Liquidia Corporation Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 4, 2023

MORRISVILLE, N.C., May 04, 2023 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) today reported financial results for the first quarter ended March 31, 2023. The Company will host a webcast at 8:30 a.m. ET to discuss the financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "We have heard from the physician community about the increasing demand for inhaled treprostinil to treat both pulmonary arterial hypertension (PAH) and pulmonary hypertension with interstitial lung disease (PH-ILD). With specific regard to PH-ILD, it is clear that the need for inhaled products to treat this previously underdiagnosed and untreated population will significantly surpass that of PAH. Based on conversations with physicians, we believe that patients with PH-ILD, who commonly suffer from lung restriction and impaired respiratory effort, may benefit from an inhaled formulation of treprostinil enabled by PRINT Technology and administered with a low-resistance dry powder inhaler. This enthusiastic feedback from physicians continues to strengthen our commitment to bring YUTREPIA™ (treprostinil) inhalation powder to patients as quickly as possible."

Corporate Updates

Secured access to additional capital with revenue interest financing. In January, HealthCare Royalty (HCRx) agreed to provide Liquidia an aggregate of up to $100 million upon certain events. To date, HCRx has funded $32.5 million, of which $22.2 million was used to repay the then existing debt obligations to Silicon Valley Bank (SVB), with excess proceeds of approximately $9.6 million funded to the Company after deduction of transaction costs. Liquidia may receive three additional tranches of funding: $7.5 million to support any acquisition of rights to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension; $35 million upon the earlier of regulatory approval of YUTREPIA or a favorable resolution of the ongoing patent litigation with United Therapeutics Corporation (UTC); and $25 million to be drawn upon the mutual agreement of the parties. In exchange for the total investment, HCRx will receive a tiered royalty on net revenue generated by YUTREPIA and other products marketed by Liquidia. The specific tiered royalty rates range between 0.36% to 10.0%, depending upon the total amount advanced to Liquidia and achievement of certain annual net sales thresholds. HCRx will also receive certain fixed quarterly payments. The aggregate payments to HCRx are capped at 175% of the total amounts advanced by HCRx, with the potential for a true-up payment to be made by Liquidia if HCRx's internal rate of return is less than 18% on the date the cap is reached.

Advanced appeals of legal rulings in Hatch-Waxman and PTAB litigation. On May 3, 2023, the Company presented oral arguments to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in the appeal of the decision of the District Court in the Hatch-Waxman litigation initiated by UTC. UTC is appealing the District Court's ruling related to U.S. Patent No. 9,593,066 (the '066 Patent) which found five of the six asserted claims of the '066 Patent are invalid and that the remaining asserted claim is not infringed by Liquidia. Liquidia is appealing the District Court's decision with respect to U.S. Patent No. 10,716,793 (the '793 Patent) which found that all of the claims of the '793 Patent were valid and infringed by Liquidia based on the arguments that were presented by Liquidia in the Hatch-Waxman Litigation.

Concurrently, in April 2023, UTC initiated an appeal to the Federal Circuit of the decision by the Patent Trial and Appeal Board (PTAB) to invalidate the '793 patent. The PTAB found in July 2022 that all claims of the '793 Patent are unpatentable based on obviousness. In February 2023, the PTAB reaffirmed that decision when it denied UTC's request for a rehearing. Should the Federal Circuit affirm the PTAB's decision, the PTAB's decision would override any finding in the Hatch-Waxman litigation that Liquidia has breached any valid claims of the '793 Patent.

Liquidia continues to anticipate that it will reach final legal resolution in late 2023 or the first half of 2024.

First Quarter 2023 Financial Results

Cash totaled $94.4 million as of March 31, 2023. During the three months ended March 31, 2023, the Company received $31.8 million net proceeds from the revenue interest financing agreement net of costs, of which $22.2 million was used to repay the Amended and Restated Loan and Security Agreement with SVB (the A&R SVB LSA) entered into in January 2022.

Revenue was $4.5 million for the three months ended March 31, 2023, compared to $3.5 million for the three months ended March 31, 2022. Revenue related primarily to the Promotion Agreement. The increase of $1.0 million was primarily due to increased quantities and favorable gross-to-net rebate adjustments.

Cost of revenue was $0.7 million for both the three months ended March 31, 2023 and 2022. Cost of revenue related to the Promotion Agreement as noted above.

Research and development expenses were $5.3 million for the three months ended March 31, 2023, compared with $4.7 million for the three months ended March 31, 2022. The increase of $0.6 million or 12% was primarily due to a $0.5 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA.

