



Aquestive Therapeutics Reports First Quarter 2022 Financial Results and Provides Business Update

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- FDA continues to consider orphan drug exclusivity issues regarding Libervant's NDA
- Common stock purchase agreement secured for up to \$40 million
- Part 3 of EPIPHAST trial for AQST-109 commenced in April and on track to report topline data in second quarter 2022
- Hosts investment community conference call on May 4, 2022

WARREN, N.J., May 03, 2022 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today reported financial results for the first quarter ended March 31, 2022 and provided an update on recent developments in its business.

"Aquestive has delivered upon the advancement of our clinical development program for AQST-109. We saw continued rapid absorption of AQST-109 as exemplified by the data from Parts 1 and 2 of the EPIPHAST study. Dosing recently commenced in Part 3, and we anticipate reporting topline results in June," said Keith Kendall, Chief Executive Officer of Aquestive. "While we are frustrated by the lack of resolution at the FDA even after further correspondence with the Office of Orphan Product Development (OOPD), we remain steadfast in our belief that Libervant has the potential to transform the lives of epilepsy patients. The addition of a common stock purchase agreement with Lincoln Park Capital gives us further flexibility and an additional source of capital as we fund our ongoing business."

Libervant™

Libervant™ is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. Aquestive developed Libervant as an alternative to the device-driven, invasive, inconvenient, and difficult to administer alternatives, including a rectal gel and nasal spray products, currently available for patients with refractory epilepsy.

Aquestive continues to interact with the United States Food and Drug Administration (FDA) regarding the orphan drug review of the New Drug Application (NDA) for Libervant after receiving a notification from the FDA indicating that the Agency would not be ready to act by the PDUFA target goal date of December 23, 2021 for the Company's NDA for Libervant, and the Agency was unable to provide an estimate of the timing of an expected action.

In a correspondence received in April 2022 from the Office of Orphan Product Development, the Agency communicated that:

"...[it] is actively working on the orphan-drug exclusivity issues related to your NDA. OOPD is also diligently coordinating with the relevant FDA stakeholders in considering each of the arguments raised in your communications. [The Agency] assure[s] you that these issues are top-of-mind and have not fallen off the Agency's radar. Although [we] cannot commit to a precise date for providing a response, [we] can answer that we are making all efforts to respond in a reasonable timeframe."

Epinephrine

Aquestive is advancing the clinical development of AQST-109, the first and only orally delivered epinephrine product candidate to have shown clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis.

In April 2022, Aquestive reported positive topline results from Part 2 of the EPIPHAST study for its AQST-109 epinephrine oral film. Utilizing a replicate crossover design, Part 2 confirmed in a larger population of 24 healthy subjects the key pharmacokinetic and pharmacodynamic measures that were observed in Part 1 of the EPIPHAST study as well as in the first-in-human pharmacokinetic study. The median time to maximum concentration (Tmax) in Part 2 was observed to be 15 minutes for AQST-109, compared to 50 minutes for the epinephrine 0.3mg manual intra-muscular (IM) injection. In addition to positive pharmacokinetic results, AQST-109 demonstrated favorable pharmacodynamic effects on systolic blood pressure, diastolic blood pressure, and heart rate.

Aquestive commenced Part 3 of the EPIPHAST study for its AQST-109 product candidate in April 2022 and expects to complete Part 3 by the end of the second quarter of 2022. The purpose of Part 3 is to continue studying the film's administration under a variety of conditions and further characterize its pharmacokinetics, pharmacodynamics, and safety.

Aquestive plans to conduct one additional study with AQST-109 before requesting an End-of-Phase 2 meeting with the FDA. This study will be designed as a repeat dosing comparative study of AQST-109 and 0.3 mg EpiPen and will be conducted during the third quarter of 2022. This data, along with the complete EPIPHAST study data, will be the basis for the anticipated discussion.

Aquestive received a written response from the FDA in December 2021 to its Pre-Investigational New Drug Application (IND) meeting submission confirming the development of AQST-109 for the treatment of anaphylaxis under the 505(b)(2) approval pathway is acceptable. In February 2022, Aquestive opened the IND for AQST-109 after receiving FDA clearance. The FDA granted Fast Track designation in March 2022 to AQST-109 for the emergency treatment of allergic reactions, including anaphylaxis. Fast Track is an FDA process designed to facilitate the development and expedite the review of potential therapies that seek to treat serious conditions and fill unmet medical needs.

