

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 5, 2020

Aquestive Therapeutics, Inc.  
(Exact name of Registrant as specified in its charter)

Delaware  
(State or Other Jurisdiction of Incorporation or  
Organization)

001-38599  
(Commission File Number)

82-3827296  
(I.R.S. Employer Identification No.)

30 Technology Drive  
Warren, NJ 07059  
(908) 941-1900  
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Not Applicable  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	AQST	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 2.02 Results of Operations and Financial Condition

On May 5, 2020, Aquestive Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2020. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and incorporated by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of, or otherwise subject to the liabilities of, Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

## Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
<a href="#">99.1</a>	Press Release, dated May 5, 2020, announcing the financial results for the first quarter ended March 31, 2020.

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 5, 2020

Aquestive Therapeutics, Inc.

By: /s/ John T. Maxwell

Name: John T. Maxwell

Title: Chief Financial Officer

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## Aquestive Therapeutics Reports First Quarter 2020 Financial Results and Provides Business Update: AQST-108 and Libervant Remain On Track

- Continues to manufacture and deliver therapies and advance R&D efforts during COVID-19 pandemic
- Expects to submit AQST-108 (epinephrine) IND by June 2020 and to commence PK trials by end of 2020
- Continues to advance Libervant (diazepam) through FDA review process as expected
- Reaffirms full year 2020 guidance including revenue, adjusted EBITDA and cash burn
- Hosts investment community conference call at 8:00 am ET on May 6, 2020

Warren, N.J., May 5, 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 financial results for the first quarter ended March 31, 2020 and provided an update on recent developments in its business.

Keith J. Kendall, President and Chief Executive Officer of Aquestive, stated, “While fulfilling our responsibility to keep our colleagues, neighbors and society as a whole safe during this unprecedented crisis caused by the novel coronavirus pandemic, we are continuing to advance the important work of the Company, ensuring the medications our patients depend on each day remain available to them without interruption. At this time, Aquestive continues to produce therapies as expected and our R&D labs continue to advance key pipeline therapies including Libervant™ (diazepam) Buccal Film for the management of seizure clusters, and AQST-108 sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis. We are continuing to interact with the FDA and responding, as expected, to information requests by the FDA related to our NDA filing for Libervant.”

“We are continuing to prudently manage our cash flow and have begun the process to seek to monetize the anticipated royalties associated with Sunovion’s apomorphine therapy, if approved by the FDA, with an expected PDUFA goal date of May 21, 2020. We have begun to communicate with potential investors and will consider market conditions, COVID related or otherwise, structure and timing of any monetization to enable us to provide appropriate additional capital for the Company. Based on our planning and expectations, we believe that we are positioned with current cash resources and a potential non-dilutive apomorphine monetization to extend our capital runway well into 2021 and possibly beyond,” concluded Mr. Kendall.

### 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.

- Aquestive expects to submit the Investigational New Drug (IND) application for AQST-108 in June 2020 and to commence PK clinical trials later this year. The Food and Drug Administration (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.
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- Aquestive is engaging as expected with the FDA related to its New Drug Application (NDA) for Libervant, including continuing information requests from the review teams, leading up to the September 27, 2020 Prescription Drug User Fee Act (PDUFA) goal date. Aquestive is seeking to demonstrate to the FDA that Libervant will, if approved by the FDA for marketing in the U.S., represent a “major contribution to patient care” within the meaning of FDA regulations and guidance as compared to currently available treatment options, and further expand patient choice as the first orally delivered and non-device driven diazepam-based therapy available to manage seizure clusters in epilepsy patients especially for patients who may not be able to effectively use nasal sprays due to nasal congestion, irritation or seasonal allergies.
- 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 progress on key performance commercialization metrics including strong quarterly growth in retail shipments, prescriber growth, repeat prescribers, and increases in covered lives, thereby helping prepare the market for a launch of Libervant, if approved by the FDA for marketing in the U.S.

