



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

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- Completed EPIPHAST trial successfully demonstrating rapid and significant epinephrine exposure under a variety of real-world conditions after administration of AQST-109 (epinephrine sublingual film)
- Initiated EPIPHAST II trial, comparing AQST-109 to epinephrine 0.3mg IM injection (repeat dose) and AQST-109 to EpiPen® 0.3mg (single dose)
- Expect End-of-Phase 2 meeting on AQST-109 with the FDA to occur in fourth quarter 2022 and commence definitive pivotal pharmacokinetic (PK) studies shortly thereafter
- Continued to engage with FDA on the progress and timing of the orphan drug review of the Libervant™ (diazepam buccal film) New Drug Application (NDA)
- Improves full-year revenue and earnings guidance
- Hosts investment community conference call on August 3, 2022

WARREN, N.J., Aug. 02, 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 second quarter ended June 30, 2022 and provided an update on recent developments in its business.

"We continue to focus our efforts on the advancement of our two product candidates, AQST-109 (epinephrine sublingual film) and Libervant (diazepam buccal film), as we believe patients, caregivers, and healthcare providers deserve to have access to orally administered treatment options, especially when it comes to acute rescue medications. The EPIPHAST trial provided clinical data under various conditions of use demonstrating the potential real-world utility of our epinephrine sublingual film. We believe millions of Americans, who are at risk of experiencing a severe allergic reaction and are reluctant to carry or use a medical device, may potentially benefit from AQST-109," said Daniel Barber, Chief Executive Officer of Aquestive. "In parallel, we continue to engage in dialogue with the FDA regarding Libervant. Most recently, the Agency has indicated that they are making progress and are expecting to respond in a reasonable timeframe. Given the current shortage of diazepam rectal gel for patients, which represents a majority of the current diazepam rescue market, we hope that the Agency understands the urgent need for additional alternate delivery options."

Epinephrine

Aquestive is advancing the 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.

According to expert data, as many as 49 million Americans are at chronic risk for acute anaphylactic reactions however only approximately 3 million prescriptions are filled for injectable epinephrine each year. AQST-109 has the potential to offer these at-risk individuals with an option that overcomes needle phobia and portability challenges seen with existing treatment options.

Data from the EPIPHAST study supported earlier clinical data and further characterized AQST-109 pharmacokinetics, pharmacodynamics, and safety. In addition, the study provided data assessing the impact of administering the film under real-world conditions of use where the film was used after consuming a peanut butter sandwich and swallowing the film whole immediately with water. The data from this study will be used to set optimal administration conditions for future clinical studies.

Aquestive is conducting its EPIPHAST II study, comparing AQST-109 to epinephrine 0.3mg intramuscular (IM) injection (repeat dose) and AQST-109 to EpiPen 0.3mg (single dose), and expects to report data from this study during the third quarter 2022. The data from the EPIPHAST and EPIPHAST II studies will be the basis for the End-of-Phase 2 meeting with the FDA that the Company expects to occur in the fourth quarter of 2022.

Libervant™

Libervant™ is a buccally, or inside of the cheek, administered 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-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products.

Approximately 1.0 million patients with epilepsy suffer from uncontrolled refractory seizures, approximately 85% of whom will not interact with the available treatments. Libervant has the potential to offer these patients a treatment option that is simple, portable, and precise. A significant unmet need exists for additional alternate delivery options given the ongoing shortage of

diazepam rectal gel, which represents a majority of the current diazepam rescue market.

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.

Commercial Operations

Aquestive's commercial proprietary product Sympazan® (clobazam), an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome, and its manufacturing operations producing PharmFilm® doses of commercial and pipeline products continue to grow and meet our expectations. The combined commercial operations of the business continue to provide positive cash flow to the Company.

