



Aquestive Therapeutics Reports Third Quarter 2021 Financial Results, Provides Business Update and Improves Full Year Guidance

November 2, 2021

- Libervant™ (diazepam) Buccal Film continues to progress through the FDA review process in advance of PDUFA goal date of December 23, 2021
- AQST-109 top line Phase 1 trial demonstrates clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis
- Improves full year revenue and earnings guidance
- Hosts conference call at 8:00 a.m. ET on November 3, 2021

WARREN, N.J., Nov. 02, 2021 (GLOBE NEWSWIRE) -- 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, 2021 and provided an update on recent developments in its business.

"We continue to interact with the FDA regarding the NDA submission for Libervant, including responding to several information requests to date, having a recent inspection of our post-marketing adverse event capabilities, regarding changes in language relating to our packaging, approval of the product trade name and an update to the patent information included in the resubmission. We are continuing to prepare for commercialization with payer and sales force planning underway," said Keith Kendall, Chief Executive Officer of Aquestive. "We recently demonstrated clinical results comparable to the autoinjectors in the recently completed Phase 1 trial for AQST-109, potentially the first orally administered epinephrine product for the emergency treatment of allergic reactions, including anaphylaxis. Before year end, we anticipate receiving written feedback from the FDA following our pre-IND meeting request and plan to commence an adaptive design crossover study that will determine the final formulation and dose strength leading to our pivotal PK study in 2022."

Libervant™

Libervant™ is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for rapid treatment of acute uncontrolled seizures in selected, refractory patients with epilepsy on stable regimens of AEDs who require intermittent use of diazepam to control bouts of increased seizure activity. The Company believes that Libervant, if approved by the U.S. Food and Drug Administration (FDA) for U.S. market access, will enable a larger share of patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. Aquestive is developing Libervant as an alternative to more invasive, inconvenient, and difficult to administer device driven products, including a rectal gel and nasal spray, for patients with refractory epilepsy. A large portion of the patient population still does not access either one of these existing products and remains underserved with regard to having an important medication where they need it, when they need it and in a form they prefer.

Aquestive continues to actively engage with the FDA regarding its accepted New Drug Application (NDA) for Libervant ahead of the Prescription Drug User Fee Act (PDUFA) target goal date of December 23, 2021. Aquestive has again spoken with and provided additional information to the FDA Office of Orphan Products Development (OOPD) that the Company believes provides a clear position of clinical superiority as a major contribution to patient care as compared to the device driven rectal gel and nasal spray alternatives.

Epinephrine

Aquestive continues to advance its development of product candidate AQST-109 (epinephrine prodrug sublingual film) for the emergency treatment of severe allergic reactions, including anaphylaxis, utilizing Aquestive's PharmFilm® technologies. The Company reported positive topline data from its first-in-human Phase 1 pharmacokinetic (PK) trial for AQST-109. Findings from this study support AQST-109's potential as the first orally administered and transformative epinephrine-based product for the treatment of allergic reactions including anaphylaxis with safety, tolerability, PK and pharmacodynamics (PD) measures comparable to those of the standard of care autoinjectors, such as EpiPen® and Auvi-Q®. These products require patients or caregivers to inject epinephrine into their thighs during an emergency allergic reaction. However, AQST-109 would, if approved by the FDA, allow a patient to simply place a dissolvable strip, approximately the size and weight of a postage stamp, under the tongue, again providing an appropriate medication where it is needed, when it is needed and in a form preferred by patients.

Aquestive has submitted its request for a pre-Investigational New Drug (IND) meeting with the FDA and anticipates receiving a written response from the FDA before year end 2021. Aquestive is on track to conduct a crossover study using an adaptive design for AQST-109 beginning in the fourth quarter 2021. This study will determine the final formulation and dose for AQST-109 and allow the Company to move forward to the manufacture of registration batches and a pivotal PK study in 2022.

Sympazan®

The Company's proprietary product Sympazan® (clobazam), an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome, continued to grow in shipment volumes to the prescriber base for the third quarter 2021. Sympazan has grown quarterly over the past eleven sequential quarters since its launch.

Third Quarter 2021 Financials

Total revenues were \$13.3 million in the third quarter 2021, compared to \$8.3 million in the third quarter 2020. For the third quarter 2021 compared to the prior year period, the Company saw an 18% increase in Sympazan net revenue and a 77% increase in manufacture and supply revenue.

Aquestive's net loss for the third quarter 2021 was \$14.6 million, or \$0.37 loss per share. The net loss for the third quarter 2020 was \$16.6 million, or \$0.49 loss per share. The year-over-year change in net loss was driven by higher revenue, lower costs and expenses, offset by an increase in non-cash interest expense related to the KYNMOBI[®] monetization transaction, which does not represent a cash output or monetary obligation at any time during the life of the transaction.

