

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): November 4, 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 November 4, 2020, Aquestive Therapeutics, Inc. (the “Company”) issued a press release announcing its reported financial results for the third quarter ended September 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 November 4, 2020, announcing the Company’s reported financial results for the third quarter ended September 30, 2020 and providing an update on recent developments in its business.

SIGNATURE

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

Dated: November 4, 2020

Aquestive Therapeutics, Inc.

By: /s/ John T. Maxwell

Name: John T. Maxwell

Title: Chief Financial Officer



Aquestive Therapeutics Reports Third Quarter 2020 Financial Results and Provides Business Update

- Sympazan® (clobazam) continues to meet key performance metrics and market penetration
- FDA Type A meeting for Libervant™ (diazepam) Buccal Film scheduled for November 12, 2020
- Completed dosing in Phase 1 Pharmacokinetic (PK) trial for AQST-108 (epinephrine)
- Execution of monetization agreement providing up to \$125 million for royalty rights in KYNMOBI™ (apomorphine HCl)
- Updates full year 2020 financial guidance, improving its outlook for revenue and adjusted loss before interest, taxes, depreciation and amortization
- Hosts conference call at 8:00 a.m. ET on November 5, 2020

Warren, N.J., November 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, today reported financial results for the third quarter ended September 30, 2020 and provided an update on recent developments in its business.

“Amidst the unprecedented uncertainty of the COVID-19 pandemic, our Company has made progress this quarter in advancing our CNS product portfolio and other important therapeutics in our product pipeline, highlighted by the completion of dosing in a Phase 1 pharmacokinetic trial for our product candidate AQST-108, a “first of its kind” oral sublingual film formulation delivering systemic epinephrine, and we are on track to assess the validity and quality of that data in the coming weeks,” said Keith J. Kendall, President and Chief Executive Officer of Aquestive. “Importantly, we are advancing our lead product candidate, Libervant™ (diazepam) Buccal Film for the management of seizure clusters, through the approval process with the Food and Drug Administration (FDA). We received confirmation from the FDA that, after submitting our meeting package this past October, a review meeting with the Agency is set for November 12, 2020. We look forward to working with the FDA in seeking feedback and clarity on the pathway for approval of Libervant. Moreover, the KYNMOBI royalty monetization transaction, which was signed this week and is expected to close and fund later this month, provides the Company with substantial capital to support our key clinical and commercial initiatives and reduce our senior debt,” concluded Mr. Kendall.

Despite limitations on provider in-person interactions caused by the COVID-19 pandemic, the Company’s proprietary product Sympazan® (clobazam), an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome, continues to meet key performance metrics. Shipment volume sequentially quarter over quarter has grown 18% and by 130% over the same period last year. During the third quarter 2020, Sympazan saw continued growth in the prescriber base, approaching 700 healthcare providers, which represents over 26% penetration into the Company’s focused group of prescribers, with over 77% of those prescribers writing multiple scripts. Sympazan net revenue grew 102% for the three month period ended September 30, 2020 versus the same period last year, and 86% for the nine month period ended September 30, 2020 versus the same period last year. Sympazan currently has over 72% of commercial lives covered and an 82% coverage of State Medicaid regions. Given the substantial overlap of prescribers, Sympazan is strategically accomplishing what was intended when it was developed and launched last year, to build an important foundation for a successful launch of Libervant, if approved by the FDA for U.S. market access.

As indicated in the Company's investor call on September 25, 2020, the Company submitted in October the data and information it believes addresses the FDA's concerns expressed in the FDA's Complete Response Letter relating to Libervant. The Company received confirmation that the FDA agreed to a Type A meeting with the Company to be held on November 12, 2020. A Type A meeting is granted for candidate drugs on hold to discuss impeding issues and a path forward for approval. Based on the data and information submitted to the FDA, the Company does not believe at this time that further clinical studies are necessary. At that meeting, the Company expects to discuss the information submitted in the October 2020 meeting package and to seek to confirm the pathway for approval and propose the immediate resubmission of the NDA for Libervant. If the FDA agrees with the Company's proposal, then the Company plans on resubmitting the NDA before the end of the year. If the FDA does not agree with the Company's proposal, then the Company will seek to understand the best path forward for resubmission and approval. The Company will update the market regarding the FDA's comments, the Company's plans for resubmitting the NDA, and the potential range of PDUFA dates for Libervant once meeting minutes are finalized.

