Liquidia Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 10, 2021

- *Launched subcutaneous delivery of Treprostinil Injection, doubling market opportunity*
- *Resubmitted New Drug Application (NDA) for LIQ861 (treprostinil) inhalation powder*
- *Improved balance sheet with private placement and increased financial discipline*
- *Company to host webcast and conference call today at 8:30 a.m. ET*

MORRISVILLE, N.C., Aug. 10, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the quarter ended June 30, 2021. The Company will host a webcast and conference call at 8:30 a.m. Eastern Daylight Time to discuss the second quarter financial results and provide a corporate update.

Damian deGoa, Liquidia's Chief Executive Officer, said: "We continue to execute on our corporate priorities and strengthen the company's position. We are excited to have overcome the restrictions that were placed on the CADD-MS 3 cartridges so that we can offer generic Treprostinil Injection to all PAH patients on Remodulin and to offer meaningful savings to the healthcare system. We are in the early stages of the launch of the RG 3ml Medication Cartridge but are encouraged by the increased interest in Treprostinil Injection now that it is available through both intravenous and subcutaneous administration."

Corporate Update

Launched subcutaneous delivery of generic Treprostinil Injection, providing access to all pulmonary arterial hypertension (PAH) patients. On May 21, 2021, Liquidia PAH's manufacturing partner began selling the RG 3ml Medication Cartridge for use with the CADD-MS 3 pump to administer subcutaneous treprostinil injection. Since its commercial launch two years ago, Treprostinil Injection has only been used through intravenous administration. The cartridges required to operate the CADD-MS 3 pump were not available to patients using generic Treprostinil Injection due to restrictions imposed by other companies. The introduction of the RG 3ml Medication Cartridge will more than double the addressable market for Treprostinil Injection.

Resubmitted and confirmed FDA acceptance for review of NDA for LIQ861 for the treatment of PAH. On June 2, 2021, the FDA accepted for review the New Drug Application (NDA) resubmission for LIQ861 (treprostinil) inhalation powder. The resubmitted NDA included additional information and clarification on chemistry, manufacturing, and controls (CMC) pertaining to the drug product as well as data on device biocompatibility. No additional data from clinical trials or studies related to toxicology or clinical pharmacology was required. In accepting the NDA for review, the FDA confirmed that the resubmission was a complete, class 2 response to the previous action letter issued in November 2020 and set a PDUFA goal date of November 7, 2021. The FDA's pre-approval inspection of the Company's Morrisville, NC facility is on-going. If the FDA determines, following its substantive review of the NDA, that all requirements for approval have been met, the FDA may issue tentative approval on a timeline generally informed by the PDUFA goal date. The FDA may then issue a final approval after the expiration of the 30-month regulatory stay in October 2022 or an earlier judgment by the court that is unfavorable to United Therapeutics who initiated related Hatch-Waxman litigation.

Continued to defend right to advance innovation for PAH patients. In support of LIQ861, the Company is actively involved in Hatch-Waxman litigation brought by United Therapeutics Corporation (United Therapeutics), as well as pursuing *inter partes review* (IPR) of certain related patents at the U.S. Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office (USPTO). On May 24, Judge Andrews, presiding over the Hatch-Waxman Litigation, conducted a claim construction hearing. The Court subsequently issued an order that two of the terms under consideration would be given their plain and ordinary meaning and ruling in Liquidia's favor regarding a third term. Two of the terms that were under consideration at the claim construction hearing remain under consideration by the Court. The trial date has been set for March 28-30, 2022.

In related IPR proceedings, the PTAB held a hearing on June 23, 2021, with respect to U.S. Patent No. 9,604,901 ('901 patent). A final written decision determining the validity of the challenged claims of the '901 patent is expected in October 2021, approximately 12 months from institution of the IPR. The PTAB is also considering the petition submitted by Liquidia in January of this year for IPR of U.S. Patent No. 10,716,793 (the '793 patent). The PTAB's decision on whether to institute the IPR for the '793 patent is expected in August 2021, and if instituted, would conclude with a final written decision within 12 months from institution.

