Aquestive Therapeutics Reports Second Quarter 2023 Financial Results and Provides Business Update

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- Submitted proposed pivotal trial protocol for Anaphylm™ (epinephrine) Sublingual Film to the FDA
- Submitted an NDA to the FDA for Libervant™ (diazepam) Buccal Film for patients between two and five years of age
- Reported 24% year-over-year growth in quarterly revenue adjusted for the out-license of Sympazan®
- Raises full year 2023 revenue and improves non-GAAP adjusted EBITDA loss guidance
- To host investment community conference call at 8:00 am ET on August 8, 2023

WARREN, N.J., Aug. 07, 2023 (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, 2023 and provided an update on recent developments in its business.

“Our strong second quarter 2023 results continue to drive the Company forward,” said Daniel Barber, Chief Executive Officer of Aquestive. “At the beginning of the year, we outlined five key initiatives for the Company in 2023. Now that we are halfway through the year, I am delighted with the progress the team has made against these initiatives. We have meaningfully progressed both Anaphylm and Libervant, expanded our collaborations, strengthened our balance sheet, and continued to explore expanding our capabilities. Our focus is now on the important upcoming inflection points that we expect to occur in the second half of the year.”

Anaphylm ™
Aquestive is advancing the development of Anaphylm, the first and only non-invasive, orally delivered epinephrine product candidate to demonstrate clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of severe allergic reactions, including anaphylaxis.

In May 2023, Aquestive released topline clinical data from recent pilot studies that were completed following the End-of-Phase 2 meeting with the U.S. Food and Drug Administration (“FDA”). These studies included examining (1) differences in pharmacokinetic (PK) results based on changes to administration instructions, (2) additional repeat dose data on Anaphylm, and (3) the differences between approved autoinjectors.

In July 2023, Aquestive announced positive topline data from pilot PK study AQ109103 (the “103” study) that was designed to establish the finalized dosing instructions expected for use in the upcoming pivotal PK clinical trial. As previously stated by the Company, the 103 study demonstrated that Anaphylm, using the finalized dosing administration instructions, delivers epinephrine systemically as effectively as either commercially available autoinjectors or the manual intramuscular (IM) injection. Importantly, in the 103 study, the Anaphylm 12mg data met all of the critical parameters, including maximum concentration (Cmax) and partial area under the curve (pAUCs), during the critical early time periods by falling between the levels demonstrated for comparator products (bracketing) that the Company anticipates measuring in the pivotal PK clinical trial. The Anaphylm 12mg also generated Tmax data similar to the autoinjectors. In the 103 study, Anaphylm was safe and well-tolerated with no serious adverse events.

In August 2023, Aquestive submitted a revised protocol for the proposed pivotal PK clinical trial to the FDA. The Company intends to commence the pivotal trial in the fourth quarter 2023, following alignment with the FDA.

Libervant ™
Libervant was tentatively approved by the FDA in August 2022 for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient’s usual seizure pattern in patients with epilepsy 12 years of age and older. Importantly, the recommended dosage of Libervant considers the impact of food and may be administered without regard to food. This is a critical feature for a product intended for urgent and acute use.

In June 2023, Aquestive submitted an NDA to the FDA for approval of Libervant™ (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients between two and five years of age. The Company expects to hear from the FDA on the acceptance of the application within approximately two months.

The NDA for Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients twelve years of age and older is currently subject to an orphan drug market exclusivity block until January 2027 based on an FDA approved nasal spray product. The Company submitted clinical data to the FDA in September 2022 to address the orphan drug market exclusivity block. The Company continues to engage with the FDA on Libervant’s approval for U.S. market access and remains committed to bringing Libervant to patients.

Commercial Collaborations
Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 48 million doses in the second quarter 2023, compared to 47 million in the second quarter 2022.

Sales of royalty-based products Sympazan® (clobazam) oral film, for the treatment of seizures associated with Lennox-Gastaut Syndrome in patients 2 years of age and older, and Azstarys®, for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older, continued to improve in the second quarter of 2023.

Second Quarter 2023 Financials
Excluding the impact of prior year proprietary sales of Sympazan, total revenues increased from $10.7 million in the second quarter 2022 to $13.2 million in the second quarter 2023. This 24% increase in revenue was primarily driven by higher revenue from the Company's five out-licensed products.

Total reported revenues were $13.2 million in the second quarter 2023, compared to $13.3 million in the second quarter 2022. For the second quarter 2023 compared to the prior year period, the Company saw an 168% increase in license and royalty revenue, a 49% decrease in co-development and research fees, and an 18% increase in manufacture and supply revenue.