The Company anticipates conducting an End-of-Phase 2 meeting with the FDA during the second half of 2022 and commencing the pivotal study before the end of 2022.

Lincoln Park Facility

As recently disclosed, on April 12, 2022, the Company entered into a purchase agreement ("Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which provides that, upon the terms and subject to the conditions and limitations set forth in the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to \$40 million worth of shares of its common stock, from time to time over the 36-month term of the Lincoln Park Purchase Agreement. Concurrently with entering into the Lincoln Park Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park, pursuant to which the Company agreed to register the sale of the shares of its common stock that have been and may be issued to Lincoln Park under the Lincoln Park Purchase Agreement pursuant to the Company's existing shelf registration statement on Form S-3 or a new registration statement. Lincoln Park has covenanted under the Lincoln Park Purchase Agreement not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's common stock.

Core Business

Aquestive is a commercial stage pharmaceutical company with comprehensive integrated capabilities that enable the advancement of product candidates through preclinical and clinical development, and through commercialization. Aquestive has world-class manufacturing capabilities that it has leveraged to produce more than two billion doses of PharmFilm®-based products to meet the needs of patients worldwide. The Company's commercialized portfolio consists of five FDA approved products, both proprietary and third-party licensed. Aquestive has generated more than ten years of product sales contributing to its cash flow positive business. Aquestive has a valuable intellectual property portfolio with over 200 worldwide patents and more than 75 additional patents pending that offer protection through 2037.

The Company's proprietary product Sympazan® (clobazam), an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome, has grown for thirteen straight quarters since launch.

First Quarter 2022 Financials

Total revenues were \$12.3 million in the first quarter 2022, compared to \$11.1 million in the first quarter 2021. For the first quarter 2022 compared to the prior year period, the Company saw an 21% increase in proprietary products net revenue and a 41% increase in manufacture and supply revenue.

Aquestive's net loss for the first quarter 2022 was \$13.2 million, or \$0.32 loss per share. The net loss for the first quarter 2021 was \$14.7 million, or \$0.41 loss per share. The year-over-year change in net loss was driven by higher revenue, a decrease in interest expense, and a decrease 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. This was offset by an increase in costs and expenses.

Adjusted EBITDA loss was \$8.1 million in the first quarter 2022, compared to a loss of \$6.3 million in the first quarter of 2021. The year-over-year change in adjusted EBITDA was driven by an increase in costs and expenses, offset by a decrease in interest expense, a decrease 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, and a decrease in share-based compensation expense.

2022 Outlook

Aquestive is reconfirming its full-year 2022 financial outlook.

The Company expects:

- Total revenues of approximately \$42 to \$47 million
- Non-GAAP adjusted gross margin of approximately 70% to 75%
- Non-GAAP adjusted EBITDA loss of approximately \$51 to \$58 million

Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. ET on Wednesday, May 4, 2022. 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: 8453318.

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, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut syndrome. Our licensees market their products in the U.S. and around the world. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product pipeline focused on treating diseases of the central nervous system, or CNS, and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. For more information, visit [Aquestive.com](https://www.aquestive.com) and follow us on LinkedIn.

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 2022 and 2021 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 approval of Libervant by the FDA for U.S. market access; clinical advancement and related timing of AQST-109 through the regulatory and development pipeline; the potential for AQST-109 as the first orally administered epinephrine product candidate 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; the timing of the PDUFA target goal date for Libervant; the availability of funds under the Lincoln Park Purchase Agreement; 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 due 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-109, AQST-108 and our other drug candidates; risk of delays in regulatory advancement through the FDA of Libervant, AQST-109, AQST-108, 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, including under the Company's At-The-Market facility, 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, or at all; risks and uncertainties concerning the royalty and other revenue stream of the KYNMOBI® monetization transaction, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction; risk of our ability to collect the upfront cash payment under the Company's license agreement with Haisco Pharmaceutical Group Co., Ltd.; 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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AQUESTIVE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

March 31, December 31,

	<u>2022</u>	<u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,736	\$ 28,024
Trade and other receivables, net	19,896	12,120
Inventories, net	4,629	4,038
Prepaid expenses and other current assets	3,324	3,077
Total current assets	<u>42,585</u>	<u>47,259</u>
Property and equipment, net	4,496	5,055
Right-of-use assets, net	2,524	2,725
Intangible assets, net	38	51
Other non-current assets	6,886	6,903
Total assets	<u>\$ 56,529</u>	<u>\$ 61,993</u>

