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

05.02.23 at 4:31 PM EDT

- Continues to advance development of AQST-109 (epinephrine sublingual film); received FDA conditional approval of brand name Anaphylm™
- Raises full year 2023 revenue and non-GAAP adjusted EBITDA guidance
- Reaffirms commitment to pursue early market access for Libervant™ (diazepam) Buccal Film
- Obtains dismissal of outstanding shareholder lawsuits
- Generated $47 million non-dilutive cash in the last 12 months
- Hosts investment community conference call on May 3, 2023

WARREN, N.J., May 02, 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 first quarter ended March 31, 2023 and provided an update on recent developments in its business.

“Our first quarter 2023 results continue to drive the Company towards important upcoming inflection points,” said Daniel Barber, Chief Executive Officer of Aquestive. “We achieved strong year-over-year revenue and EBITDA growth in our commercial collaboration and manufacturing business, significantly reduced our debt, and continued to execute on all of our key 2023 initiatives. We will seek to carry this momentum into the rest of the year as we focus on meeting our product development milestones and pursuing opportunities to secure additional collaborations and refinancing our debt.”

Anaphylm ™
Aquestive is advancing the development of Anaphylm, the first and only non-device based, 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.

The United States Food and Drug Administration (FDA) has conditionally accepted the proprietary name Anaphylm™ (pronounced “ana-PHYLM”) as the proposed brand name for AQST-109, the Company’s polymer matrix-based epinephrine prodrug administered as a sublingual film in development for the treatment of severe allergic reactions, including anaphylaxis. Final approval of the Anaphylm™ proprietary name is conditioned on FDA approval of the product candidate, AQST-109.

Aquestive received final minutes in December 2022 from the End-of-Phase 2 (EOP2) meeting with the FDA and obtained further clarification from the FDA in March 2023 indicating that the Company should submit its pivotal study protocol for review once the Company selects its reference listed drugs (RLDs). The Company has completed additional studies to identify the appropriate autoinjector RLDs and continues to work on the optimal administration parameters. Aquestive expects to submit a revised pivotal trial protocol to the FDA and commence the pivotal trial immediately following alignment with the FDA.

Commercial Collaborations
Aquestive is continuing to manufacture products for the licensing and supply collaborations that it has established. The Company continues to anticipate strong order demand for the manufacture of Indivior’s Suboxone ® Sublingual Film, as well as to support the continued growth of Hypera’s Ondif ® (ondansetron) Oral Film in Brazil and the ongoing marketing efforts of Assertio with Sympazan® (clobazam) Oral Film.

In March 2023, Aquestive expanded its exclusive license and supply agreement with Atnahs Pharma UK Limited (“Pharmanovia”) for Libervant ™ (diazepam) Buccal Film to cover the rest of the world, excluding the United States, Canada, and China. The original licensing agreement with Pharmanovia announced in September 2022 covered the European Union, United Kingdom, Sweden, Switzerland, and Norway, as well as countries in the Middle East and North Africa (MENA). Pursuant to the expanded agreement, Aquestive will serve as the exclusive sole manufacturer and supplier for the product and Pharmanovia will be responsible for all regulatory and commercialization activities. Aquestive received an undisclosed upfront payment and, if approved for market access, will receive additional milestone payments and double-digit royalties on net sales of the diazepam buccal film in the licensed territories.

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.

Libervant is subject to an orphan drug market exclusivity block until January 2027 based on a competing 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 exclusivity block and remains committed to bringing Libervant to patients.

Litigation Update
The Company recently won two important court decisions resulting in the final dismissal of two shareholder litigation cases against the Company. On April 10, 2023, the United States District Court for the District of New Jersey (the "New Jersey District Court") dismissed with prejudice the federal securities class action brought by a purported shareholder, *Deanna Lewakowski v. Aquestive Therapeutics, Inc., et al.* In a separate ruling on April 21, 2023 by the same judge presiding in the securities class action, the New Jersey District Court dismissed with prejudice a related shareholder derivative lawsuit, *Loreen Niewenhuis v. Keith Kendall, et al*., bringing both actions to a close.

The Company is pleased that the court acknowledged that these two lawsuits were without merit and that the Company was able to avoid defending these cases in trials and is now able to focus its efforts on its core business and executing on its key initiatives.

First Quarter 2023 Financials
Excluding the impact of prior year proprietary sales of Sympazan, total revenues increased from $10.1 million in the first quarter of 2022 to $11.1 million in the first quarter 2023. This 10% increase in revenue was primarily driven by higher revenue from licensed products including Suboxone from Indivior, Ondif from Hypera and Sympazan from Assertio.

Total reported revenues were $11.1 million in the first quarter 2023, compared to $12.3 million in the first quarter 2022. For the first quarter 2023 compared to the prior year period, the Company saw an 82% increase in license and royalty revenue, a 12% increase in co-development and research fees, and a 6% increase in manufacture and supply revenue.

Aquestive's net income for the first quarter 2023 was $8.1 million, or $0.15 basic earnings per share and $0.11 diluted earnings per share. The net loss for the first quarter 2022 was $13.2 million, or $0.32 for both basic and diluted loss per share. The change in net income was primarily driven by $14.5 million of other income, which consisted of $6.0 million related to the amendment to the Indivior Commercial Exploitation Agreement, and $8.5 million from the patent litigation settlement with BioDelivery Sciences International, Inc., as well as decreases in selling, general and administrative expenses and research and development expenses and non-cash interest expense related to the KYNMOBI® monetization transaction. These decreases in expenses were partially offset by lower revenue due to the outlicensing of Sympazan.

