



Aquestive Therapeutics Reports Third Quarter 2019 Financial Results and Raises 2019 Guidance

November 5, 2019

- Increases full year 2019 revenue and earnings guidance
- Expects to complete its rolling New Drug Application (NDA) submission for Libervant™ (diazepam) Buccal Film around the end of November 2019
- Reported successful completion of its Phase 1 dose escalation proof-of-concept study in healthy subjects for AQST-108, oral sublingual film formulation delivering systemic epinephrine for the treatment of allergic reactions including anaphylaxis
- Hosts investment community conference call at 8:00 a.m. ET on November 6, 2019

WARREN, N.J., Nov. 05, 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 third quarter ended September 30, 2019 and provided an update on recent developments in its business.

"The third quarter was an important one in our evolution. We successfully completed the crossover study requested by the U.S. Food and Drug Administration (FDA) for Libervant compared to the reference listed rectal gel. We also completed our proof-of-concept study for epinephrine, AQST-108, for the treatment of allergic reactions including anaphylaxis, and requested a pre-IND meeting with the FDA. In addition, we advanced the commercialization of Sympazan® with more than 50% growth of shipments to retailers since the end of the second quarter," said Keith J. Kendall, Chief Executive Officer of Aquestive.

Proprietary Pipeline Overview and Business Update

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

- Aquestive is expected to complete its rolling NDA submission for Libervant (diazepam) Buccal Film around the end of November 2019, after having filed the CMC portion in September 2019. Libervant has the potential to be the first oral therapy approved by the FDA for the management of seizure clusters in the population of 1.2 million refractory epilepsy patients and the first diazepam based treatment usable by and delivering a consistent predictable dose to virtually all patients to whom it is prescribed.
- Positive data reported from Phase 1 dose escalation proof-of-concept study in healthy subjects for AQST-108, a "first in class" oral sublingual film formulation of epinephrine, demonstrated the ability to deliver systemic epinephrine using Aquestive's proprietary PharmFilm formulation.
- Adoption of Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) continues to grow, with shipments to retailers increasing over 50% as compared to the quarter ended in June.

Third Quarter 2019 Financial Results

Total revenues were \$12.4 million in the third quarter 2019, compared to \$13.3 million in the third quarter 2018. This year-over-year decrease reflected lower license and royalty revenue in 2019 as expected, offset by growth from manufacturing and supply revenue related to Suboxone and the authorized generic product volume growth, as well as proprietary net revenue from Sympazan sales.

Aquestive's net loss for the third quarter 2019 was \$18.4 million, or \$0.74 loss per share. The net loss for the third quarter 2018 was \$15.0 million, or \$0.64 loss per share. The year-over-year change in net loss was driven primarily by higher investments in 2019 in the commercialization of Sympazan, and in the development of Libervant and AQST-108. Cash and cash equivalents as of September 30, 2019 were \$20.9 million.

2019 Outlook

Aquestive is raising its full year revenue and earnings guidance and updating its financial outlook for 2019. The Company expects:

- Total revenues of \$45 million to \$47 million;
- Non-GAAP gross margins of 67% to 69% on total revenues;
- Non-GAAP adjusted EBITDA loss of \$49 million to \$50 million; and
- Cash burn of approximately \$60 million to \$65 million after considering interest, capital spending and working capital effects, but prior to any additional non-dilutive capital transactions.

Today's Conference Call and Webcast Reminder

Aquestive announced that it will report results for the third quarter ended September 30, 2019 and provide a business update on Wednesday, November 6, 2019 before the market open. The Company will host an investment community conference call at 8:00 a.m. ET on Wednesday, November 6, 2019. 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: 4779544. 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 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, 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; loss on the extinguishment of debt; recurring non-cash expenditures, including share-based compensation expenses; 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-based compensation expense and depreciation and amortization. Adjusted EBITDA and these non-GAAP expense categories are used as a supplement to the corresponding GAAP measures to provide additional insight regarding the Company's ongoing operating performance.

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

Non-GAAP Outlook

In providing outlook for non-GAAP adjusted EBITDA and non-GAAP gross margin, we exclude certain items which are otherwise included in determining the comparable GAAP financial measures. A description of the adjustments which have been applicable in determining Adjusted EBITDA for the three and nine month periods ended September 30, 2019 and 2018 are reflected in the table below. In providing outlook for non-GAAP gross margin, we adjust for non-cash share-based compensation expense and depreciation and amortization. We are providing such outlook only on a non-GAAP basis because the Company is unable to predict with reasonable certainty the totality or ultimate outcome or occurrence of these adjustments for the forward-looking period such as share-based compensation expense, income tax, amortization, and certain other adjusted items, which can be dependent on future events that may not be reliably predicted. Based on past reported results, where one or more of these items have been applicable, such excluded items could be material, individually or in the aggregate, to reported results.

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements may include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approval of Libervant and other product candidates; statements about our growth and future financial and operating results and financial position, ability to advance Libervant and our other product candidates 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; risk of delays in FDA approval of our drug candidates or failure to receive approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk that a competitor obtains orphan drug exclusivity and blocks our product for the same indication for seven years; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; risks associated with Indivior's announcement of its intention to cease 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 sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in governmental laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K filed with the SEC 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.

PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc.

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.

