# Liquidia Reports First Quarter 2021 Financial Results and Provides Corporate Update

May 13, 2021

*- Doubled the market opportunity for Treprostinil Injection by adding subcutaneous delivery*
*- Resubmitted New Drug Application for LIQ861 (treprostinil) Inhalation Powder*
*- Improved financial position with private placement and access to new credit facility*
*- Company to host webcast and conference call today at 8:30 a.m. ET*

MORRISVILLE, N.C., May 13, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the quarter ended March 31, 2021. The Company will host a webcast and conference call at 8:30 a.m. ET to discuss the first quarter financial results and provide a corporate update.

Damian deGoa, Liquidia's Chief Executive Officer, said: "This first quarter has been an important time of transition and re-structuring for the company as it strengthens its position and commitment to the products and patients that we support. We believe that our renewed focus and financial discipline are essential in order for the company to achieve its objectives in 2021 and beyond."

**Corporate Update**

**Enabled subcutaneous delivery of generic Treprostinil Injection, providing lower cost option to all patients on branded Remodulin.** On March 26, 2021, the U.S. Food and Drug Administration ("FDA") cleared the 510(k) application submitted by Liquidia PAH's manufacturing partner, Chengdu Shifeng Medical Technologies LTD ("Chengdu") for the RG 3ml Medication Cartridge which is indicated for use with the CADD-MS 3 pump. It is anticipated that Chengdu will start selling the RG 3ml Medication Cartridge in May, enabling the subcutaneous delivery of Treprostinil Injection for the first time. Until now, Treprostinil Injection could only be delivered by intravenous administration. The availability of the new cartridge will more than double the addressable market for Treprostinil Injection, which has been provided to patients with the same level of high-touch support and services as the branded product but at a lower cost since 2019.

**Resubmitted NDA for LIQ861 (treprostinil) Inhalation Powder for the treatment of Pulmonary Arterial Hypertension (PAH).** On May 7, 2021, the Company resubmitted its New Drug Application ("NDA") for LIQ861 in response to the Complete Response Letter ("CRL") received in November 2020. The resubmitted NDA was informed by discussion with FDA during a Type A meeting in January 2021 and included additional information and clarification on chemistry, manufacturing and controls 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. The Company anticipates that the FDA will classify the resubmitted NDA, if accepted, as a Class 2 Resubmission, which would result in a six-month review cycle from the date of resubmission.

**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"). In January 2021, the Company submitted a petition for IPR of U.S. Patent 10,716,793 (the "'793 patent"), which was added in July 2020 to the Hatch-Waxman complaint filed by United Therapeutics. A decision by the PTAB whether to institute an IPR related to the '793 patent is expected in the third quarter of 2021 and, if instituted, a decision would be expected approximately 12 months from the date on which the IPR is instituted. A favorable decision invalidating this patent may also be considered by the court in the concurrent Hatch-Waxman litigation. Unless the Hatch-Waxman litigation is resolved earlier, the statutory 30-month regulatory stay as a result of the Hatch-Waxman litigation will expire in October 2022.

**Strengthened financial position by reducing annual net spending and increasing available cash resources.** During the course of this year, the Company has taken several actions to improve the balance sheet as it progresses towards potential value-creating events in 2021 and 2022. Management implemented measures that reduced net annual spending in 2021 by more than 40% compared to 2020, which included, among other measures, reducing internal staff and consulting spending, refinancing equipment leases, and terminating development of LIQ865 to treat post-operative pain. The Company also refinanced its former credit facility with a new facility through Silicon Valley Bank that provides interest-only payments for 24 months, eliminating more than $10 million in required principal repayments over the next two years, while also providing access to an additional $10 million upon the achievement of key milestones paralleling FDA review of LIQ861. Lastly, the Company raised $21.7 million in April 2021 by entering a common stock purchase agreement with certain institutional investors led by Caligan Partners LP. At closing, David Johnson, a Partner and Co-Founder of Caligan Partners LP, was appointed to the board of directors of Liquidia Corporation as a Class II Director and a member of the Audit Committee.

**First Quarter 2021 Financial Results**

Cash totaled $53.6 million and $65.3 million as of March 31, 2021 and December 30, 2020, respectively. This cash total does not include proceeds from the private placement of common stock in April 2021.

Revenue of $3.1 million was recognized for the three months ended March 31, 2021 as compared to no revenue for the three months ended March 31, 2020. Revenue recognized during 2021 related 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 March 30, 2021, compared to no cost of revenue for the three months ended March 31, 2020. Cost of revenue recognized during 2021 related to the promotion agreement as noted above.

Research and development expenses were $6.1 million for the three months ended March 31, 2021 compared with $10.8 million for the three months ended March 31, 2020, a decrease of $4.7 million or 44.1%. The decrease primarily related to lower expenses from our LIQ861 clinical program, which was substantially completed prior to filing the NDA in April 2020, lower expenses from our LIQ865 clinical program, and lower employee and consulting expenses.

General and administrative expenses were $5.3 million for the three months ended March 31, 2021, compared with $3.8 million for the three months ended March 31, 2020. The increase of $1.5 million, or 39.6%, was primarily due to $2.1 million higher legal and professional fees associated with corporate activities as well as our ongoing LIQ861-related litigation, offset by lower consulting and personnel expenses as a result of lower headcount year-over-year.

Net loss for the quarter ended March 31, 2021 was $9.2 million, or $0.21 per basic and diluted share, compared to a net loss of $14.8 million, or $0.52 per basic and diluted share, for the quarter ended March 31, 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.

**Contact Information**

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**Liquidia Corporation**
**Select Balance Sheet Data**

| | March 31, 2021 | December 31, 2020 |
|---|---|---|

| | | |
|---|---|---|
| Cash | $ 53,637,155 | $ 65,316,481 |
| Total assets | $ 88,451,874 | $ 99,531,760 |
| Total liabilities | $ 25,542,695 | $ 28,445,922 |
| Accumulated deficit | $ (284,185,372) | $ (275,002,219) |
| Total stockholders' equity | $ 62,909,179 | $ 71,085,838 |

**Liquidia Corporation**
**Consolidated Statements of Operations and Comprehensive Loss**

| | March 31, | |
|---|---|---|
| | **2021** | **2020** |
| Revenue | $ 3,083,631 | $ — |
| Costs and expenses: | | |
| Cost of revenue | 693,735 | — |
| Research and development | 6,053,726 | 10,822,924 |
| General and administrative | 5,337,253 | 3,823,197 |
| Total costs and expenses | 12,084,714 | 14,646,121 |
| Loss from operations | (9,001,083) | (14,646,121) |
| Other income (expense): | | |
| Interest income | 20,766 | 109,590 |
| Interest expense | (202,836) | (254,948) |
| Total other income (expense), net | (182,070) | (145,358) |
| Net loss and comprehensive loss | $ (9,183,153) | $ (14,791,479) |
| Net loss per common share, basic and diluted | $ (0.21) | $ (0.52) |
| Weighted average common shares outstanding, basic and diluted | 43,443,361 | 28,428,616 |

Source: Liquidia Corporation