaviors. Advise them to be alert for and report immediately to healthcare providers any emergence or worsening signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm.

ADVERSE REACTIONS
Adverse reactions (≥10% and more frequently than placebo) included constipation, somnolence or sedation, pyrexia, lethargy, and drooling.

DRUG INTERACTIONS
The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression. Limit dosage and duration of concomitant use of benzodiazepines and opioids and follow patients closely for respiratory depression and sedation. Concomitant use of SYMPAZAN with other CNS depressants, including alcohol, may increase the risk of sedation and somnolence. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol, as effects of other CNS depressants or alcohol may be potentiated.
Hormonal contraceptives that are metabolized by CYP3A4; effectiveness may be diminished when given with SYMPAZAN. Additional non-hormonal forms of contraception are recommended when using SYMPAZAN. Dose adjustment may be necessary of drugs metabolized by CYP2D6 and of SYMPAZAN when co-administered with strong CYP2C19 inhibitors (e.g., fluconazole, fluvoxamine, ticlopidine).

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation: SYMPAZAN may cause fetal harm and should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have taken benzodiazepines during the later stages of pregnancy can develop dependence, withdrawal syndrome and symptoms suggestive of floppy infant syndrome. SYMPAZAN is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from SYMPAZAN, discontinue nursing or discontinue the drug. Encourage patients to call the toll-free number 1-888-233-2334 to enroll in the Pregnancy Registry or visit http://www.aedpregnancyregistry.org/.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please click here to see full Prescribing Information, including the Boxed Warning.

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

(Audited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues	$ 16,419	$ 16,824	$ 52,609	$ 67,430
Costs and expenses:				
Manufacture and supply	6,792	4,787	20,361	20,988
Research and development	3,057	5,683	20,574	23,112
Selling, general and administrative	16,474	18,710	64,342	72,269
Total costs and expenses	26,323	29,180	105,277	116,369
Loss from operations	(9,904)	(12,356)	(52,668)	(48,939)
Other income/(expenses):				
Interest expense	(2,803)	(1,902)	(9,318)	(7,711)
Interest income	71	314	636	552
Loss on extinguishment of debt	-	-	(4,896)	-
Change in fair value of warrant	-	-	-	(5,278)
Loss before income taxes	(12,636)	(13,944)	(66,246)	(61,376)
Income taxes	-	-	-	-
Net loss	$ (12,636)	$ (13,944)	$ (66,246)	$ (61,376)
Net loss per share - basic and diluted	$ (0.48)	$ (0.56)	$ (2.61)	$ (2.96)
Weighted-average number of common shares outstanding - basic and diluted	26,435,840	24,942,185	25,356,098	20,725,526

AQUESTIVE THERAPEUTICS, INC.
Consolidated Balance Sheets
(In thousands, except share amounts)
(Audited)

Assets	December 31, 2019	December 31, 2018
Current assets:		
Cash and cash equivalents	$ 49,326	$ 60,599
Trade and other receivables, net	13,130	6,481
Inventories, net	2,859	5,441
Prepaid expenses and other current assets	2,999	1,680
Total current assets	68,314	74,201
Property and equipment, net	9,726	12,207
Intangible assets, net and other assets	439	443
Total assets	$ 78,479	$ 86,851
Liabilities and stockholders' deficit/equity		
Current liabilities:		
Accounts payable	$ 12,274	$ 20,436
Accrued expenses	5,475	7,195
Deferred revenue, current	806	721
Loans payable, current	-	4,600
Total current liabilities	18,555	32,952
Deferred revenue, net of current portion	4,348	-
Loans payable, net	60,338	42,603
Asset retirement obligations	1,360	1,216
Total liabilities	84,601	76,771
Commitments and contingencies		
Stockholders' (deficit)/equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 33,562,885 and 24,957,309 shares issued and outstanding at December 31, 2019 and 2018, respecitively	34	25
Additional paid-in capital	124,318	71,431
Accumulated deficit	(130,474)	(61,376)
Total stockholders' (deficit)/equity	(6,122)	10,080
Total liabilities and stockholders' (deficit)/equity	$ 78,479	$ 86,851

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Total costs and expenses	$ 26,323	$ 29,180	$ 105,277	$ 116,369
Non-GAAP adjustments:				
Share-based compensation expense	(1,873)	(1,399)	(7,071)	(29,940)
Depreciation and amortization	(723)	(760)	(2,905)	(3,236)
Adjusted costs and expenses	$ 23,727	$ 27,021	$ 95,013	$ 83,193

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Manufacture and supply expense	$ 6,792	$ 4,787	$ 20,361	$ 20,988
Gross margin on total revenue	*59%*	*72%*	*61%*	*69%*
Non-GAAP adjustments:				
Share-based compensation expense	(50)	(37)	(221)	(414)
Depreciation and amortization	(585)	(615)	(2,350)	(2,618)
Adjusted manufacture and supply expense	$ 6,157	$ 4,135	$ 17,790	$ 17,956
Non-GAAP gross margin on total revenue	*63%*	*75%*	*66%*	*73%*

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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Research and development expense	$ 3,057	$ 5,683	$ 20,574	$ 23,112
Non-GAAP adjustments:				
Share-based compensation expense	(185)	(205)	(720)	(2,583)
Depreciation and amortization	(65)	(109)	(265)	(368)
Adjusted research and development expense	$ 2,807	$ 5,369	$ 19,589	$ 20,161

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Selling, general and administrative expenses	$ 16,474	$ 18,710	$ 64,342	$ 72,269
Non-GAAP adjustments:				
Share-based compensation expense	(1,638)	(1,157)	(6,130)	(26,943)
Depreciation and amortization	(73)	(36)	(290)	(250)
Adjusted selling, general and administrative expenses	$ 14,763	$ 17,517	$ 57,922	$ 45,076

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,	
	2019	2018	2019	2018
Net loss	$ (12,636)	$ (13,944)	$ (66,246)	$ (61,376)
Share-based compensation	1,872	1,399	7,071	29,940
Interest expense, net	2,732	1,588	8,682	7,159
Loss on extinguishment of debt	-	-	4,896	-
Income taxes	-	-	-	-
Depreciation and amortization	723	760	2,905	3,236
Change in fair value of warrant	-	-	-	5,278
Adjusted EBITDA	$ (7,309)	$ (10,197)	$ (42,692)	$ (15,763)

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