AQUESTIVE THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

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

(Unaudited)

Three Months Ended

Nine Months Ended

	September 30, 2019	2018	September 30, 2019	2018
Revenues	\$ 12,418	\$ 13,267	\$ 36,190	\$ 50,606
Costs and Expenses:				
Manufacture and supply	4,643	5,592	13,569	16,201
Research and development	5,063	4,534	17,517	17,429
Selling, general and administrative	13,714	12,346	47,868	53,559
Total costs and expenses	23,420	22,472	78,954	87,189
(Loss) from operations	(11,002)	(9,205)	(42,764)	(36,583)
Other income/(expenses):				
Interest expense	(2,652)	(1,933)	(6,515)	(5,809)
Interest income	138	216	565	238
Loss on extinguishment of debt	(4,896)	-	(4,896)	-
Change in fair value of warrant	-	(4,116)	-	(5,278)
Net (loss) before income taxes	(18,412)	(15,038)	(53,610)	(47,432)
Income taxes	-	-	-	-
Net (loss)	(18,412)	(15,038)	(53,610)	(47,432)
Comprehensive (loss)	\$ (18,412)	\$ (15,038)	\$ (53,610)	\$ (47,432)
Net (loss) per share - basic and diluted	\$ (0.74)	\$ (0.64)	\$ (2.15)	\$ (2.45)
Weighted-average number of common shares outstanding - basic and diluted	25,031,478	23,646,192	24,992,229	19,335,541

AQUESTIVE THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

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

(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,914	\$ 60,599
Accounts receivable, net	10,316	6,481
Inventories, net	4,124	5,441
Prepaid expenses and other current assets	2,706	1,680
Total current assets	38,060	74,201
Property and equipment, net	10,351	12,207
Intangible assets, net	165	204
Other assets	242	239
Total assets	\$ 48,818	\$ 86,851
Liabilities and shareholders' (deficit)/equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 19,218	\$ 27,631
Deferred revenue, current	835	721
Loans payable, current	-	4,600
Total current liabilities	20,053	32,952
Loans payable, net	59,775	42,603
Deferred revenue, net of current portion	2,127	-
Asset retirement obligations	1,322	1,216
Total liabilities	83,277	76,771
Commitments and contingencies		

Shareholders' (deficit)/equity:

Common stock, \$.001 par value. Authorized 250,000,000 shares; 25,042,964 and 24,957,309

shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	25	25	
Additional paid-in capital	83,354	71,431	
Accumulated deficit	(117,838)	(61,376))
Total shareholders' (deficit)/equity	(34,459)	10,080)
Total liabilities and shareholders' (deficit) /equity	\$ 48,818	\$ 86,851	

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - GAAP Costs and Expenses to Adjusted Costs and Expenses

(In Thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total Costs and Expenses	\$ 23,420	\$ 22,472	\$ 78,954	\$ 87,189
Non-GAAP adjustments:				
Share-based Compensation Expense	(1,869)	(1,236)	(5,199)	(28,541)
Depreciation and Amortization	(707)	(746)	(2,182)	(2,476)
Adjusted Costs and Expenses	\$ 20,844	\$ 20,490	\$ 71,573	\$ 56,172

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - GAAP Manufacture and Supply Expense to Adjusted Manufacture and Supply Expense

(In Thousands, except percentages)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Manufacture and Supply Expense	\$ 4,643	\$ 5,592	\$ 13,569	\$ 16,201
Gross Margin on total revenue	63	% 58	% 63	% 68
Non-GAAP adjustments:				
Share-based Compensation Expense	(60)	(32)	(176)	(377)
Depreciation and Amortization	(572)	(602)	(1,765)	(2,003)
Adjusted Manufacture and Supply Expense	\$ 4,011	\$ 4,958	\$ 11,628	\$ 13,821
Non-GAAP Gross Margin on total revenue	68	% 63	% 68	% 73

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - GAAP Research and Development Expense to Adjusted Research and Development Expense

(In Thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and Development Expense	\$ 5,063	\$ 4,534	\$ 17,517	\$ 17,429
Non-GAAP adjustments:				
Share-based Compensation Expense	(187)	(192)	(535)	(2,378)
Depreciation and Amortization	(79)	(117)	(200)	(259)
Adjusted Research and Development Expense	\$ 4,797	\$ 4,225	\$ 16,782	\$ 14,792

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,	
	2019	2018	2019	2018
Selling, General and Administrative Expenses	\$ 13,714	\$ 12,346	\$ 47,868	\$ 53,559
Non-GAAP adjustments:				
Share-based Compensation Expense	(1,622)	(1,012)	(4,488)	(25,786)
Depreciation and Amortization	(57)	(27)	(217)	(214)
Adjusted Selling, General and Administrative Expenses	\$ 12,035	\$ 11,307	\$ 43,163	\$ 27,559

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	\$ (18,412)	\$ (15,038)	\$ (53,610)	\$ (47,432)
Share-based Compensation Expense	1,869	1,236	5,199	28,541
Interest Expense, net	2,514	1,717	5,950	5,571
Income Taxes	-	-	-	-
Depreciation and Amortization	707	746	2,182	2,476
Loss on Extinguishment of Debt	4,896	-	4,896	-
Change in Fair Value of Warrant	-	4,116	-	5,278
Adjusted EBITDA	\$ (8,426)	\$ (7,223)	\$ (35,383)	\$ (5,566)

Investor inquiries:

Stephanie Carrington

stephanie.carrington@icrinc.com

646-277-1282

Media inquiries

Mark Corbae

mark.corbae@icrinc.com

203-682-8288



Source: Aquestive Therapeutics, Inc.