Liquidia Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 12, 2022

- *Secured access to new capital through debt and equity transactions*

- *Increased utilization of Treprostinil Injection with increasing payer generic mandates*

- *Advanced Hatch-Waxman litigation in support of final regulatory approval of YUTREPIA™ (treprostinil) inhalation powder*

- *Company to host webcast and conference call today at 8:30 a.m. ET*

MORRISVILLE, N.C., May 12, 2022 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the first quarter ended March 31, 2022. The Company will host a webcast and conference call at 8:30 a.m. ET to discuss the first quarter 2022 financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "Over the last quarter, the Company has continued to build a strong position clinically, commercially, and financially. Clinically, our patient experience continues to expand as we have now accrued more than 280 patient years of exposure with YUTREPIA (treprostinil) inhalation powder in our ongoing open-label study, supporting that YUTREPIA can be a durable treatment option for PAH patients. We remain confident in our ability to navigate our way to final FDA approval of YUTREPIA following our arguments presented at trial in Hatch-Waxman proceedings in March and the arguments we will make as part of the *inter partes* review at the Patent Trial Appeal Board this week. Commercially, we continue to increase the utilization of Treprostinil Injection with growing support from payers. And financially, as we prepare for a potential launch of YUTREPIA later this year, we fortified our balance sheet to support growing commercial, clinical and pipeline activities and continue to build an experienced and passionate team that is prepared to fulfill the unmet needs of patients seeking better treatment options."

Corporate Updates

Secured access to additional capital through restructured debt and equity transactions to support commercialization and pipeline activity. In January 2022, the Company increased its existing credit facility with Silicon Valley Bank, providing access to up to $40.0 million in term loans of which the first $20.0 million was funded during the first quarter of 2022. On April 18, 2022, the Company closed on the sale of 11,274,510 shares of common stock in an underwritten registered public offering at an offering price of $5.10 per share with 19% of shares sold to Company insiders. Net proceeds of approximately $53.7 million were received after deducting the underwriting discounts and commissions and other offering expenses. The total cash on-hand enables the Company to launch YUTREPIA pending final FDA approval, initiate new clinical trials, including for WHO Group 3 patients, and advance its pre-clinical pipeline.

Drove increased utilization of Treprostinil Injection with increasing support of payer mandates. Liquidia's revenue increased slightly to $3.5 million in the first quarter 2022 as compared to $3.1 million in first quarter 2021 despite a decrease in the profit split percentage from 80% to 50% per the terms of the promotion agreement with Sandoz. The increase in the number of units sold was driven largely by the implementation of payer mandates at national and regional levels to use generic treprostinil formulations over branded Remodulin® (treprostinil). Additional payers are expected to implement generic mandates in the second half of 2022 and into 2023.

Progressed legal proceedings to allow for final approval of YUTREPIA. The Company is actively involved in Hatch-Waxman litigation brought by United Therapeutics Corporation (UTC) in June 2020 involving three U.S. patents: No. 9,604,901 (the '901 Patent), 9,593,066 (the '066 Patent) and 10,716,793 (the '793 Patent). Trial proceedings were held from March 28-31, 2022, and the Court set a post-trial briefing schedule to be concluded on June 15, 2022. The Company currently expects that a decision regarding the Hatch-Waxman litigation will be issued prior to the expiration of the 30-month regulatory stay in October 2022. At trial, the Company presented evidence of non-infringement and invalidity with respect to both the '066 patent and the '793 patent, the two patents that remain at issue in the litigation. The '901 patent was withdrawn from litigation when UTC stipulated Liquidia's non-infringement in December 2021. Concurrently, the U.S. Patent Trial and Appeal Board (PTAB) instituted an *inter partes* review (IPR) of the '793 Patent, finding that the Company had demonstrated a reasonable likelihood that it would prevail with respect to showing that at least one challenged claim of the '793 patent is unpatentable as obvious over the combination of certain prior art cited by the Company in its petition to the PTAB. A hearing before the PTAB will be held on May 13, 2022, and a final written decision determining the validity of the challenged claims of the '793 patent is expected in August 2022.

First Quarter 2022 Financial Results

Cash totaled $57.8 million as of March 31, 2022. On April 18, 2022, the Company received net proceeds of approximately $53.7 million from the sale of the common stock after deducting the underwriting discounts and commissions and other offering

expenses related to the registered public offering.

Revenue was $3.5 million for the three months ended March 31, 2022, compared to $3.1 million for the three months ended March 31, 2021. Revenue related primarily to the Promotion Agreement. During the three months ended March 31, 2021, the profit split percentage the Company received under the Promotion Agreement was 80%, whereas during the three months ended March 31, 2022, the profit split percentage was 50%. This decrease in profit split percentage was offset by an increase in the number of units sold.

Cost of revenue was $0.7 million for the three months ended March 31, 2022, compared to $0.7 million for the three months ended March 31, 2021. Cost of revenue related to the Promotion Agreement as noted above.

Research and development expenses were $4.7 million for the three months ended March 31, 2022, compared with $6.1 million for the three months ended March 31, 2021. The decrease of $1.4 million or 21.9% was primarily due to the timing of manufacturing related to our YUTREPIA program. During the three months ended March 31, 2022, the Company incurred $1.6 million in expenses related to YUTREPIA compared to $2.7 million during the three months ended March 31, 2021.

General and administrative expenses were $12.5 million for the three months ended March 31, 2022, compared with $5.3 million for the three months ended March 31, 2021. The increase of $7.2 million or 135.0% was primarily due to a $3.3 million increase in stock-based compensation expense driven by a $2.9 million option modification charge during the three months ended March 31, 2022, as well as a $3.4 million increase in legal fees related to our ongoing YUTREPIA-related litigation.

Other Expenses totaled $1.5 million for the three months ended March 31, 2022, compared with $0.2 million for the three months ended March 31, 2021. The increase of $1.3 million was primarily due to a $1.0 million loss on extinguishment of debt related to the refinance of our long-term debt for the three months ended March 31, 2022.

Net loss for the three months ended March 31, 2022, was $15.9 million, or $0.30 per basic and diluted share, compared to a net loss of $9.2 million, or $0.21 per basic and diluted share, for the three months ended March 31, 2021.

Remodulin® (treprostinil) is a registered trademark of United Therapeutics Corporation.

About YUTREPIA™(treprostinil) inhalation powder
YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a proven, convenient, 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. 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 our patent litigation pending in the U.S. District Court for the District of Delaware or our *inter partes* review with the PTAB or any related appeals, 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 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, 2022	December 31, 2021
Cash and cash equivalents	$ 57,794	$ 57,494
Total assets	$ 93,525	$ 93,729
Total liabilities	$ 38,136	$ 28,464
Accumulated deficit	$ (325,524)	$ (309,581)
Total stockholders' equity	$ 55,389	$ 65,265

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

	Three Months Ended March 31,	
	2022	2021
Revenue	$ 3,492	$ 3,084
Costs and expenses:		
Cost of revenue	694	694
Research and development	4,728	6,054
General and administrative	12,542	5,337
Total costs and expenses	17,964	12,085
Loss from operations	(14,472)	(9,001)
Other income (expense):		
Interest income	4	21
Interest expense	(478)	(150)
Loss on extinguishment of debt	(997)	(53)
Total other income (expense), net	(1,471)	(182)
Net loss and comprehensive loss	$ (15,943)	$ (9,183)
Net loss per common share, basic and diluted	$ (0.30)	$ (0.21)
Weighted average common shares outstanding, basic and diluted	52,465,283	43,443,361


Primary Logo

Source: Liquidia Corporation