Liquidia Corporation Reports Full-Year 2020 Financial Results and Provides Corporate Update

March 23, 2021

- Integrated RareGen (now known as Liquidia PAH) to establish commercial presence in PAH
- Clarified path towards submitting response to CRL for LIQ861 in mid-2021
- Reducing net annual spending more than 40% in 2021 compared to 2020 cash burn
- Company to host webcast and conference call today at 8:30 a.m. ET

RESEARCH TRIANGLE PARK, N.C., March 23, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the full-year ended December 31, 2020. The Company will host a webcast and conference call at 8:30 a.m. ET to discuss the 2020 financial results and provide a corporate update.

Damian deGoa, Liquidia's Chief Executive Officer, said: "Activity level has been high. We closed the acquisition and integration of RareGen, LLC, now known as Liquidia PAH, LLC, which provides a commercial presence in PAH. There have been several changes to the Liquidia executive team, including at CEO, CFO, Commercial and General Counsel. We are executing our response plan to the CRL for LIQ861 with a thorough and efficient approach as informed by our Type A meeting with the FDA in January. We also took immediate steps to improve the balance sheet and cash spend, which when combined with the expected positive contribution from Treprostinil Injection sales, mean Liquidia is creating a more solid foundation."

Corporate Update

Formed Liquidia Corporation to develop and commercialize treatments for pulmonary hypertension and further leverage PRINT technology. On November 18, 2020, the Company closed the previously announced agreement to combine RareGen, LLC (now known as Liquidia PAH, LLC) and Liquidia Technologies, Inc. as wholly owned operating subsidiaries under Liquidia Corporation (the "Merger Transaction"). The new corporate entity includes commercialization capabilities and expertise in pulmonary arterial hypertension (PAH) in support of Treprostinil Injection, the first-to-file generic formulation of Remodulin® (treprostinil) from Sandoz Inc. ("Sandoz"). This also provides the initial infrastructure needed to commercialize LIQ861. The combined entity reinforces Liquidia's commitment to patients in the PAH community and the healthcare professionals who treat them.

Confirmed plan to submit response to LIQ861 CRL in mid-2021. On November 25, 2020, the Company announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for LIQ861, an investigational inhaled dry powder formulation of treprostinil designed using Liquidia's PRINT® technology. As previously announced, the CRL identified the need for additional information and clarification on chemistry, manufacturing and controls (CMC) data pertaining to the drug product and device biocompatibility. A Type A meeting was conducted with the FDA in January 2021 to confirm and clarify the items included in the CRL. The Company intends to submit a response to the CRL to the FDA in the middle of 2021.

Strengthened intellectual property tied to inhaled dry powder treprostinil. On January 26, 2021, the United States Patent and Trademark Office (USPTO) issued patent No. 10,898,494 (the "'494 patent") to Liquidia relating to inhaled dry powder treprostinil. The '494 patent, which expires in 2037, includes claims covering methods of treating patients with any form of pulmonary hypertension through the inhalation of dry powder treprostinil at doses between approximately 100 micrograms to approximately 300 micrograms. For reference, more than 75 percent of patients enrolled in the Company's pivotal "INSPIRE" and extension studies of LIQ861 have titrated to doses of 100 micrograms or greater, and results from pharmacokinetic studies demonstrated that the 79.5 microgram dose of LIQ861 correlates with nine breaths of Tyvaso® (54 micrograms), the maximum recommended label dose of Tyvaso®. Currently, more than 75 patients have now received therapy with LIQ861 for more than two years.

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 related patents at the U.S. Patent Trial and Appeal Board (PTAB) of the USPTO. The PTAB formally instituted an IPR in October 2020 against U.S. Patent No. 9,604,901 (the "'901 patent") and subsequently rejected United Therapeutics' request for reconsideration to revoke institution of the IPR. A final written decision determining the validity of the challenged claims of the '901 patent is expected by October 2021. On January 7, 2021, the Company submitted a petition for IPR of U.S. Patent 10,716,793 (the "'793 patent"), which was amended to the original Hatch-Waxman complaint filed by United Therapeutics. A decision by the PTAB to institute the petition related to the '793 patent is expected in the third quarter of 2021 and, if instituted, would conclude approximately 12 months later. A favorable decision invalidating these patents may be considered by the court in concurrent Hatch-Waxman litigation.