Adjusted EBITDA loss was \$5.3 million in the third quarter 2021, compared to a loss of \$11.3 million in the third quarter of 2020. The year-over-year change in adjusted EBITDA was primarily driven by higher revenue and an increase in non-cash interest expense related to the KYNMOBI[®] monetization transaction, which does not represent a cash output or monetary obligation at any time during the life of the transaction.

As of September 30, 2021, cash and cash equivalents were \$31.2 million. During the third quarter 2021, Aquestive accessed capital under its "At-The-Market" (ATM) facility resulting in net proceeds of \$6.1 million.

On September 30, 2021, the Company entered into a waiver agreement with the holders of the 12.5% Notes (the "Notes") pursuant to which the principal payment due under the Notes on September 30, 2021 was deferred in order to provide sufficient time for the execution of the Fourth Supplemental Indenture of the existing debt facility. The Fourth Supplemental Indenture was subsequently executed in October 2021 which extended the date of the first amortization payment to March 30, 2023, resulting in a deferral of \$10.3M in principal payments through December 2022. The Fourth Supplemental Indenture did not change the maturity date of the Notes or the interest payment obligation due under the Notes. As part of the agreement, the Company entered into a Consent Fee Letter pursuant to which the Company agreed to pay the holders of the Notes a \$2.7 million fee, payable in four quarterly installments beginning May 15, 2022.

2021 Outlook

Sympazan and the Company's other on-going business activities generated strong operating results during the first half of 2021. As a result, the Company has revised its full year expectations as follows:

	<u>Updated Guidance</u>	<u>Prior Guidance</u>
Total revenue (in millions)	\$47 to \$49	\$46 to \$48
Non-GAAP adjusted gross margins	70% to 75%	70% to 75%
Non-GAAP adjusted EBITDA loss (in millions)	\$32 to \$34	\$39 to \$42

Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. ET on Wednesday, November 3, 2021. 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: 4285256.

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 non-GAAP 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 expense, interest expense, interest expense related to the sale of future revenue, 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 related to the sale of future revenue, interest income and other income (expense), net 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. The Company 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 the 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 2021 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, the Company adjusts for non-cash share-based compensation expense and depreciation and amortization. The Company is 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

Certain statements in this press release are “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 the clinical advancement and related timing of Libervant and AQST-109 through the regulatory and development pipeline; the potential for AQST-109 as the first orally administered epinephrine prodrug for the treatment of anaphylaxis; the focus on growing the Company’s commercial sales of Sympazan®; the ability to address the concerns identified in the FDA’s Complete Response Letter dated September 25, 2020 regarding the NDA for Libervant; obtaining FDA approval of Libervant for U.S. market access; the timing of the PDUFA target goal date; the 2021 financial outlook; and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand 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 also 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 for AQST-108, AQST-109 and our other drug candidates; risk of delays in regulatory advancement through the FDA of Libervant, AQST-108, AQST-109 and our other drug candidates or failure to receive approval, including the risk that the FDA may require additional clinical studies for FDA approval of Libervant for U.S. market access; risk of our ability to demonstrate to the FDA the “clinical superiority” of Libervant within the meaning of the FDA regulations 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 the Company 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 product candidates 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 that a competitor will obtain other market exclusivity with respect to our product candidates; risk in obtaining market access for our product candidates for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risks and uncertainties concerning the royalty and other revenue stream of the KYNMOBI® monetization, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction; risk of failure to satisfy all financial and other debt covenants and of any default; short-term and long-term liquidity and cash requirements, cash funding and cash burn; 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 of eroding market share for Suboxone and risk of a sunset 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; including anticipated sales of Sympazan®; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, securities, 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. 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.

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

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,164	\$ 31,807
Trade and other receivables, net	13,643	6,955
Inventories, net	2,863	2,461
Prepaid expenses and other current assets	2,540	3,402
Total current assets	50,210	44,625
Property and equipment, net	5,197	6,873
Right-of-use assets, net	2,917	3,448
Intangible assets, net	64	102
Other non-current assets	6,905	7,836
Total assets	\$ 65,293	\$ 62,884
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 6,215	\$ 7,089
Accrued expenses	7,624	8,569
Lease liabilities, current	860	728
Deferred revenue, current	767	693
Liability related to the sale of future revenue, current	1,848	1,450
Loans payable, current	7,725	2,575
Total current liabilities	25,039	21,104
Loans payable, net	32,673	34,329
Liability related to the sale of future revenue, net	56,615	47,524
Lease liabilities	2,185	2,846
Deferred revenue	7,316	3,633
Other non-current liabilities	1,810	1,945
Total liabilities	125,638	111,381
Contingencies (Note 19)		
Stockholders' deficit:		
Common stock, \$0.001 par value. Authorized 250,000,000 shares; 40,083,245 and 34,569,254 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	40	35
Additional paid-in capital	167,466	137,725
Accumulated deficit	(227,851)	(186,257)
Total stockholders' deficit	(60,345)	(48,497)
Total liabilities and stockholders' deficit	\$ 65,293	\$ 62,884

