



Aquestive Therapeutics Reports Second Quarter 2019 Financial Results and Recent Business Highlights

August 6, 2019

- Reported positive topline data from single dose crossover pharmacokinetic (PK) trial for Libervant™ (diazepam) Buccal Film and expects to complete its rolling New Drug Application (NDA) submission in fourth quarter 2019
- Reported a 250% increase in Sympazan® shipments compared to the end of the first quarter 2019
- Completed debt refinancing in July 2019, with a \$100 million total facility that provided \$70 million at closing and an opportunity for up to an additional \$30 million subject to certain conditions
- Raises full year guidance for Suboxone-related manufacturing revenue
- Hosts investment community conference call at 8:00 a.m. ET on August 7, 2019

WARREN, N.J., Aug. 06, 2019 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products that meet patients' unmet needs and solve therapeutic problems, today reported financial results for the second quarter ended June 30, 2019 and provided an update on recent developments in its business.

"We made significant progress across our programs in recent months. Most importantly, for Libervant, based on preliminary analysis we reported positive topline data from the recently completed crossover study that confirms our dosing algorithm," said Keith J. Kendall, Chief Executive Officer of Aquestive. "This is an exciting result for Aquestive. Libervant is an important driver of shareholder value and we are pleased that we successfully completed the final clinical step requested by the FDA. We look forward to moving as quickly as possible to complete our NDA filing for Libervant expected later this year."

Portfolio and Pipeline Update

Aquestive is building a portfolio of differentiated medicines based on its proprietary PharmFilm® technology to overcome shortfalls in medication design and other barriers patients face to using their prescribed medications. The Company's late stage proprietary products are initially focused on CNS conditions, and other conditions with high unmet need.

- The Company reported positive topline data from the single dose crossover study, which compared the pharmacokinetic responses in a common set of patients receiving a dose of Libervant™ (diazepam) Buccal Film and a dose of diazepam rectal gel. Preliminary analyses show that the overall diazepam exposure achieved from the buccal film was the same as for gel based on the patient dosing algorithm and there was no difference between buccal film and gel in the effect of enzyme induction from taking concurrent anti-epileptic medications. Additionally, there were no instances of low or non-responders observed after Libervant administration, while over 10% of those same patients failed to achieve adequate exposure following gel administration.
- The rolling NDA submission for Libervant commenced in the second quarter 2019 and we expect it to be completed in the fourth quarter 2019. Libervant has the potential to be the first oral therapy approved by the U.S. Food and Drug Administration (FDA) for the management of seizure clusters or breakthrough seizures in the population of 1.2 million refractory epilepsy patients.
- The launch of Sympazan® (clobazam) Oral Film for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years and older, with the potential we believe has the potential to reach \$65 million in peak net revenue within 5 years and driving market understanding about the value of Aquestive's PharmFilm® technology. Sympazan shipment volume has grown over 250% since the end of the first quarter and the prescribing base has grown over 125%, with over 80% of prescribers writing multiple scripts.
- An optimized product formulation of AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis and severe allergic reactions, is being evaluated in a Phase I Proof of Concept study. Data from this trial is expected in late third quarter 2019.
- Suboxone® and the authorized generic buprenorphine-naloxone film continue to retain approximately 75% of the market for film treatments as of July 2019, despite the at risk launches of several generic products in the U.S. Aquestive has a strong order book through the first ten months of 2019, based on the slow erosion of brand market share, strong uptake of the authorized generic, and trusted product quality.

Completion of Debt Refinancing

In July 2019, Aquestive completed a \$100 million facility of 12.5% Senior Secured Notes due in June 2025 and warrants. Aquestive refinanced its existing credit facility at closing with \$70 million of Notes issued, netting \$15 million of incremental capital, and has an opportunity to issue up to \$30 million of additional Notes under certain conditions. The financing was led by [Madryn Asset Management, LP](#) ("Madryn"), with participation by other institutional investors. Details related to this financing can be found in Form 8-K filed by the Company on July 15, 2019.