After receiving Fast Track Designation from the FDA for AQST-108, the Company completed enrollment and dosing of 28 healthy volunteers in a Phase 1 pharmacokinetic (PK) trial for AQST-108 in October 2020. The trial features a four-treatment crossover design comparing the pharmacokinetics and pharmacodynamics of AQST-108, 0.3 mg of epinephrine subcutaneous injection (subQ), 0.3 mg of epinephrine intramuscular (IM) injection, and 0.5 mg epinephrine subQ. The study includes secondary endpoints for changes in blood pressure and heart rate. The Company is on track to assess the validity and quality of that data in the coming weeks. The Company believes that AQST-108, if approved by the FDA, will be the first orally administered epinephrine-based rescue medication for this patient population.

As previously announced, this week the Company signed a monetization agreement for up to \$125 million for its worldwide royalty rights in KYNMOBI™ (apomorphine HCl) sublingual film for the acute, intermittent treatment of OFF episodes in patients with Parkinson's disease, which received approval from the FDA on May 21, 2020. The Company expects to close and fund the monetization transaction later this month. Under the terms of the monetization agreement, the Company will receive at closing of the transaction \$40 million and is eligible to receive up to the additional \$85 million of contingent payments at various points, beginning as early as the fourth quarter of 2020, based on the achievement of worldwide royalty targets and certain other commercial milestones. This includes up to \$25 million potentially available between now and mid-2022. The net proceeds of the transaction will be used to repay certain senior notes and fund the Company's ongoing development and commercialization of its proprietary product and pipeline candidates, as well as for working capital purposes. In connection with the monetization transaction, the Company will repay \$22.5 million of its senior notes and issue \$4.0 million of new senior notes in lieu of paying a prepayment premium on the early repayment of the senior notes, bringing the Company's outstanding senior debt from \$70 million to \$51.5 million, and reducing the principal and interest obligations under the senior note debt facility in the future.

Third Quarter 2020 Financials

Total revenues were \$8.3 million in the third quarter 2020, compared to \$12.4 million in the third quarter 2019. This year-over-year decrease reflected lower Suboxone manufacture and supply revenue, as well as lower license and royalty revenue, offset partially by growth in Sympazan revenue. Aquestive saw revenue growth in the third quarter 2020 compared to the prior year period of 102% for Sympazan, the first of its proprietary products to be launched.

Aquestive's net loss for the third quarter 2020 was \$16.6 million, or \$0.49 loss per share. The net loss for the third quarter 2019 was \$18.4 million, or \$0.74 loss per share. The change in net loss was driven by lower revenue and reductions in costs and expenses, primarily in manufacture and supply expense reflecting the lower volume of production in the third quarter 2020, compared to the third quarter 2019. In addition, the third quarter of 2019 included a \$4.9 million loss on extinguishment of debt.

Non GAAP adjusted loss before interest, taxes, depreciation and amortization, share-based compensation and other adjustments (adjusted EBITDA loss) was \$11.6 million in the third quarter 2020, compared to \$8.4 million of losses in the comparable prior period. The year-over-year change in adjusted EBITDA loss was driven primarily by lower revenue partially offset by reductions in costs and expenses, primarily in manufacture and supply expenses, in the third quarter 2020, compared to the third quarter 2019.

As of September 30, 2020, cash and cash equivalents were \$17.1 million.

2020 Outlook

Aquestive is updating its full year 2020 financial outlook. The Company's full year guidance does not include the accounting for the monetization of the KYNMOBI royalty stream.

The Company expects:

- Total revenues of approximately \$42 million to \$46 million
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
- Non-GAAP adjusted EBITDA loss of approximately \$38 million to \$42 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 Thursday, November 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: 8266119.