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,	
	2021	2020	2021	2020
Revenues	\$ 13,287	\$ 8,260	\$ 39,754	\$ 38,700
Costs and expenses:				
Manufacture and supply	4,400	2,978	11,623	10,176
Research and development	4,726	7,260	12,647	15,461
Selling, general and administrative	12,129	11,803	38,494	40,310
Total costs and expenses	21,255	22,041	62,764	65,947
Loss from operations	(7,968)	(13,781)	(23,010)	(27,247)
Other income/(expenses):				
Interest expense	(2,787)	(2,778)	(8,305)	(8,296)
Interest expense related to the sale of future revenue, net	(3,767)	—	(10,567)	—
Interest and other (expense) income, net	(33)	8	288	128

Net loss before income taxes	(14,555)	(16,551)	(41,594)	(35,415)
Income taxes	—	—	—	—
Net loss	<u>\$ (14,555)</u>	<u>\$ (16,551)</u>	<u>\$ (41,594)</u>	<u>\$ (35,415)</u>
Comprehensive loss	<u>\$ (14,555)</u>	<u>\$ (16,551)</u>	<u>\$ (41,594)</u>	<u>\$ (35,415)</u>
Net loss per share - basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.49)</u>	<u>\$ (1.12)</u>	<u>\$ (1.05)</u>
Weighted-average number of common shares outstanding - basic and diluted	39,224,863	33,619,379	37,297,892	33,592,846

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,	
	2021	2020	2021	2020
GAAP net loss	\$ (14,555)	\$ (16,551)	\$ (41,594)	\$ (35,415)
Share-based Compensation Expense	1,900	1,765	5,128	3,625
Interest expense	2,787	2,778	8,305	8,296
Interest expense related to the sale of future revenue, net	3,767	—	10,567	—
Interest and other (income) expense, net	33	(8)	(288)	(128)
Income Taxes	—	—	—	—
Depreciation and Amortization	736	754	2,233	2,337
Total non-GAAP adjustments	<u>\$ 9,223</u>	<u>\$ 5,289</u>	<u>\$ 25,945</u>	<u>\$ 14,130</u>
Adjusted EBITDA	\$ (5,332)	\$ (11,262)	\$ (15,649)	\$ (21,285)

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,	
	2021	2020	2021	2020
Total costs and expenses	\$ 21,255	\$ 22,041	\$ 62,764	\$ 65,947
Non-GAAP adjustments:				
Share-based compensation expense	(1,900)	(1,765)	(5,128)	(3,625)
Depreciation and amortization	(736)	(754)	(2,233)	(2,337)
Adjusted costs and expenses	<u>\$ 18,619</u>	<u>\$ 19,522</u>	<u>\$ 55,403</u>	<u>\$ 59,985</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,	
	2021	2020	2021	2020
Manufacture and Supply Expense	\$ 4,400	\$ 2,978	\$ 11,623	\$ 10,176
Gross Margin on total revenue	67%	64%	71%	74%
Non-GAAP adjustments:				
Share-based compensation expense	(88)	(72)	(241)	(135)
Depreciation and amortization	(579)	(617)	(1,744)	(1,163)
Adjusted manufacture and supply expense	<u>\$ 3,733</u>	<u>\$ 2,289</u>	<u>\$ 9,638</u>	<u>\$ 8,878</u>
Non-GAAP Gross Margin on total revenue	72%	72%	76%	77%

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 Nine Months Ended

	September 30,		September 30,	
	2021	2020	2021	2020
Research and Development Expense	\$ 4,726	\$ 7,260	\$ 12,647	\$ 15,461
Non-GAAP adjustments:				
Share-based compensation expense	(230)	(183)	(670)	(365)
Depreciation and amortization	(51)	(59)	(160)	(119)
Adjusted research and development expense	\$ 4,445	\$ 7,018	\$ 11,817	\$ 14,977

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,	
	2021	2020	2021	2020
Selling, General and Administrative Expenses	\$ 12,129	\$ 11,803	\$ 38,494	\$ 40,310
Non-GAAP adjustments:				
Share-based compensation expense	(1,582)	(1,510)	(4,217)	(3,125)
Depreciation and amortization	(106)	(78)	(329)	(1,055)
Adjusted selling, general and administrative expenses	\$ 10,441	\$ 10,215	\$ 33,948	\$ 36,130



Source: Aquestive Therapeutics, Inc.