### **First Quarter 2020 Financials**

Total revenues were \$8.8 million in the first quarter 2020, compared to \$12.6 million in the first quarter 2019. This year-over-year decrease reflected license fees received in early 2019 that did not repeat in 2020, offset by strong growth in Sympazan, the first of its proprietary products to be launched, and consistent year-over-year performance of Suboxone®.

Aquestive’s net loss for the first quarter 2020 was \$16.5 million, or \$0.49 loss per share. The net loss for the first quarter 2019 was \$14.7 million, or \$0.59 loss per share. The change in net loss was driven by lower revenue and higher interest expense in the first quarter 2020, compared to the first quarter 2019, partially offset by reductions in costs and expenses, primarily selling, general and administrative expenses.

Losses before interest, taxes, depreciation and amortization, share-based compensation and other adjustments (adjusted EBITDA losses) were \$11.2 million in the first quarter 2020, compared to \$10.8 million in the comparable prior period. The year-over-year change in adjusted EBITDA loss was driven primarily by lower revenue in the first quarter 2020, compared to the first quarter 2019, offset by reductions in costs and expenses, primarily selling, general and administrative expenses.

As of March 31, 2020, cash and cash equivalents were \$35.5 million.

### **2020 Outlook**

Aquestive’s full year 2020 financial outlook is unchanged from previous outlook guidance. The Company expects:

- Total revenues of approximately \$35 million to \$45 million
    - Expected revenue from Suboxone includes branded only, which is expected to continue to erode over the future
    - Expected revenues from Sympazan net sales, co-development programs, and license fees and royalties from licensed products
    - No Libervant revenues were included in the Company’s 2020 guidance
  - Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
    - Reflective of the expected 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
    - Expected to meet adjusted EBITDA targets by reducing expenses by limiting the Company’s 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 adjusted EBITDA loss guidance, interest, capital spending and working capital effects, but prior to any additional capital transactions
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The novel coronavirus pandemic continues to evolve and the extent to which it may impact our ongoing and future business operations, financial results and resources, or the success of our commercial and candidate products, including Libervant, will depend on future developments which are uncertain. While the Company cannot predict the impact from COVID-19 on the regulatory submission and review of Libervant, and cannot assure FDA approval of Libervant, the Company remains committed to helping epilepsy patients affected by seizure clusters by working to bring important innovative products to the market.

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

The management team will host an investment community conference call tomorrow, May 6, 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: 3179285.

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, and income taxes.

Specifically, the Company adjusts net income (loss) for 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.

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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 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 2019 and 2020 adjustments which have been applicable in determining non-GAAP Adjusted EBITDA and non-GAAP gross margin for these periods are reflected in the tables below. In providing outlook for non-GAAP gross margin, we adjust for non-cash share-based compensation expense and depreciation and amortization. We are providing such outlook only on a non-GAAP basis because the Company is unable to predict with reasonable certainty the totality or ultimate outcome or occurrence of these adjustments for the forward-looking period such as share-based compensation expense, income tax, amortization, and certain other adjusted items, which can be dependent on future events that may not be reliably predicted. Based on past reported results, where one or more of these items have been applicable, such excluded items could be material, individually or in the aggregate, to reported results.

### **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 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 also 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 of 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.

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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, costs 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 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 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 time 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; risk associated with Indivior's cessation of production of its authorized generic buprenorphine naloxone film product, including the impacted from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunseting product; 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 product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements, or outlook or guidance, after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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## **Additional Information Regarding FDA Regulations and Guidance on “Major Contribution to Patient Care”**

The FDA’s response to the Company’s Citizen’s Petition dated November 1, 2019 includes the following in discussing orphan drug exclusivity, including pertinent factors that may be considered by the FDA 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:

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.

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PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

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## **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**

**Potiation 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.

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## ADVERSE REACTIONS

Adverse reactions ( $\geq 10\%$  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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please click here to see full [Prescribing Information](#), including the Boxed Warning.