There will also be a simultaneous, live webcast available on the Investors section of the Company's website at <https://investors.aquestive.com/events-and-presentations>. The webcast will be archived for 30 days.

About Aquestive Therapeutics

Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, Sympazan, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven capabilities for drug development and commercialization.

Non-GAAP Financial Information

This press release and our webcast earnings call regarding our quarterly financial results contains financial measures that do not comply with U.S. generally accepted accounting principles (GAAP), such as Adjusted EBITDA loss, non-GAAP adjusted gross margins, non-GAAP adjusted costs and expenses and other adjusted expense measures, because such measures exclude, as applicable, share-based compensation, 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 loss. Similarly, manufacture and supply expense, research and development expense, and selling, general and administrative expense were adjusted for certain non-cash expenses of share-based compensation expense and depreciation and amortization. Adjusted EBITDA loss and these non-GAAP expense categories are used as a supplement to the corresponding GAAP measures to provide additional insight regarding the Company's ongoing operating performance.

These measures supplement the Company's financial results prepared in accordance with GAAP. Aquestive management uses these measures to analyze its financial results, and its future manufacture and supply expenses, gross margins, research and development expense and selling, general and administrative expense and to help make managerial decisions. In management's opinion, these non-GAAP measures provide added transparency into the operating performance of Aquestive and added insight into the effectiveness of our operating strategies and actions. We may provide one or more revenue measures adjusted for certain discrete items, such as fees collected on certain licensed products, in order to provide investors added insight into our revenue stream and breakdown, along with providing our GAAP revenue. Such measures are intended to supplement, not act as substitutes for, comparable GAAP measures and should not be read as a measure of liquidity for Aquestive. Adjusted EBITDA loss and the other non-GAAP measures are also likely calculated in a way that is not comparable to similarly titled measures reported by other companies.

Non-GAAP Outlook

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

Forward-Looking Statement

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 and Libervant; ability to address the concerns identified in the FDA’s Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant and obtain FDA approval of Libervant for U.S. market access; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; about our growth and future financial and operating results and financial position; regulatory approval and pathway; 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 for consummating the monetization transaction for KYNMOBI and other risks and uncertainties concerning the royalty and other revenue stream of KYNMOBI, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction, and of sufficiency of net proceeds of the monetization transaction after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable, and for funding the Company’s operations; 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 sunseting product; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company’s products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company’s products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, 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 for U.S. market access cannot be assured, Aquestive remains committed to helping epilepsy patients affected by seizure clusters by working to bring innovative products to the market.

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.

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.

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, or call 1-800-FDA-1088.

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

Investor inquiries:

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

Assets	September 30, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	\$ 17,064	\$ 49,326
Trade and other receivables, net	7,990	13,130
Inventories, net	3,242	2,859
Prepaid expenses and other current assets	3,388	2,999
Total current assets	31,684	68,314
Property and equipment, net	7,728	9,726
Right-of-use asset, net	3,609	-
Intangible assets, net and other assets	7,402	439
Total assets	\$ 50,423	\$ 78,479
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,237	\$ 17,749
Lease liabilities, current	664	-
Loans payable, current	1,750	-
Deferred revenue, current	722	806
Total current liabilities	18,373	18,555
Loans payable, net	60,346	60,338
Lease liabilities	3,047	-
Deferred revenue, net of current	3,694	4,348
Asset retirement obligations	1,482	1,360
Total liabilities	86,942	84,601
Contingencies		
Stockholders' deficit:		
Common stock, \$.001 par value. Authorized 250,000,000 shares; 33,619,796 and 33,562,885 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	34	34
Additional paid-in capital	129,336	124,318
Accumulated deficit	(165,889)	(130,474)
Total stockholders' deficit	(36,519)	(6,122)
Total liabilities and stockholders' deficit	\$ 50,423	\$ 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	\$ 8,260	\$ 12,418	\$ 38,700	\$ 36,190
Costs and Expenses:				
Manufacture and supply	2,978	4,643	10,176	13,569
Research and development	7,260	5,063	15,461	17,517
Selling, general and administrative	11,803	13,714	40,310	47,868
Total costs and expenses	<u>22,041</u>	<u>23,420</u>	<u>65,947</u>	<u>78,954</u>
Loss from operations	(13,781)	(11,002)	(27,247)	(42,764)
Other income (expenses):				
Interest expense	(2,778)	(2,652)	(8,296)	(6,515)
Interest income	8	138	128	565
Loss on extinguishment of debt	-	(4,896)	-	(4,896)
Net loss before income taxes	<u>(16,551)</u>	<u>(18,412)</u>	<u>(35,415)</u>	<u>(53,610)</u>
Income taxes	-	-	-	-
Net loss	<u>\$ (16,551)</u>	<u>\$ (18,412)</u>	<u>\$ (35,415)</u>	<u>\$ (53,610)</u>
Comprehensive loss	<u>\$ (16,551)</u>	<u>\$ (18,412)</u>	<u>\$ (35,415)</u>	<u>\$ (53,610)</u>
Net loss per share - basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.74)</u>	<u>\$ (1.05)</u>	<u>\$ (2.15)</u>
Weighted-average number of common shares outstanding - basic and diluted	<u>33,619,379</u>	<u>25,031,478</u>	<u>33,592,846</u>	<u>24,992,229</u>