Reduced net annual cash spending to strengthen financial position. Over the last three months, the Company has initiated actions to reduce net annual spending in 2021 by more than 40% compared to 2020 spending. Some of these measures included reducing internal staff and full-time equivalent consultants by nearly 40%, refinancing equipment leases, reducing consultant spending and concentrating on 2021 corporate priorities. The Company also refinanced its existing credit facility with a facility providing interest-only payments for 24 months, saving more than $10 million over next two years. The total reduction in planned expenses may be further strengthened by the potential positive cash contribution from the profit derived from sales of Treprostinil Injection in Liquidia PAH's partnership with Sandoz. As a result, the Company is well-positioned to drive value through key events in 2021 and 2022, beyond the projected expiration of the regulatory stay in October 2022.

Full Year 2020 Financial Results

Cash totaled $65.3 million as of December 31, 2020. There were 43.3 million shares outstanding as of December 31, 2020.

Revenue was $0.7 million for the full year of 2020, compared with $8.1 million for the full year of 2019. The decrease was due to the full recognition in the second quarter of 2019 of $8.1 million of deferred revenue from the Company's Inhaled Collaboration and Option Agreement with GlaxoSmithKline plc, for which there was no comparable revenue in 2020. Revenue related to sales of Treprostinil Injection under the Promotion Agreement with Sandoz (the "Promotion Agreement") was recognized for the period from closing of the Merger Transaction to year end 2020.

Cost of Revenue was $0.2 million for the full year of 2020, compared with $0.8 million for the full year of 2019. As noted above, the decrease of $0.6 million was due to the decrease in revenue. Cost of revenue during the full year 2020 includes sales force costs as well as the cost of a portion of the amortization of the intangible asset associated with the Promotion Agreement. Cost of revenue during the full year of 2019 represents sub-licensing fees paid to The University of North Carolina at Chapel Hill ("UNC") when licensing revenue is recognized by Liquidia from the use of the intellectual property in-licensed from UNC.

Research and development expenses were $32.2 million for the full year of 2020, compared with $40.5 million for the full year of 2019. The decrease primarily related to lower expenses from the Company's LIQ861 clinical program, which was substantially completed prior to filing the NDA in April 2020, and lower expenses from the Company's LIQ865 clinical program.

General and administrative expenses were $27.4 million for the full year of 2020, compared with $13.6 million for the full year of 2019. The increase was due to $4.8 million in expenses related to the Merger Transaction, $2.4 million in legal and patent expenses from the Company's ongoing LIQ861-related litigation, an increase of $5.8 million in outside consulting expenses and personnel costs, including share-based compensation, and a one-time charge of $1.4 million associated with a reduction of headcount.

Net loss for the full year of 2020 was $59.8 million, or $1.76 per basic and diluted share, compared to a net loss of $47.6 million, or $2.57 per basic and diluted share, for the full year of 2019.

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 Sandoz, Inc., 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 two product candidates: LIQ861, an inhaled dry powder formulation of treprostinil for the treatment of PAH, and LIQ865, an injectable, sustained-release formulation of bupivacaine for the management of local post-operative pain for three to five days after a procedure. Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as Treprostinil Injection, Sandoz Inc.'s first-to-file, generic treprostinil for PAH.

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 anticipate submission contents and timelines, including our potential 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 its *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 risk that the expected benefits and synergies from the Merger Transaction are not realized, 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.

Liquidia Corporation is headquartered in Research Triangle Park, NC. For more information, please visit www.liquidia.com.

Contact Information

Media & Investors:
Jason Adair
Vice President, Corporate Development and Strategy
919.328.4400

jason.adair@liquidia.com

Liquidia Corporation
Select Balance Sheet Data

	December 31, 2020	December 31, 2019
Cash	$ 65,316,481	$ 55,796,378
Total assets	$ 99,531,760	$ 68,842,067
Total liabilities	$ 28,445,922	$ 33,894,520
Accumulated deficit	$ (275,002,219)	$ (215,239,450)
Total stockholders' equity	$ 71,085,838	$ 34,947,547

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2020	2019
Net service revenue	$ 739,628	$ —
Collaboration revenue	—	8,072,120
Total revenue	739,628	8,072,120
Costs and expenses:		
Cost of net service revenue	237,712	—
Cost of collaboration revenue	—	807,192
Research and development	32,222,393	40,491,358
General and administrative	27,368,653	13,597,119
Total costs and expenses	59,828,758	54,895,669
Loss from operations	(59,089,130)	(46,823,549)
Other income (expense):		
Interest income	184,359	613,716
Interest expense	(857,998)	(1,373,622)
Total other expense, net	(673,639)	(759,906)
Net loss and comprehensive loss	$ (59,762,769)	$ (47,583,455)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.76)	$ (2.57)
Weighted average common shares outstanding, basic and diluted	33,888,434	18,482,455

Source: Liquidia Technologies, Inc.