Liabilities and stockholders' deficit

Current liabilities:		
Accounts payable	\$ 8,496	\$ 8,314
Accrued expenses	4,868	8,736
Lease liabilities, current	926	899
Deferred revenue, current	1,599	765
Liability related to the sale of future revenue, current	1,732	1,225
Loans payable, current	6,563	2,025
Total current liabilities	<u>24,184</u>	<u>21,964</u>
Loans payable, net	47,680	51,551
Liability related to the sale of future revenue, net	60,346	59,059
Lease liabilities	1,710	1,946
Deferred revenue	13,890	7,122
Other non-current liabilities	1,862	2,485
Total liabilities	<u>149,672</u>	<u>144,127</u>

Contingencies (Note 19)

Stockholders' deficit:

Common stock, \$0.001 par value. Authorized 250,000,000 shares; 41,620,388 and 41,228,736 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively

	41	41
Additional paid-in capital	176,833	174,621
Accumulated deficit	(270,017)	(256,796)
Total stockholders' deficit	<u>(93,143)</u>	<u>(82,134)</u>
Total liabilities and stockholders' deficit	<u>\$ 56,529</u>	<u>\$ 61,993</u>

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

	Three Months Ended March 31,	
	<u>2022</u>	<u>2021</u>
Revenues	\$ 12,270	\$ 11,122
Costs and expenses:		
Manufacture and supply	4,214	2,757
Research and development	4,773	3,659
Selling, general and administrative	13,021	13,231
Total costs and expenses	<u>22,008</u>	<u>19,647</u>
Loss from operations	(9,738)	(8,525)
Other expenses:		
Interest expense	(1,618)	(2,761)

Interest expense related to the sale of future revenue, net	(1,861)	(3,334)
Interest and other expense, net	(3)	(52)
Net loss before income taxes	(13,220)	(14,672)
Income taxes	—	—
Net loss	\$ (13,220)	\$ (14,672)
Comprehensive loss	\$ (13,220)	\$ (14,672)
Net loss per share - basic and diluted	\$ (0.32)	\$ (0.41)
Weighted-average number of common shares outstanding - basic and diluted	41,465,798	35,563,275

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

	Three Months Ended March 31,	
	2022	2021
GAAP net loss	\$ (13,220)	\$ (14,672)
Share-based Compensation Expense	913	1,507
Interest expense	1,618	2,761
Interest expense related to the sale of future revenue, net	1,861	3,334
Interest and other (income) expense, net	3	52
Income Taxes	—	—
Depreciation and Amortization	727	755
Total non-GAAP adjustments	\$ 5,122	\$ 8,409
Adjusted EBITDA	\$ (8,098)	\$ (6,263)

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

	Three Months Ended March 31,	
	2022	2021
Total costs and expenses	\$ 22,008	\$ 19,647
Non-GAAP adjustments:		
Share-based compensation expense	(913)	(1,507)
Depreciation and amortization	(727)	(755)
Adjusted costs and expenses	\$ 20,368	\$ 17,385

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 March 31,	
	2022	2021
Manufacture and Supply Expense	\$ 4,214	\$ 2,757
<i>Gross Margin on total revenue</i>	66%	75%
Non-GAAP adjustments:		
Share-based compensation expense	(48)	(82)

Depreciation and amortization	(585)	(585)
Adjusted manufacture and supply expense	\$ 3,581	\$ 2,090
<i>Non-GAAP Gross Margin on total revenue</i>	71%	81%

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 March 31,	
	2022	2021
Research and Development Expense	\$ 4,773	\$ 3,659
Non-GAAP adjustments:		
Share-based compensation expense	(169)	(232)
Depreciation and amortization	(47)	(57)
Adjusted research and development expense	\$ 4,557	\$ 3,370

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 March 31,	
	2022	2021
Selling, General and Administrative Expenses	\$ 13,021	\$ 13,231
Non-GAAP adjustments:		
Share-based compensation expense	(696)	(1,193)
Depreciation and amortization	(95)	(113)
Adjusted selling, general and administrative expenses	\$ 12,230	\$ 11,925



Source: Aquestive Therapeutics, Inc.