Maintained financial discipline from reduced annual net spending and increased available cash resources. The Company's balance sheet has benefited from several actions taken during the first half of 2021, including a decrease in net annual spending by reducing internal staff and consultants, refinancing equipment leases, and refinancing the credit facility. In addition, the Company raised $21.7 million in April 2021 by entering a common stock purchase agreement with certain institutional investors, after which David Johnson, a Partner and Co-Founder of Caligan Partners LP, was appointed to the board of directors of Liquidia Corporation.

Second Quarter 2021 Financial Results

Cash totaled $67.9 million and $65.3 million as of June 30, 2021, and December 30, 2020, respectively.

Revenue of $3.4 million was recognized for the three months ended June 30, 2021, as compared to no revenue for the three months ended June 30, 2020. Revenue recognized during 2021 related primarily to the promotion agreement with Sandoz Inc., after the acquisition of Liquidia PAH in November 2020.

Cost of revenue was $0.7 million for the three months ended June 30, 2021, compared to no cost of revenue for the three months ended June 30, 2020. Cost of revenue recognized during 2021 related to the promotion agreement as noted above.

Research and development expenses were $4.6 million for the three months ended June 30, 2021, compared with $8.5 million for the three months

ended June 30, 2020, a decrease of $3.9 million or 45.9%. The decrease primarily related to lower expenses from our LIQ861 clinical program, which was substantially completed prior to filing the NDA in April 2020 and lower employee and consulting expenses.

General and administrative expenses were $4.4 million for the three months ended June 30, 2021, compared with $5.2 million for the three months ended June 30, 2020. The decrease of $0.8 million or 15.4% was primarily due to lower professional fees associated with corporate activities and lower consulting and personnel expenses as a result of lower headcount year-over-year. These decreases were partially offset by an increase in legal fees related to our ongoing LIQ861-related litigation.

Net loss for the quarter ended June 30, 2021, was $6.5 million, or $0.13 per basic and diluted share, compared to a net loss of $13.9 million, or $0.49 per basic and diluted share, for the quarter ended June 30, 2020.

Remodulin® (treprostinil) is a registered trademark of United Therapeutics Corporation.
CADD-MS® 3 is a registered trademark of Smiths Medical ASD, Inc.

About LIQ861
LIQ861 is an investigational inhaled dry powder formulation of treprostinil designed using Liquidia's PRINT® technology with the goal of enhancing deep-lung delivery using a convenient, palm-sized dry powder inhaler for the treatment of pulmonary arterial hypertension (PAH). PRINT® technology 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 believes LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs. Liquidia has completed an open-label, multi-center phase 3 clinical study of LIQ861 in patients diagnosed with PAH known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil.

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 is developing LIQ861, an inhaled dry powder formulation of treprostinil for the treatment of PAH. Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as 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 our response to the Complete Response Letter received in November 2020, the potential for eventual FDA approval of the NDA for LIQ861, 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, 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) outbreak 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 Balance Sheet Data

	June 30, 2021	December 31, 2020

Cash	$ 67,889,494	$ 65,316,481
Total assets	$ 104,381,689	$ 99,531,760
Total liabilities	$ 25,360,832	$ 28,445,922
Accumulated deficit	$ (290,736,858)	$ (275,002,219)
Total stockholders' equity	$ 79,020,857	$ 71,085,838

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	$ 3,376,086	$ —	$ 6,459,717	$ —
Costs and expenses:				
Cost of revenue	713,736	—	1,407,471	—
Research and development	4,595,418	8,490,418	10,649,104	19,313,342
General and administrative	4,420,790	5,226,264	9,758,083	9,049,460
Total costs and expenses	9,729,944	13,716,682	21,814,658	28,362,802
Loss from operations	(6,353,858)	(13,716,682)	(15,354,941)	(28,362,802)
Other income (expense):				
Interest income	4,880	11,631	25,646	121,220
Interest expense	(202,508)	(211,050)	(405,344)	(465,998)
Total other income (expense), net	(197,628)	(199,419)	(379,698)	(344,778)
Net loss and comprehensive loss	$ (6,551,486)	$ (13,916,101)	$ (15,734,639)	$ (28,707,580)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.49)	$ (0.33)	$ (1.01)
Weighted average common shares outstanding, basic and diluted	50,847,126	28,479,016	47,165,696	28,453,812

Source: Liquidia Corporation