Non-GAAP Adjusted EBITDA loss was $3.9 million in the first quarter 2023, compared to an adjusted EBITDA loss of $8.1 million in the first quarter of 2022.

Cash and cash equivalents were $26.9 million as of March 31, 2023.

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

The Company expects:

	Updated Guidance	Prior Guidance
Total revenue (in millions)	$42 to $46	$37 to $41
Non-GAAP adjusted EBITDA loss (in millions)	$24 to $28	$31 to $36

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Wednesday, May 3, 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: **First 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 new drug application (NDA) submission to address the FDA's concerns; statements regarding the potential benefits our products could bring to patients; statements regarding the approval of Libervant by the FDA for U.S. market access and overcoming the orphan drug market exclusivity of a competing FDA approved nasal spray product extending to January 2027; statements regarding the demand for the manufacture of Indivior's Suboxone® Sublingual Film and other licensed products; 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 entering into commercial transactions with other companies and potential milestone, royalty and supply payments thereunder; statements regarding potential outlicensing of our product pipeline, including Libervant and Anaphylm in the U.S. and abroad; statements regarding our ability to refinance our existing debt; 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 competing product in effect until January 2027, 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 out 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.

Investor inquiries:
ICR Westwicke
Stephanie Carrington
stephanie.carrington@westwicke.com
646-277-1282

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 26,882	$ 27,273
Trade and other receivables, net	7,551	4,704
Inventories, net	6,981	5,780
Prepaid expenses and other current assets	2,292	2,131
Total current assets	43,706	39,888
Property and equipment, net	3,814	4,085
Right-of-use assets, net	5,884	5,211
Intangible assets, net	1,396	1,435
Other non-current assets	6,485	6,451
Total assets	$ 61,285	$ 57,070
Liabilities and stockholders' deficit		

Current liabilities:		
Accounts payable	$ 12,440	$ 9,946
Accrued expenses	4,508	7,967
Lease liabilities, current	328	255
Deferred revenue, current	4,765	1,513
Liability related to the sale of future revenue, current	1,147	1,147
Loans payable, current	17,195	18,700
Total current liabilities	40,383	39,528
Loans payable, net	25,196	33,448
Liability related to the sale of future revenue, net	64,137	64,112
Lease liabilities	5,706	5,085
Deferred revenue	33,039	31,417
Other non-current liabilities	2,059	2,034
Total liabilities	170,520	175,624
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 55,922,361 and 54,827,734 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	56	55
Additional paid-in capital	193,848	192,598
Accumulated deficit	(303,139)	(311,207)
Total stockholders' deficit	(109,235)	(118,554)
Total liabilities and stockholders' deficit	$ 61,285	$ 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 March 31,	
	2023	**2022**
Revenues	$ 11,134	$ 12,270
Costs and expenses:		
Manufacture and supply	4,737	4,214
Research and development	3,547	4,773
Selling, general and administrative	7,455	13,021
Total costs and expenses	15,739	22,008
Loss from operations	(4,605)	(9,738)
Other income/ (expenses):		
Interest expense	(1,435)	(1,618)
Interest expense related to the sale of future revenue, net	(52)	(1,861)
Interest and other income (expense), net	14,513	(3)
Loss on extinguishment of debt	(353)	—
Net income (loss) before income taxes	8,068	(13,220)
Income taxes	—	—
Net income (loss)	$ 8,068	$ (13,220)
Comprehensive income (loss)	$ 8,068	$ (13,220)
Earnings (loss) per share attributable to common stockholders:		
Basic (in dollars per share)	$ 0.15	$ (0.32)
Diluted (in dollars per share)	$ 0.11	$ (0.32)
Weighted average common shares outstanding:		
Basic (in shares)	55,631,947	41,465,798

Diluted (in shares)	73,792,886	41,465,798

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

	Three Months Ended March 31,	
	2023	**2022**
GAAP net loss	$ 8,068	$ (13,220)
Share-based Compensation Expense	344	913
Interest expense	1,435	1,618
Interest expense related to the sale of future revenue, net	52	1,861
Interest and other (income) expense, net	(14,513)	3
Loss on extinguishment of debt	353	—
Income Taxes	—	—
Depreciation and Amortization	325	727
Total non-GAAP adjustments	$ (12,004)	$ 5,122
Adjusted EBITDA	$ (3,936)	$ (8,098)

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

	Three Months Ended March 31,	
	2023	**2022**
Total costs and expenses	$ 15,739	$ 22,008
Non-GAAP adjustments:		
Share-based compensation expense	(344)	(913)
Depreciation and amortization	(325)	(727)
Adjusted costs and expenses	$ 15,070	$ 20,368

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,	
	2023	**2022**
Manufacture and Supply Expense	$ 4,737	$ 4,214
Gross Margin on total revenue	*57%*	*66%*
Non-GAAP adjustments:		
Share-based compensation expense	(41)	(48)
Depreciation and amortization	(281)	(585)
Adjusted manufacture and supply expense	$ 4,415	$ 3,581
Non-GAAP Gross Margin on total revenue	*60%*	*71%*

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,	
	2023	**2022**
Research and Development Expense	$ 3,547	$ 4,773
Non-GAAP adjustments:		
Share-based compensation expense	(72)	(169)
Depreciation and amortization	(25)	(47)
Adjusted research and development expense	$ 3,450	$ 4,557

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,	
	2023	**2022**
Selling, General and Administrative Expenses	$ 7,455	$ 13,021
Non-GAAP adjustments:		
Share-based compensation expense	(231)	(696)
Depreciation and amortization	(19)	(95)
Adjusted selling, general and administrative expenses	$ 7,205	$ 12,230

Source: Aquestive Therapeutics, Inc.