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): August 4, 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 August 4, 2020, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the second quarter ended June 30, 2020 and provided an update on recent developments in its business. A copy of the Company's press release is attached hereto as Exhibit 99.1 and incorporated by reference.

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

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated August 4, 2020, announcing the Company's reported financial results for the second quarter ended June 30, 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: August 4, 2020

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive Therapeutics Reports Second Quarter 2020 Financial Results and Provides Business Update: AQST-108 Progress Remains On Track; Libervant PDUFA Goal Date Approaches

- Generated 59% year-over-year revenue growth for Sympazan®(clobazam)
- FDA completed safety review of IND for AQST-108 (epinephrine) and approved commencement of first planned pharmacokinetics (PK) clinical trials
- Continues to advance Libervant™ (diazepam) through FDA review and on-going inspection process of manufacturing and clinical investigational sites
- Ongoing process for potential monetization of royalty rights in KYNMOBI™ (apomorphine) continues
- Re-affirms full year 2020 financial guidance
- Hosts conference call at 8:00 a.m. ET on August 5, 2020

Warren, N.J., August 4, 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, announced today reported financial results for the second quarter ended June 30, 2020 and provided an update on recent developments in its business.

Keith J. Kendall, President and Chief Executive Officer of Aquestive, stated, "While continuing to navigate the health crisis caused by the COVID-19 pandemic and, to the best of our ability, fulfilling our responsibility to keep our colleagues and neighbors safe, we are advancing the important work of the Company, as expected, and ensuring the medications our patients depend on each day remain available to them without interruption. We are pleased that Sympazan continued its commercial growth during the second quarter. Also, in July 2020, the FDA accepted our IND for AQST-108, our drug candidate in development to deliver systemic epinephrine for the treatment of anaphylaxis, and we are progressing toward commencing our planned PK trials expected later in the third quarter of this year. Concurrently, we are continuing to advance through the FDA review process for our product candidate, Libervant™ (diazepam) Buccal Film for the management of seizure clusters, including providing information to the agency, responding to its information requests and working with the agency on its inspection of our manufacturing and clinical investigational sites. With the commercial foundation we have built for Sympazan, we will be prepared to launch Libervant quickly, if approved by the FDA for U.S. marketing access. The formal process for a potential monetization of our KYNMOBI royalty asset is ongoing."

Proprietary Pipeline Overview and Business Update

Aquestive is building a portfolio of differentiated therapeutics 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 submitted an Investigational New Drug (IND) application on June 26, 2020 to the U.S. Food and Drug Administration (FDA) for PK clinical trials of its drug candidate AQST-108, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies. As proposed by Aquestive and confirmed by the FDA at the pre-IND meeting held in February 2020, the clinical development for AQST-108 will be reviewed under the 505(b)(2) regulatory approval pathway. On July 23, 2020, Aquestive received confirmation from the FDA that the agency had completed its safety review of the IND and concluded that the Company could proceed with the first planned PK clinical trials of AQST-108. The Company expects to commence a crossover study to compare the pharmacokinetics and pharmacodynamics of epinephrine administered as sublingual film to that of epinephrine administered as an injection before the end of the third quarter of 2020.

- Aquestive is engaging as expected with the FDA related to its New Drug Application (NDA) for Libervant™ (diazepam) Buccal Film for the management of seizure clusters. The review to date has progressed with our providing information to the agency, responding to its information requests and working with the agency on its inspections of the Company's manufacturing and clinical investigational sites. The Company expects that it will continue to have exchanges with the FDA as the September 27, 2020 Prescription Drug User Fee Act (PDUFA) goal date approaches. 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 only orally delivered and non-device driven diazepam-based therapy available to manage seizure clusters in epilepsy patients. Although we cannot assure FDA approval of Libervant for U.S. marketing access, we remain committed to helping epilepsy patients affected by seizure clusters by working to bring innovative products to the market.

- 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 quarterly growth in retail shipments, number of prescribers, repeat prescribers, and covered lives, with the goal of helping prepare the market for a launch of Libervant, if approved by the FDA for marketing in the U.S.