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

	Three Months Ended		Nine Months Ended	
	Sept 30,		Sept 30,	
	2020	2019	2020	2019
GAAP net loss	\$ (16,551)	\$ (18,412)	\$ (35,415)	\$ (53,610)
Share-based Compensation Expense	1,427	1,869	5,052	5,199
Interest Expense, net	2,770	2,514	8,168	5,950
Income Taxes	-	-	-	-
Depreciation and Amortization	766	707	2,286	2,182
Loss on Extinguishment of Debt	-	4,896	-	4,896
Total non-GAAP adjustments	4,963	9,986	15,506	18,227
Adjusted EBITDA	\$ (11,588)	\$ (8,426)	\$ (19,909)	\$ (35,383)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Total costs and expenses	\$ 22,041	\$ 23,420	\$ 65,947	\$ 78,954
Non-GAAP adjustments:				
Share-based compensation expense	(1,427)	(1,869)	(5,052)	(5,199)
Depreciation and amortization	(766)	(707)	(2,286)	(2,182)
Adjusted costs and expenses	<u>\$ 19,848</u>	<u>\$ 20,844</u>	<u>\$ 58,609</u>	<u>\$ 71,573</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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Manufacture and Supply Expense	\$ 2,978	\$ 4,643	\$ 10,176	\$ 13,569
<i>Gross Margin on total revenue</i>	64%	63%	74%	63%
Non-GAAP adjustments:				
Share-based compensation expense	(72)	(60)	(208)	(176)
Depreciation and amortization	(627)	(572)	(1,871)	(1,765)
Adjusted manufacture and supply expense	<u>\$ 2,279</u>	<u>\$ 4,011</u>	<u>\$ 8,097</u>	<u>\$ 11,628</u>
<i>Non-GAAP Gross Margin on total revenue</i>	<u>72%</u>	<u>68%</u>	<u>79%</u>	<u>68%</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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and Development Expense	\$ 7,260	\$ 5,063	\$ 15,461	\$ 17,517
Non-GAAP adjustments:				
Share-based compensation expense	(178)	(187)	(543)	(535)
Depreciation and amortization	(60)	(79)	(179)	(200)
Adjusted research and development expense	<u>\$ 7,022</u>	<u>\$ 4,797</u>	<u>\$ 14,739</u>	<u>\$ 16,782</u>

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Selling, General and Administrative Expenses	\$ 11,803	\$ 13,714	\$ 40,310	\$ 47,868
Non-GAAP adjustments:				
Share-based compensation expense	(1,176)	(1,622)	(4,301)	(4,488)
Depreciation and amortization	(79)	(57)	(236)	(217)
Adjusted selling, general and administrative expenses	<u>\$ 10,548</u>	<u>\$ 12,035</u>	<u>\$ 35,773</u>	<u>\$ 43,163</u>