Second Quarter 2022 Financials

Total revenues were \$13.3 million in the second quarter 2022, compared to \$15.3 million in the second quarter 2021. Excluding a one-time milestone earned from KemPharm, Inc. of \$2.0 million that was recognized in 2021, total revenue decreased by 1%. For the second quarter 2022 compared to the prior year period, the Company saw a 36% increase in Sympazan net revenue offset by reductions in manufacture and supply revenue as well as co-development and research fees.

Aquestive's net loss for the second quarter 2022 was \$16.3 million, or \$0.36 loss per share. The net loss for the second quarter 2021 was \$12.4 million, or \$0.33 loss per share. Excluding the one-time severance costs of \$2.3 million in the second quarter of 2022 and the one-time milestone from KemPharm, Inc. of \$2.0 million in the second quarter of 2021, the net loss was comparable year-over-year with a second quarter of 2022 net loss of \$14.0 million compared to a second quarter of 2021 net loss of \$14.4 million. Additional year-over-year changes in net loss were driven by higher expenses related to the advancement of AQST-109 and manufacturing offset by a decrease in interest expense and a decrease in non-cash interest expense related to the KYNMOBI® monetization transaction.

Adjusted EBITDA loss was \$9.9 million in the second quarter 2022, compared to an adjusted EBITDA loss of \$4.1 million in the second quarter of 2021. The change in adjusted EBITDA loss year over year includes a higher net loss described above, a decrease in interest expense and a decrease in non-cash interest expense related to the KYNMOBI® monetization transaction.

Cash and cash equivalents were \$17.7 million as of June 30, 2022.

2022 Outlook

Aquestive is updating its full-year 2022 financial outlook. The already implemented expense reductions, continued growth of Sympazan, the performance of our manufacturing and supply operations, and other ongoing business activities are expected to provide strong operating results during 2022. Spending on R&D will continue to focus on the continued development of AQST-109 during 2022. Our updated full year financial expectations as follows:

The Company expects:

	Updated Guidance	Prior Guidance
Total revenue (in millions)	\$46 to \$49	\$42 to \$47
Non-GAAP adjusted gross margins	70% to 75%	70% to 75%
Non-GAAP adjusted EBITDA loss (in millions)	\$37 to \$43	\$51 to \$58

Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. ET on Wednesday, August 3, 2022.

In order to participate, please register in advance [here](#) to obtain a local or toll-free phone number and your personal pin.

A live webcast of the call will be available on Aquestive's website at: [Second Quarter 2022 Results](#). 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](#) 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 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; the ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the NDA for Libervant; 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)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,695	\$ 28,024
Trade and other receivables, net	19,165	12,120
Inventories, net	5,008	4,038
Prepaid expenses and other current assets	1,637	3,077
Total current assets	43,505	47,259
Property and equipment, net	4,569	5,055
Right-of-use assets, net	2,314	2,725
Intangible assets, net	25	51
Other non-current assets	5,897	6,903
Total assets	<u>\$ 56,310</u>	<u>\$ 61,993</u>

Liabilities and stockholders' deficit

Current liabilities:

Accounts payable	\$ 8,887	\$ 8,314
Accrued expenses	7,042	8,736
Lease liabilities, current	913	899
Deferred revenue, current	1,599	765
Liability related to the sale of future revenue, current	1,445	1,225
Loans payable, current	9,750	2,025
Total current liabilities	29,636	21,964
Loans payable, net	43,821	51,551
Liability related to the sale of future revenue, net	61,839	59,059
Lease liabilities	1,502	1,946
Deferred revenue	13,490	7,122
Other non-current liabilities	2,379	2,485
Total liabilities	152,667	144,127

Contingencies

Stockholders' deficit:

Common stock, \$0.001 par value. Authorized 250,000,000 shares; 53,343,989 and 41,228,736 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively

	53	41
Additional paid-in capital	189,908	174,621
Accumulated deficit	(286,318)	(256,796)
Total stockholders' deficit	(96,357)	(82,134)
Total liabilities and stockholders' deficit	\$ 56,310	\$ 61,993