Aquestive's net loss for the second quarter 2023 was $5.8 million, or $0.10, for both basic and diluted loss per share. The net loss for the second quarter 2022 was $16.3 million, or $0.36, for both basic and diluted loss per share. The decrease in net loss was primarily driven by increases in revenue described above, and decreases in selling, general and administrative expenses and research and development expenses, and non-cash interest expense related to the KYNMOBI® monetization transaction.

Non-GAAP Adjusted EBITDA loss was $3.3 million in the second quarter 2023, compared to a Non-GAAP Adjusted EBITDA loss of $9.9 million in the second quarter 2022.

Cash and cash equivalents were $22.4 million as of June 30, 2023.

2023 Outlook
Aquestive is updating its full-year 2023 financial guidance based on second quarter 2023 results and updated outlook for the remainder of 2023.

The Company expects:

	Updated Guidance	Prior Guidance
Total revenue (in millions)	$44 to $48	$42 to $46
Non-GAAP adjusted EBITDA loss (in millions)	$19 to $22	$24 to $28

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Tuesday, August 8, 2023.

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 2023, 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 marketed by its licensees in the U.S. and around the world, and is the exclusive manufacturer of these licensed products. 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 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 2023 and 2022 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 include "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 advancement and related timing of our product candidate Anaphylm™ (epinephrine sublingual film) through clinical development and approval by the FDA, including the Company's ability to provide sufficient data in its NDA submission to address the FDA's concerns following the End-of-Phase 2 meeting with the FDA; statements regarding the approval of Libervant™ (diazepam) Buccal Film by the FDA for U.S. market access and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product extending to January 2027; statements regarding the advancement and related timing of the Company's NDA for Libervant for the treatment of patients between two and five years of age; statements regarding the potential benefits our products, including Anaphylm and Libervant, could bring to patients; statements regarding the potential and related timing for expanding the Company's manufacturing capabilities and supporting the growth of demand for existing and potential future licensed products in the U.S. and other countries; statements regarding the Company's ability to execute on its key initiatives and strengthen its balance sheet, available cash and cash equivalents and the ability to fund our business operations; statements regarding the 2023 financial outlook of the Company; statements about our growth and future financial and operating results and financial position; and business strategies, market opportunities, financing 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 the Company's business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

These forward-looking statements are based on the Company's 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 the Company's product development activities and clinical trials for Anaphylm and other product candidates; risk of the Company's failure to generate sufficient data in its NDA submission for FDA approval of Anaphylm; risk of the Company's failure to address the concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm, including the risk that the FDA may require additional clinical studies for FDA approval of Anaphylm, and there can be no assurance that the Company will be successful in obtaining such approval; risks that the FDA will not approve Libervant for U.S. market access by overcoming the seven year orphan drug market exclusivity of an FDA approved nasal spray product in effect until January 2027, and there can be no assurance that the Company will be successful in obtaining such approval; risk of delays in or the failure to receive FDA approval of the NDA for Libervant for patients between two and five years of age, including the risk that the FDA may require additional clinical studies for FDA approval of Libervant for this age group, and there can be no assurance that the Company will be successful in obtaining such approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of our ability to license our proprietary products in the U.S. or abroad and risks that such product candidates will receive regulatory approval in those licensed territories; risk of our ability to enter into other commercial transactions with third parties that will support growth of the business and execution of key initiatives; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's short-term and longer term liquidity and 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; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk that we are unable to refinance our current corporate debt on terms and conditions satisfactory to the Company, or not at all; risk of eroding market share for Suboxone® and risk of a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of the rate and degree of market acceptance of our licensed and product candidates in the U.S. and abroad; 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; uncertainties related to general economic, political, business, industry, regulatory, financial and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K and our other filings with the Securities and 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 the Company or any person acting on its 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.

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AQUESTIVE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

(Unaudited)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 22,436	$ 27,273
Trade and other receivables, net	10,101	4,704
Inventories, net	5,950	5,780
Prepaid expenses and other current assets	1,301	2,131
Total current assets	39,788	39,888
Property and equipment, net	4,602	4,085
Right-of-use assets, net	5,778	5,211
Intangible assets, net	1,357	1,435
Other non-current assets	5,469	6,451
Total assets	$ 56,994	$ 57,070
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 10,689	$ 9,946
Accrued expenses	4,263	7,967
Lease liabilities, current	347	255
Deferred revenue, current	3,992	1,513
Liability related to the sale of future revenue, current	1,000	1,147
Loans payable, current	18,362	18,700
Total current liabilities	38,653	39,528
Loans payable, net	20,801	33,448
Liability related to the sale of future revenue, net	63,455	64,112
Lease liabilities	5,610	5,085
Deferred revenue	33,120	31,417
Other non-current liabilities	2,006	2,034
Total liabilities	163,645	175,624
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 61,615,959 and 54,827,734 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	62	55
Additional paid-in capital	202,218	192,598
Accumulated deficit	(308,931)	(311,207)
Total stockholders' deficit	(106,651)	(118,554)
Total liabilities and stockholders' deficit	$ 56,994	$ 57,070

