Liquidia Reports Third Quarter 2021 Financial Results and Provides Corporate Update

November 3, 2021

- *Increased adoption of generic Treprostinil Injection by patients, physicians and payers*
- *Completed on-site pre-approval inspections by FDA of two U.S. manufacturing facilities*
- *Anticipate FDA action on LIQ861 near PDUFA goal date of November 7, 2021*

MORRISVILLE, N.C., Nov. 03, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the quarter and nine-months ended September 30, 2021.

Damian deGoa, Liquidia's Chief Executive Officer, said: "We had another productive quarter. Sales performance of Treprostinil Injection was ahead of target. The initial uptake has been very positive as patients continue to transition to, or start on, Treprostinil Injection with clear support from payers and healthcare providers. We also had positive developments in our ongoing litigation with United Therapeutics. We look forward to hearing from the FDA in the coming days about the potential tentative approval of LIQ861."

Corporate Updates

Increased adoption of generic Treprostinil Injection by patients, physicians and payers. During the third quarter, unit sales of Treprostinil Injection increased across intravenous and subcutaneous routes of administration, more than doubling the number of patients being treated as compared to the number of patients prior to the launch of the subcutaneous route of administration in late May of 2021. Revenue was impacted by a reduction in the contractual profit split percentage earned pursuant to the Promotion Agreement between Liquidia PAH and Sandoz as a result of achievement of pre-determined cumulative sales thresholds. As a result, the increase in unit sales did not result in a corresponding increase in revenue reflected on the income statement on a quarter-over-quarter basis.

Completed on-site pre-approval inspections by FDA of two U.S. manufacturing facilities in advance of LIQ861 PDUFA goal date. As part of the FDA review of LIQ861, the FDA conducted two prior-approval inspections, one at the Company's Morrisville, NC facility and the other at the facility of a third-party provider of encapsulation and packaging services for LIQ861. These pre-approval inspections were completed in August 2021 and October 2021, respectively.

Successfully advanced *inter partes* review (IPR) proceedings against two patents owned by United Therapeutics (UTC) being asserted in related Hatch-Waxman litigation. In August 2021, the U.S. Patent Trial and Appeal Board (PTAB) instituted an IPR against U.S. Patent No. 10,716,793 ('793 patent) owned by UTC. In its decision, the PTAB stated that Liquidia had demonstrated a reasonable likelihood of prevailing in its assertion that all of the claims of the '793 patent are unpatentable as obvious over the combination of certain prior art cited by Liquidia in its petition to the PTAB. A final written decision determining the validity of the challenged claims of the '793 patent is expected within 12 months from institution.

More recently in October 2021, the PTAB ruled in Liquidia's favor in the IPR proceeding against U.S. Patent No. 9,604,901 ('901 patent). In its ruling, the PTAB found that seven of the nine claims were unpatentable. Only the narrower dependent claims 6 and 7 remain, both of which require actual storage at ambient temperature of treprostinil sodium.

The '901 and '793 patents, along with U.S. Patent No. 9,593,066 ('066 patent), are the subject of Hatch-Waxman litigation filed by UTC in June 2020. The trial is expected in March 2022 in U.S. District Court for the District of Delaware. As a result of this litigation, the FDA is automatically precluded from fully approving the LIQ861 NDA until October 2022 absent an earlier judgment unfavorable to United Therapeutics by the court or other settlement.

Third Quarter 2021 Financial Results

Cash totaled $64.1 million and $65.3 million as of September 30, 2021, and December 30, 2020, respectively.

Revenue of $3.2 million was recognized for the three months ended September 30, 2021, as compared to no revenue for the three months ended September 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 $0.9 million for the three months ended September 30, 2021, compared to no cost of revenue for the three months ended September 30, 2020. Cost of revenue recognized during 2021 related to the promotion agreement as noted above.

Research and development expenses were $4.5 million for the three months ended September 30, 2021, compared with $7.7 million for the three months ended September 30, 2020, a decrease of $3.2 million or 41.4%. The decrease primarily related to lower expenses from the LIQ861 clinical program as well as lower employee and consulting expenses.

General and administrative expenses were $4.9 million for the three months ended September 30, 2021, compared with $7.2 million for the three months ended September 30, 2020. The decrease of $2.3 million or 31.7% was primarily due to $2.9 million lower consulting expenses and professional fees associated with corporate activities offset by a $0.6 million increase in legal fees related to the ongoing LIQ861-related litigation.

Net loss for the quarter ended September 30, 2021, was $7.3 million, or $0.14 per basic and diluted share, compared to a net loss of $15.0 million, or $0.40 per basic and diluted share, for the quarter ended September 30, 2020.

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

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 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) 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

	September 30, 2021	December 31, 2020
Cash	$ 64,053,795	$ 65,316,481
Total assets	$ 100,299,409	$ 99,531,760
Total liabilities	$ 27,335,398	$ 28,445,922
Accumulated deficit	$ (298,017,750)	$ (275,002,219)
Total stockholders’ equity	$ 72,764,011	$ 71,085,838

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 3,178,621	$ —	$ 9,638,338	$ —
Costs and expenses:				
Cost of revenue	889,511	—	2,296,983	—
Research and development	4,487,098	7,660,979	15,136,201	26,974,320
General and administrative	4,881,669	7,151,788	14,639,752	16,201,249
Total costs and expenses	10,258,278	14,812,767	32,072,936	43,175,569
Loss from operations	(7,079,657)	(14,812,767)	(22,434,598)	(43,175,569)
Other income (expense):				
Interest income	3,875	34,633	29,521	155,852
Interest expense	(205,110)	(190,546)	(610,454)	(656,543)
Total other income (expense), net	(201,235)	(155,913)	(580,933)	(500,691)
Net loss and comprehensive loss	$ (7,280,892)	$ (14,968,680)	$ (23,015,531)	$ (43,676,260)
Net loss per common share, basic and diluted	$ (0.14)	$ (0.40)	$ (0.47)	$ (1.38)
Weighted average common shares outstanding, basic and diluted	52,081,497	37,755,472	48,822,303	31,576,992

Source: Liquidia Corporation