Second Quarter 2019 Financial Results

Total revenues were \$11.1 million in the second quarter 2019, compared to \$13.9 million reported for the second quarter 2018. This year-over-year decrease reflected a decline in license fees, mostly due to the suspension of license fees related to Suboxone that are pending the outcome of patent litigation against the generics, which launched at risk, partially offset by higher revenue as a result of the launch of Sympazan in late 2018.

Aquestive's net loss for the second quarter 2019 was \$20.5 million, or \$0.82 loss per share. The net loss for the second quarter 2018 was \$36.5 million. The decrease in year-over-year net loss in the second quarter 2019 was driven primarily by lower one-time expenses related to the IPO incurred in the second quarter of 2018, offset by higher investments in commercialization expenses from the launch of Sympazan, higher litigation costs related to the generics in the market at-risk, and higher costs associated with becoming a public company in the second quarter 2019 period compared to the same period in 2018.

2019 Outlook

Aquestive is revising its full year guidance and financial outlook for 2019. The Company expects:

- Total revenues of \$38 million to \$45 million, including Suboxone and Sandoz authorized generic manufacturing revenue of \$29 million to \$32 million;
- Non-GAAP gross margins of 67% to 69% on total revenues;
- Non-GAAP Adjusted EBITDA loss of \$50 million to \$52 million; and
- Cash burn of approximately \$60 to \$65 million after considering non-GAAP Adjusted EBITDA, net interest expense and principal paid on debt prior to refinancing.

Today's Conference Call and Webcast Reminder

The management team will host an investment community conference call on August 7, 2019, at 8:00 a.m. EDT. 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: 9956838.

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 recorded webcast will be available on that same link approximately two hours after the completion of the call and will be archived for 30 days.

About Aquestive Therapeutics

Aquestive Therapeutics is a specialty 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 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 non-GAAP net income (loss), 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 one-time IPO related expenditures; change in fair value of warrants; for recurring non-cash expenditures, including share compensation expenses – post-IPO; depreciation and amortization; and for 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 compensation expenses – post-IPO and depreciation and amortization. Adjusted EBITDA and these non-GAAP expense categories are used as a supplement to the corresponding GAAP measures to provide additional insight regarding the Company's ongoing operating performance.

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

Non-GAAP Outlook

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

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements may include, but are not limited to, statements about our growth and future financial and operating results and financial position, ability to advance Libervant to the market, regulatory approvals and pathways, clinical trial timing and plans, short-term and long-term liquidity and cash requirements, cash funding and cash burn, business strategies, market opportunities, and other

statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; the risks of delays in FDA approval of our drug candidates or failure to receive approval; the risks inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risk of the effectiveness and safety of our products and product candidates; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in governmental laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019 and in our quarterly reports on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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.

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AQUESTIVE THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Revenues	\$ 11,129	\$ 13,928	\$ 23,772	\$ 37,339
Costs and Expenses:				
Manufacture and supply	5,420	4,973	8,926	10,609
Research and development	8,151	7,994	12,454	12,895
Selling, general and administrative	16,246	33,668	34,154	41,213
Total costs and expenses	29,817	46,635	55,534	64,717
Loss from operations	(18,688)	(32,707)	(31,762)	(27,378)
Other income/(expenses):				
Interest expense	(1,937)	(1,927)	(3,863)	(3,876)
Interest income	153	-	427	22
Change in fair value of warrant	-	(1,859)	-	(1,162)
Net loss before income taxes	(20,472)	(36,493)	(35,198)	(32,394)
Income taxes	-	-	-	-
Net loss	(20,472)	(36,493)	(35,198)	(32,394)
Comprehensive loss	\$ (20,472)	\$ (36,493)	\$ (35,198)	\$ (32,394)
Net loss per share - basic and diluted	\$ (0.82)	\$ (1.90)	\$ (1.41)	\$ (1.89)
Weighted-average number of common shares outstanding - basic and diluted	24,980,861	19,188,624	24,972,280	17,144,492