General and administrative expenses were $7.8 million for the three months ended March 31, 2023, compared with $12.5 million for the three months ended March 31, 2022. The decrease of $4.7 million or 38% was primarily due to a $4.0 million decrease in legal fees related to ongoing YUTREPIA-related litigation and a $1.8 million decrease in stock-based compensation expense driven by an option modification charge recorded in 2022. These decreases were offset by a $1.1 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA.

Other expenses, net was $2.5 million for the three months ended March 31, 2023, compared with $1.5 million for the three months ended March 31, 2022. The three months ended March 31, 2023 included a $2.3 million loss on extinguishment of debt related to repayment of the A&R SVB LSA in January 2023. The three months ended March 31, 2022 included a $1.0 million loss on extinguishment of debt related to the refinance of long-term

debt with SVB during January 2022.

Net loss for the three months ended March 31, 2023, was $11.7 million, or $0.18 per basic and diluted share, compared to a net loss of $15.9 million, or $0.30 per basic and diluted share, for the three months ended March 31, 2022.

About YUTREPIA™(treprostinil) inhalation powder
YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-resistance, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA, which is indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) without additional clinical studies.
YUTREPIA was designed using Liquidia's PRINT ® technology, which enables the development of drug particles that are precise and uniform in size, shape, and composition, and that are engineered for optimal deposition in the lung following oral inhalation. Liquidia has completed INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, an open-label, multi-center phase 3 clinical study of YUTREPIA in patients diagnosed with PAH who are naïve to inhaled treprostinil or who are transitioning from Tyvaso® (nebulized treprostinil). YUTREPIA was previously referred to as LIQ861 in investigational studies.

About Treprostinil Injection
Treprostinil Injection is the first-to-file, fully substitutable generic treprostinil for parenteral administration. Treprostinil Injection contains the same active ingredient, same strengths, same dosage form and same inactive ingredients as Remodulin® (treprostinil) and is offered to patients and physicians with the same level of service and support, but at a lower price than the branded drug. Liquidia PAH promotes the appropriate use of Treprostinil Injection for the treatment of PAH in the United States in partnership with its commercial partner, who holds the Abbreviated New Drug Application (ANDA) with the FDA.

About Liquidia Corporation
Liquidia Corporation is a biopharmaceutical company focused on the development and commercialization of products in pulmonary hypertension and other applications of its PRINT® Technology. The company operates through its two wholly owned subsidiaries, Liquidia Technologies, Inc. and Liquidia PAH, LLC. Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

Cautionary Statements Regarding Forward-Looking Statements
This press release may include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts, including statements regarding our future results of operations and financial position, our strategic and financial initiatives, our business strategy and plans and our objectives for future operations, are forward-looking statements. Such forward-looking statements, including statements regarding clinical trials, clinical studies and other clinical work (including the funding therefor, anticipated patient enrollment, safety data, study data, trial outcomes, timing or associated costs), regulatory applications and related submission contents and timelines, including the potential for final FDA approval of the NDA for YUTREPIA, the timeline or outcome related to appeals arising from our patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at the PTAB, the issuance of patents by the USPTO and our ability to execute on our strategic or financial initiatives, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The favorable decisions of the PTAB in the IPRs for the '793 and '901 patents and of the District Court in the Hatch-Waxman Litigation are not determinative of the outcome of any appeal of those decisions. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks discussed in our filings with the SEC, including the impact of the coronavirus (COVID-19) pandemic on our Company and our financial condition and results of operations, as well as a number of uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and our industry has inherent risks. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Nothing in this press release should be regarded as a representation by any person that these goals will be achieved, and we undertake no duty to update our goals or to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

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Liquidia Corporation
Select Consolidated Balance Sheet Data
(in thousands)

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 94,412	$ 93,283

Total assets	$ 128,922	$ 129,198
Total liabilities	$ 47,279	38,776
Accumulated deficit	$ (362,341)	(350,596)
Total stockholders' equity	$ 81,643	90,422

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Revenue	$ 4,493	$ 3,492
Costs and expenses:		
Cost of revenue	654	694
Research and development	5,278	4,728
General and administrative	7,793	12,542
Total costs and expenses	13,725	17,964
Loss from operations	(9,232)	(14,472)
Other income (expense):		
Interest income	922	4
Interest expense	(1,124)	(478)
Loss on extinguishment of debt	(2,311)	(997)
Total other expense, net	(2,513)	(1,471)
Net loss and comprehensive loss	$ (11,745)	$ (15,943)
Net loss per common share, basic and diluted	$ (0.18)	$ (0.30)
Weighted average common shares outstanding, basic and diluted	64,656,424	52,465,283

Source: Liquidia Corporation