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues	\$ 13,265	\$ 15,345	\$ 25,535	\$ 26,467
Costs and expenses:				
Manufacture and supply	5,242	4,466	9,456	7,223
Research and development	5,198	4,262	9,971	7,921
Selling, general and administrative	15,587	13,134	28,608	26,365
Total costs and expenses	26,027	21,862	48,035	41,509
Loss from operations	(12,762)	(6,517)	(22,500)	(15,042)
Other income/ (expenses):				
Interest expense	(1,635)	(2,757)	(3,253)	(5,518)
Interest expense related to the sale of future revenue, net	(1,937)	(3,466)	(3,798)	(6,800)
Interest and other income, net	32	373	29	321
Net loss before income taxes	(16,302)	(12,367)	(29,522)	(27,039)
Income taxes	—	—	—	—
Net loss	\$ (16,302)	\$ (12,367)	\$ (29,522)	\$ (27,039)
Comprehensive loss	\$ (16,302)	\$ (12,367)	\$ (29,522)	\$ (27,039)
Net loss per share - basic and diluted	\$ (0.36)	\$ (0.33)	\$ (0.68)	\$ (0.74)
Weighted-average number of common shares outstanding - basic and diluted	45,462,516	37,065,300	43,475,198	36,318,437

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP net loss	\$ (16,302)	\$ (12,367)	\$ (29,522)	\$ (27,039)
Share-based Compensation Expense	2,221	1,721	3,134	3,228
Interest expense	1,635	2,757	3,253	5,518
Interest expense related to the sale of future revenue, net	1,937	3,466	3,798	6,800
Interest and other (income) expense, net	(32)	(373)	(29)	(321)
Income Taxes	—	—	—	—
Depreciation and Amortization	667	742	1,394	1,497
Total non-GAAP adjustments	\$ 6,428	\$ 8,313	\$ 11,550	\$ 16,722
Adjusted EBITDA	\$ (9,874)	\$ (4,054)	\$ (17,972)	\$ (10,317)

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,	
	2022	2021	2022	2021
Total costs and expenses	\$ 26,027	\$ 21,862	\$ 48,035	\$ 41,509
Non-GAAP adjustments:				
Share-based compensation expense	(2,221)	(1,721)	(3,134)	(3,228)
Depreciation and amortization	(667)	(742)	(1,394)	(1,497)
Adjusted costs and expenses	\$ 23,139	\$ 19,399	\$ 43,507	\$ 36,784

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,	
	2022	2021	2022	2021
Manufacture and Supply Expense	\$ 5,242	\$ 4,466	\$ 9,456	\$ 7,223
<i>Gross Margin on total revenue</i>	60%	71%	63%	73%
Non-GAAP adjustments:				
Share-based compensation expense	(45)	(71)	(93)	(153)
Depreciation and amortization	(529)	(580)	(1,114)	(1,165)
Adjusted manufacture and supply expense	\$ 4,668	\$ 3,815	\$ 8,249	\$ 5,905
<i>Non-GAAP Gross Margin on total revenue</i>	65%	75%	68%	78%

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and Development Expense	\$ 5,198	\$ 4,262	\$ 9,971	\$ 7,921
Non-GAAP adjustments:				
Share-based compensation expense	(162)	(208)	(331)	(440)

Depreciation and amortization	(46)	(52)	(93)	(109)
Adjusted research and development expense	\$ 4,990	\$ 4,002	\$ 9,547	\$ 7,372

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Selling, General and Administrative Expenses	\$ 15,587	\$ 13,134	\$ 28,608	\$ 26,365
Non-GAAP adjustments:				
Share-based compensation expense	(2,014)	(1,442)	(2,710)	(2,635)
Depreciation and amortization	(92)	(110)	(187)	(223)
Adjusted selling, general and administrative expenses	\$ 13,481	\$ 11,582	\$ 25,711	\$ 23,507



Source: Aquestive Therapeutics, Inc.