AQUESTIVE THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except for share and per share amounts)

(Unaudited)

June 30,
2019

December 31,
2018

Assets

Current assets:

Cash and cash equivalents	\$ 22,165	\$ 60,599
Trade and other receivables, net	10,150	6,481
Inventories, net	4,647	5,441
Prepaid expenses and other current assets	2,102	1,680
Total current assets	39,064	74,201
Property and equipment, net	10,933	12,207
Intangible assets, net	178	204
Other assets	233	239
Total assets	\$ 50,408	\$ 86,851

Liabilities and shareholders' (deficit)/equity

Current liabilities:

Accounts payable and accrued expenses	\$ 23,479	\$ 27,631
Deferred revenue, current	600	721
Loans payable, current	550	4,600
Total current liabilities	24,629	32,952
Loans payable, net	46,884	42,603
Deferred revenue, net of current portion	2,266	-
Asset retirement obligations	1,286	1,216
Total liabilities	75,065	76,771

Commitments and contingencies

Shareholders' (deficit)/equity:

Common stock, \$.001 par value. Authorized 250,000,000 shares; 25,022,660 and 24,957,309 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	25	25
Additional paid-in capital	74,744	71,431
Accumulated deficit	(99,426)	(61,376)
Total shareholders' (deficit)/equity	(24,657)	10,080
Total liabilities and shareholders' (deficit) /equity	\$ 50,408	\$ 86,851

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,	
	2019	2018	2019	2018
Total Costs and Expenses	\$ 29,817	\$ 46,635	\$ 55,534	\$ 64,717
Non-GAAP adjustments:				
Share-based Compensation Expense	(1,810)	(27,305)	(3,330)	(27,305)
Depreciation and Amortization	(724)	(777)	(1,473)	(1,730)
Adjusted Costs and Expenses	\$ 27,283	\$ 18,553	\$ 50,731	\$ 35,682

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,	
	2019	2018	2019	2018
Manufacture and Supply Expense	\$ 5,420	\$ 4,973	\$ 8,926	\$ 10,609
Gross Margin on total revenue	51	% 64	% 62	% 72
Non-GAAP adjustments:				

Share-based Compensation Expense	(72)	(345)	(116)	(345)
Depreciation and Amortization	(586)	(629)	(1,193)	(1,401)
Adjusted Manufacture and Supply Expense	\$ 4,762		\$ 3,999		\$ 7,617		\$ 8,863	
Non-GAAP Gross Margin on total revenue	57	%	71	%	68	%	76	%

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		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Research and Development Expense	\$ 8,151	\$ 7,994	\$ 12,454	\$ 12,895
Non-GAAP adjustments:				
Share-based Compensation Expense	(140) (2,186) (348) (2,186
Depreciation and Amortization	(60) (64) (121) (142
Adjusted Research and Development Expense	\$ 7,951	\$ 5,744	\$ 11,985	\$ 10,567

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		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Selling, General and Administrative Expenses	\$ 16,246	\$ 33,668	\$ 34,154	\$ 41,213
Non-GAAP adjustments:				
Share-based Compensation Expense	(1,598) (24,774) (2,866) (24,774
Depreciation and Amortization	(78) (84) (159) (187
Adjusted Selling, General and Administrative Expenses	\$ 14,570	\$ 8,810	\$ 31,129	\$ 16,252

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - Net Loss to Adjusted EBITDA

(In Thousands)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Net loss	\$ (20,472) \$ (36,493) \$ (35,198) \$ (32,394
Share-based Compensation Expense	1,810	27,305	3,330	27,305
Interest Expense	1,937	1,927	3,863	3,876
Interest Income	(153) -	(427) (22
Depreciation and Amortization	724	777	1,473	1,730
Income Taxes	-	-	-	-
Change in Fair Value of Warrant	-	1,859	-	1,162
Adjusted EBITDA	\$ (16,154) \$ (4,625) \$ (26,959) \$ 1,657



Source: Aquestive Therapeutics, Inc.