Investor inquiries:

Stephanie Carrington

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646-277-1282

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

Assets	March 31, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	\$ 35,521	\$ 49,326
Trade and other receivables, net	9,536	13,130
Inventories, net	3,087	2,859
Prepaid expenses and other current assets	2,944	2,999
Total current assets	51,088	68,314
Property and equipment, net	9,059	9,726
Right-of-use asset, net	3,912	-
Intangible assets, net and other assets	428	439
Total assets	<u>\$ 64,487</u>	<u>\$ 78,479</u>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 14,090	\$ 17,749
Lease liabilities, current	609	-
Deferred revenue, current	663	806
Total current liabilities	15,362	18,555
Deferred revenue, net of current portion	4,209	4,348
Loans payable, net	60,922	60,338
Lease liabilities	3,424	-
Asset retirement obligations	1,399	1,360
Total liabilities	<u>85,316</u>	<u>84,601</u>
Contingencies		
Stockholders' deficit:		
Common stock, \$.001 par value. Authorized 250,000,000 shares; 33,582,696 and 33,562,885 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	34	34
Additional paid-in capital	126,141	124,318
Accumulated deficit	(147,004)	(130,474)
Total stockholders' deficit	<u>(20,829)</u>	<u>(6,122)</u>
Total liabilities and stockholders' deficit	<u>\$ 64,487</u>	<u>\$ 78,479</u>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Revenues	\$ 8,765	\$ 12,643
Costs and Expenses:		
Manufacture and supply	3,659	3,506
Research and development	4,354	4,303
Selling, general and administrative	14,613	17,908
Total costs and expenses	<u>22,626</u>	<u>25,717</u>
Loss from operations	(13,861)	(13,074)
Other income/(expenses):		
Interest expense	(2,771)	(1,926)
Interest income	102	274
Net loss before income taxes	(16,530)	(14,726)
Income taxes	-	-
Net loss	<u>\$ (16,530)</u>	<u>\$ (14,726)</u>
Net loss per share - basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.59)</u>
Weighted-average number of common shares outstanding - basic and diluted	<u>33,569,694</u>	<u>24,963,603</u>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
GAAP net loss	\$ (16,530)	\$ (14,726)
Share-based Compensation Expense	1,860	1,520
Interest Expense, net	2,669	1,652
Income Taxes	-	-
Depreciation and Amortization	766	749
Total non-GAAP adjustments	<u>5,295</u>	<u>3,921</u>
Adjusted EBITDA	<u>\$ (11,235)</u>	<u>\$ (10,805)</u>

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

	Three Months Ended March 31,	
	2020	2019
Total costs and expenses	\$ 22,626	\$ 25,717
Non-GAAP adjustments:		
Share-based compensation expense	(1,860)	(1,520)
Depreciation and amortization	(766)	(749)
Adjusted costs and expenses	<u>\$ 20,000</u>	<u>\$ 23,448</u>

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

	Three Months Ended March 31,	
	2020	2019
Manufacture and Supply Expense	\$ 3,659	\$ 3,506
<i>Gross Margin on total revenue</i>	58%	72%
Non-GAAP adjustments:		
Share-based compensation expense	(63)	(44)
Depreciation and amortization	(627)	(606)
Adjusted manufacture and supply expense	<u>\$ 2,969</u>	<u>\$ 2,856</u>
<i>Non-GAAP Gross Margin on total revenue</i>	<u>66%</u>	<u>77%</u>

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

	Three Months Ended March 31,	
	2020	2019
Research and Development Expense	\$ 4,354	\$ 4,303
Non-GAAP adjustments:		
Share-based compensation expense	(182)	(208)
Depreciation and amortization	(60)	(62)
Adjusted research and development expense	<u>\$ 4,112</u>	<u>\$ 4,033</u>

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Selling, General and Administrative Expenses	\$ 14,613	\$ 17,908
Non-GAAP adjustments:		
Share-based compensation expense	(1,615)	(1,268)
Depreciation and amortization	(79)	(81)
Adjusted selling, general and administrative expenses	<u>\$ 12,919</u>	<u>\$ 16,559</u>

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