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues	$ 13,241	$ 13,265	$ 24,375	$ 25,535
Costs and expenses:				
Manufacture and supply	6,617	5,242	11,354	9,456
Research and development	3,473	5,198	7,020	9,971
Selling, general and administrative	7,360	15,587	14,815	28,608
Total costs and expenses	17,450	26,027	33,189	48,035
Loss from operations	(4,209)	(12,762)	(8,814)	(22,500)
Other income/ (expenses):				
Interest expense	(1,373)	(1,635)	(2,808)	(3,253)
Interest expense related to the sale of future revenue, net	(55)	(1,937)	(107)	(3,798)
Interest and other income (expense), net	129	32	14,642	29

Loss on extinguishment of debt	—	—	(353)	—
Net income (loss) before income taxes	(5,508)	(16,302)	2,560	(29,522)
Income taxes	284	—	284	—
Net income (loss)	$ (5,792)	$ (16,302)	$ 2,276	$ (29,522)
Comprehensive income (loss)	$ (5,792)	$ (16,302)	$ 2,276	$ (29,522)
Earnings (loss) per share attributable to common stockholders:				
Basic (in dollars per share)	$ (0.10)	$ (0.36)	$ 0.04	$ (0.68)
Diluted (in dollars per share)	(0.10)	(0.36)	$ 0.04	$ (0.68)
Weighted average common shares outstanding:				
Basic (in shares)	57,350,902	45,462,516	56,494,805	43,475,198
Diluted (in shares)	57,350,902	45,462,516	58,938,222	43,475,198

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP net loss	$ (5,792)	$ (16,302)	$ 2,276	$ (29,522)
Share-based Compensation Expense	648	2,221	992	3,134
Interest expense	1,373	1,635	2,808	3,253
Interest expense related to the sale of future revenue, net	55	1,937	107	3,798
Interest and other (income) expense, net	(129)	(32)	(14,642)	(29)
Loss on extinguishment of debt	—	—	353	—
Income Taxes	284	—	284	—
Depreciation and Amortization	289	667	614	1,394
Total non-GAAP adjustments	$ 2,520	$ 6,428	$ (9,484)	$ 11,550
Adjusted EBITDA	$ (3,272)	$ (9,874)	$ (7,208)	$ (17,972)

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,	
	2023	2022	2023	2022
Total costs and expenses	$ 17,450	$ 26,027	$ 33,189	$ 48,035
Non-GAAP adjustments:				
Share-based compensation expense	(648)	(2,221)	(992)	(3,134)
Depreciation and amortization	(289)	(667)	(614)	(1,394)
Adjusted costs and expenses	$ 16,513	$ 23,139	$ 31,583	$ 43,507

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,	
	2023	2022	2023	2022
Manufacture and Supply Expense	$ 6,617	$ 5,242	$ 11,354	$ 9,456
Gross Margin on total revenue	*50%*	*60%*	*53%*	*63%*
Non-GAAP adjustments:				
Share-based compensation expense	(55)	(45)	(96)	(93)
Depreciation and amortization	(251)	(529)	(532)	(1,114)

Adjusted manufacture and supply expense	$ 6,311	$ 4,668	$ 10,726	$ 8,249
Non-GAAP Gross Margin on total revenue	*52%*	*65%*	*56%*	*68%*

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,	
	2023	**2022**	**2023**	**2022**
Research and Development Expense	$ 3,473	$ 5,198	$ 7,020	$ 9,971
Non-GAAP adjustments:				
Share-based compensation expense	(100)	(162)	(172)	(331)
Depreciation and amortization	(23)	(46)	(48)	(93)
Adjusted research and development expense	$ 3,350	$ 4,990	$ 6,800	$ 9,547

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,	
	2023	**2022**	**2023**	**2022**
Selling, General and Administrative Expenses	$ 7,360	$ 15,587	$ 14,815	$ 28,608
Non-GAAP adjustments:				
Share-based compensation expense	(493)	(2,014)	(724)	(2,710)
Depreciation and amortization	(15)	(92)	(34)	(187)
Adjusted selling, general and administrative expenses	$ 6,852	$ 13,481	$ 14,057	$ 25,711