Liquidia Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 11, 2022

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

MORRISVILLE, N.C., Aug. 11, 2022 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the second quarter ended June 30, 2022. The Company will host a webcast and conference call at 8:30 a.m. ET to discuss the second quarter 2022 financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "We continue to work towards the goal of launching YUTREPIA™ (treprostinil) inhalation powder as soon as possible upon resolution of the Hatch-Waxman litigation. It is encouraging to see the momentum and excitement building within the Company, between securing key wins on the legal front and bringing in new hires to help us achieve our near-term and long-term goals. We look forward to launching the next chapter in the Company's evolution pending the final approval of YUTREPIA."

Corporate Updates

Strengthened financial position through equity transactions to support commercialization and pipeline activity. In April, 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. The net proceeds of approximately $54.5 million helped to increase the total cash on-hand to $103.8 million at the end of second quarter 2022. The Company is positioned to launch YUTREPIA, pending final regulatory approval, as well as advance additional development efforts. The Company was also added as a member of the US small-cap Russell 2000® Index as part of the 2022 Russell indexes reconstitution in June.

Confirmed the regulatory path to seeking a second indication for YUTREPIA in 2024. The U.S. Food and Drug Administration (FDA) confirmed that the Company is not required to conduct additional studies when seeking the indication to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD). The Company can submit a supplemental New Drug Application (sNDA) for YUTREPIA and could potentially receive approval for the additional indication upon the expiration in March 2024 of regulatory exclusivity granted to Tyvaso® (treprostinil) inhalation solution.

Completed trial proceedings in Hatch-Waxman litigation and received favorable ruling in *inter partes* review (IPR). The Company is actively involved in Hatch-Waxman litigation brought by United Therapeutics Corporation (UTC), which asserted at trial the infringement of U.S. patents 9,593,066 (the '066 Patent) and 10,716,793 (the '793 Patent). At the conclusion of the trial in March 2022, the Court set a post-trial briefing schedule, which was completed 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 by October 27, 2022.

In a concurrent IPR proceeding, the Patent Trial and Appeal Board (PTAB) found in July 2022 that all the claims of the '793 patent have been shown to be unpatentable. The PTAB's decision does not resolve the on-going Hatch-Waxman litigation and would not override an order of the District Court unless and until the decision of the PTAB is affirmed on appeal.

Continued to build team with key hires in R&D and Commercial. In June, Rajeev Saggar, M.D, joined as Chief Medical Officer. With more than 15 years of experience as a practicing pulmonologist, Dr. Saggar's expertise in researching and treating pulmonary arterial hypertension (PAH), pulmonary hypertension with interstitial lung disease (PH-ILD) and other rare diseases will help the Company fully explore the benefits of YUTREPIA and inform the product portfolio. Additionally, the commercial team continued to expand with key hires in sales and marketing roles as the organization prepares for the potential launch of YUTREPIA.

Second Quarter 2022 Financial Results

Cash totaled $103.8 million as of June 30, 2022, compared to $57.5 million as of December 31, 2021.

Revenue was $3.9 million for the three months ended June 30, 2022, compared to $3.4 million for the three months ended June 30, 2021. Revenue related primarily to the sale of Treprostinil Injection under the Promotion Agreement. During the three months ended June 30, 2022, the profit split percentage we received under the Promotion Agreement was 50%, whereas during the three months ended June 30, 2021, the profit split percentage was 80%. 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 June 30, 2022, compared to $0.7 million for the three months ended June 30, 2021. Cost of revenue related to the Promotion Agreement as noted above.

Research and development expenses were $5.2 million for the three months ended June 30, 2022, compared with $4.6 million for the three months ended June 30, 2021. The increase of $0.6 million or 14% was primarily due a $0.3 million increase in expenses related to our YUTREPIA program, which had higher manufacturing costs offset by lower clinical costs, and a $0.3 million increase in personnel expenses associated with a one-time severance charge. During the three months ended June 30, 2022, we incurred $1.9 million of expenses related to YUTREPIA, of which approximately $0.8 million directly related to manufacturing in preparation for potential commercialization compared to $1.6 million during the three months ended June 30, 2021.

General and administrative expenses were $6.9 million for the three months ended June 30, 2022, compared with $4.4 million for the three months ended June 30, 2021. The increase of $2.5 million or 57% was primarily due to a $1.6 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA.

Other Expenses net total was $0.5 million for the three months ended June 30, 2022, compared with $0.2 million for the three months ended June 30, 2021. The increase of $0.3 million was primarily due to a $0.3 million increase in interest expense due to a higher debt balance and interest rate on our debt from Amended and Restated Loan and Security Agreement dated as of January 7, 2022 with Silicon Valley Bank and Innovation.

Net loss for the three months ended June 30, 2022, was $9.4 million, or $0.15 per basic and diluted share, compared to a net loss of $6.5 million, or $0.13 per basic and diluted share, for the three months ended June 30, 2021.

Tyvaso® 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 enhanced 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 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, 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)

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 103,840	$ 57,494
Total assets	$ 139,082	$ 93,729
Total liabilities	$ 36,975	$ 28,464
Accumulated deficit	$ (334,971)	$ (309,581)
Total stockholders' equity	$ 102,107	$ 65,265

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	$ 3,918	$ 3,376	$ 7,410	$ 6,460
Costs and expenses:				
Cost of revenue	731	714	1,425	1,407
Research and development	5,219	4,595	9,947	10,649
General and administrative	6,938	4,421	19,480	9,758
Total costs and expenses	12,888	9,730	30,852	21,814
Loss from operations	(8,970)	(6,354)	(23,442)	(15,354)
Other income (expense):				
Interest income	65	5	69	25
Interest expense	(542)	(203)	(1,020)	(352)
Loss on extinguishment of debt	—	—	(997)	(53)
Total other income (expense), net	(477)	(198)	(1,948)	(380)
Net loss and comprehensive loss	$ (9,447)	$ (6,552)	$ (25,390)	$ (15,734)
Net loss per common share, basic and diluted	$ (0.15)	$ (0.13)	$ (0.44)	$ (0.33)
Weighted average common shares outstanding, basic and diluted	62,179,305	50,847,126	57,349,129	47,165,696

Primary Logo

Source: Liquidia Corporation