- KYNMOBI, an apomorphine thin film therapy for the treatment of off episodes in Parkinson's disease patients, is licensed by the Company to Sunovion Pharmaceuticals, Inc. KNYMOBI received FDA approval on May 21, 2020. Under the terms of the license agreement with Sunovion, Aquestive is entitled to receive certain milestone payments and ongoing royalties on the world-wide net sales of KYNMOBI. The Company is in the process of seeking to monetize this asset. The formal process for a potential monetization of the Company's KYNMOBI royalty asset is ongoing.

Second Quarter 2020 Financials

Total revenues were $21.7 million in the second quarter 2020, compared to $11.1 million in the second quarter 2019. This year-over-year increase reflected license fees and royalty revenue in the second quarter of 2020 primarily related to $12 million recognized as a result of the KYNMOBI approval, of which $8 million is non-cash revenue related to minimum royalties that will be received over future years. In addition, Aquestive saw revenue growth in the second quarter of 2020 compared to the prior year period of 59% for Sympazan, the first of its proprietary products to be launched, offset in part, by lower year-over-year performance of Suboxone®.

Aquestive's net loss for the second quarter 2020 was $2.3 million, or $0.07 loss per share. The net loss for the second quarter 2019 was $20.5 million, or $0.82 loss per share. The change in net loss was driven by higher revenue and reductions in costs and expenses, primarily in research and development and selling, general and administrative expenses in the second quarter 2020, compared to the second quarter 2019, partially offset by higher interest expense.

Earnings before interest, taxes, depreciation and amortization, share-based compensation and other adjustments (adjusted EBITDA) was $2.9 million in the second quarter 2020, compared to $16.2 million of losses in the comparable prior period. The year-over-year change in adjusted EBITDA was driven primarily by higher revenue and reductions in costs and expenses, primarily in research and development and selling, general and administrative expenses in the second quarter 2020, compared to the second quarter 2019, partially offset by higher interest expense.

As of June 30, 2020, cash and cash equivalents were $25.4 million.

2020 Outlook

Aquestive is re-affirming its full year 2020 financial outlook. The Company's full year guidance does not include the revenue recognized this quarter as a result of minimum royalty payments that will be received over future years from KYNMOBI.

The Company expects:

- Total revenues of approximately $35 million to $45 million
  - No Libervant revenues are included in the Company's 2020 guidance
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
- Non-GAAP adjusted EBITDA loss of approximately $45 million to $50 million
- Cash burn of approximately $45 million to $50 million

The novel coronavirus pandemic continues to evolve and the extent to which it may impact Aquestive's ongoing and future business operations, financial results and resources, or the success of the Company's commercial and candidate products, including Libervant, will depend on future developments which are uncertain.

Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. ET on Wednesday, August 5, 2020. 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: 6069891.

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 a late-stage proprietary product pipeline to treat CNS and other 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 adjusted gross margins, non-GAAP adjusted 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; certain non-cash expenses, 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 certain non-cash expenses 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, 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 are also subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers’ ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials 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 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 inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks and uncertainties concerning any potential monetization of royalty and other revenue stream of KYNMOBI (apomorphine), including timing, structure, terms and market conditions of any such potential monetization and of sufficiency of net proceeds of any such monetization after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable; 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; 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 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.

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.

Although FDA approval cannot be assured, Aquestive remains committed to helping epilepsy patients affected by seizure clusters by working to bring innovative products to the market.

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.

Investor inquiries:
Stephanie Carrington
stephanie.carington@icrinc.com
646-277-1282

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

Assets	June 30, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	$ 25,422	$ 49,326
Trade and other receivables, net	12,891	13,130
Inventories, net	3,173	2,859
Prepaid expenses and other current assets	2,423	2,999
Total current assets	43,909	68,314
Property and equipment, net	8,457	9,726
Right-of-use asset, net	3,764	-
Intangible assets, net and other assets	7,416	439
Total assets	$ 63,546	$ 78,479
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,390	$ 17,749
Lease liabilities, current	689	-
Deferred revenue, current	803	806
Total current liabilities	14,882	18,555
Loans payable, net	61,505	60,338
Lease liabilities	3,240	-
Deferred revenue, net of current	3,867	4,348
Asset retirement obligations	1,440	1,360
Total liabilities	84,934	84,601
Contingencies		
Stockholders' deficit:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 33,616,601 and 33,562,885 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	34	34
Additional paid-in capital	127,916	124,318
Accumulated deficit	(149,338)	(130,474)
Total stockholders' deficit	(21,388)	(6,122)
Total liabilities and stockholders' deficit	$ 63,546	$ 78,479

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues	$ 21,675	$ 11,129	$ 30,440	$ 23,772
Costs and Expenses:				
Manufacture and supply	3,539	5,420	7,198	8,926
Research and development	3,847	8,151	8,201	12,454
Selling, general and administrative	13,894	16,246	28,507	34,154
Total costs and expenses	21,280	29,817	43,906	55,534
Income (loss) from operations	395	(18,688)	(13,466)	(31,762)
Other income/(expenses):				
Interest expense	(2,747)	(1,937)	(5,518)	(3,863)
Interest income	18	153	120	427
Net loss before income taxes	(2,334)	(20,472)	(18,864)	(35,198)
Income taxes	-	-	-	-
Net loss	$ (2,334)	$ (20,472)	$ (18,864)	$ (35,198)
Comprehensive loss	$ (2,334)	$ (20,472)	$ (18,864)	$ (35,198)
Net loss per share - basic and diluted	$ (0.07)	$ (0.82)	$ (0.56)	$ (1.41)
Weighted-average number of common shares outstanding - basic and diluted	33,589,174	24,980,861	33,579,434	24,972,280

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP net loss	$ (2,334)	$ (20,472)	$ (18,864)	$ (35,198)
Share-based Compensation Expense	1,765	1,810	3,625	3,330
Interest Expense, net	2,729	1,784	5,398	3,436
Income Taxes	-	-	-	-
Depreciation and Amortization	754	724	1,520	1,473
Total non-GAAP adjustmentss	5,248	4,318	10,543	8,239
Adjusted EBITDA	$ 2,914	$ (16,154)	$ (8,321)	$ (26,959)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Total costs and expenses	$ 21,280	$ 29,817	$ 43,906	$ 55,534
Non-GAAP adjustments:				
Share-based compensation expense	(1,765)	(1,810)	(3,625)	(3,330)
Depreciation and amortization	(754)	(724)	(1,520)	(1,473)
Adjusted costs and expenses	$ 18,761	$ 27,283	$ 38,761	$ 50,731

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Manufacture and Supply Expense	$ 3,539	$ 5,420	$ 7,198	$ 8,926
Gross Margin on total revenue	*84%*	*51%*	*76%*	*62%*
Non-GAAP adjustments:				
Share-based compensation expense	(72)	(72)	(135)	(116)
Depreciation and amortization	(617)	(586)	(627)	(1,193)
Adjusted manufacture and supply expense	$ 2,850	$ 4,762	$ 6,436	$ 7,617
Non-GAAP Gross Margin on total revenue	*87%*	*57%*	*79%*	*68%*

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and Development Expense	$ 3,847	$ 8,151	$ 8,201	$ 12,454
Non-GAAP adjustments:				
Share-based compensation expense	(183)	(140)	(365)	(348)
Depreciation and amortization	(59)	(60)	(60)	(121)
Adjusted research and development expense	$ 3,605	$ 7,951	$ 7,776	$ 11,985

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Selling, General and Administrative Expenses	$ 13,894	$ 16,246	$ 28,507	$ 34,154
Non-GAAP adjustments:				
Share-based compensation expense	(1,510)	(1,598)	(3,125)	(2,866)
Depreciation and amortization	(78)	(78)	(79)	(159)
Adjusted selling, general and administrative expenses	$ 12,306	$ 14,570	$ 25,303	$ 31,129