Liquidia Corporation Reports Full Year 2022 Financial Results and Provides Corporate Update

March 16, 2023

- *Clarified path to potential launch YUTREPIA upon resolution of litigation in late-2023 to mid-2024*
- *Fortified financial position through 2024*
- *Company to host webcast today at 8:30 a.m. ET*

MORRISVILLE, N.C., March 16, 2023 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the full year ended December 31, 2022. The Company will host a webcast at 8:30 a.m. ET to discuss the 2022 financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "We made notable strides toward unlocking the full potential of Liquidia in 2022. Our legal and patent wins were major achievements, clarifying the path to legal resolution. If approved, YUTREPIA will provide patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension with interstitial lung disease (PH-ILD) with the option to receive a differentiated inhaled treprostinil product via a low-resistance dry powder inhaler. The ongoing open-label extension study continues to demonstrate the merits of YUTREPIA's dosing flexibility and durability by attaining dosing levels that have not been achievable historically with Tyvaso®, thus enhancing the clinical ability to manage patients over time. Our revenue interest financing with HealthCare Royalty, one of the marquee royalty firms, provided significant non-dilutive capital to advance our platform goals. As an example, our recently announced partnership with Mainbridge Health Partners will advance a new subcutaneous infusion pump for Treprostinil Injection, a therapeutically equivalent and less expensive generic option. We look forward to continuing to unlock value in 2023."

Corporate Updates

New leadership to prepare for commercialization. During the year, the Company hired key employees in the C-suite, in the sales force and in operational units to support the potential launch of YUTREPIA. The net impact added decades of combined experience in the development and commercialization of medicines to treat pulmonary hypertension between Chief Executive Officer Dr. Roger Jeffs, Chief Medical Officer Dr. Rajeev Saggar, Head of Sales Matt Snow, and Head of Medical Affairs Gareth Gwyn. Additionally, the Company established key commercial support functions to address all stakeholders and bolstered manufacturing teams to build commercial inventory in preparation for YUTREPIA's potential final approval by the U.S. Food and Drug Administration (FDA).

Clarified path to legal resolution with key wins. The Company demonstrated in at least one legal forum that all of the claims in three patents asserted by United Therapeutics Corporation (UTC) are invalid or not infringed. If every decision in favor of Liquidia is affirmed on appeal by UTC, then Liquidia would be clear to seek final regulatory approval of YUTREPIA. The Company expects legal resolution in late 2023 or the first half of 2024.

As background, in 2020, UTC filed litigation in the United States District Court for the District of Delaware (District Court) under the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Litigation) alleging that Liquidia infringes U.S. Patent No. 9,593,066 ('066 Patent), U.S. Patent No. 10,716,793 ('793 Patent) and U.S. Patent No. 9,604,901 ('901 Patent). In parallel *inter partes* review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB), the Company sought to invalidate the claims of the three asserted patents.

Briefing in appeal of Hatch-Waxman Litigation now complete. In August 2022, the District Court ruled in Liquidia's favor with respect to the '066 Patent, finding that five of the six asserted claims of the '066 Patent are invalid and that the remaining asserted claim is not infringed by Liquidia. At the same time, the District Court found that all of the claims of the '793 Patent were valid and infringed by Liquidia based on the arguments that were presented by Liquidia in the Hatch-Waxman Litigation. Liquidia appealed the District Court's decision with respect to the '793 Patent to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), and UTC appealed the District Court's decision with respect to the '066 Patent to the Federal Circuit. Briefing is now complete and the parties are awaiting a scheduled date for oral argument, which Liquidia expects to occur during the second or third quarter of 2023.

'793 Patent deemed by PTAB to be invalid. In July 2022, the PTAB found in favor of Liquidia in the '793 IPR stating that all the claims of the '793 Patent have been shown to be unpatentable based on the preponderance of the evidence. In February 2023, the PTAB denied UTC 's request for a rehearing and, in so doing, reaffirmed and clarified its earlier decision that the claims of the '793 Patent are unpatentable. Based on earlier statements, UTC is expected to file an appeal of the PTAB decision to the Federal Circuit. Should the Federal Circuit affirm the PTAB's decision, the PTAB's decision would override any finding in the Hatch-Waxman Litigation that Liquidia has breached any valid claims of the '793 Patent.

'901 Patent deemed by PTAB to be invalid and then withdrawn by UTC from litigation. In December 2021, UTC stipulated that, based on the District Court's construction of the claims in the '901 Patent, Liquidia does not infringe any of the asserted claims of that patent. UTC has not appealed any issues related to the '901 Patent, which has now been dropped from the Hatch-Waxman Litigation.

Increased long-term commitment to Treprostinil Injection market. To improve patients' access to subcutaneous infusion of treprostinil, the Company committed to alleviate the single-source dependence on the existing CADD-MS 3 system for subcutaneous delivery of Treprostinil Injection. In December, Liquidia, Sandoz and Mainbridge Health Partners established a collaboration to repurpose an FDA-approved infusion pump used for insulin with the objective of submitting a 510(k) in 2023. More recently, Liquidia and Sandoz have agreed to cooperate in taking actions designed to maintain the current inventory of CADD-MS3 pumps held at specialty pharmacies supporting PAH patients. Lastly, when establishing these new collaborations, Sandoz and Liquidia extended the term of the promotion agreement for Treprostinil Injection until December 31, 2032.

Fortified financial position through 2024. Liquidia continued to exercise financial discipline by focusing expenses and improving access to cash resources through a combination of a loan refinancing in January 2022, an underwritten public offering of equity in April 2022 and a revenue interest financing with HealthCare Royalty (HCRx) in January 2023 under which HCRx has agreed to pay Liquidia an aggregate of up to $100 million upon

certain events. To date, HCRx has funded $32.5 million, of which $22.4 million was used to satisfy in full and retire the then existing debt obligations to Silicon Valley Bank (SVB), with the excess proceeds less transaction costs of approximately $0.7 million funded to the Company. When combined with the revenue generated by sales of Treprostinil Injection, the Company is well-positioned to launch YUTREPIA within the expected time frame for legal resolution. As for the Company's exposure to Silicon Valley Bank (SVB), 99% of funds were invested in a Blackrock mutual fund, and therefore, should not have been exposed by the events of the last week. As of March 14, 2023, substantially all cash and cash equivalents have been transferred out of SVB to an account held with an accredited financial institution.

Full Year 2022 Financial Results

Cash and cash equivalents totaled $93.3 million as of December 31, 2022.

Revenue was $15.9 million for the year ended December 31, 2022, compared with $12.9 million for the year ended December 31, 2021. During the year ended December 31, 2022, the profit split percentage we received under our Promotion Agreement with Sandoz Inc. was 50%, whereas during the year ended December 31, 2021, the profit split percentage decreased from 80% to 50% as a result of achievement of predetermined cumulative sales thresholds. This decrease in profit split percentage was offset by an increase in the number of units sold. Revenue in 2022 is net of $2.7 million in amortization of the contract acquisition costs associated with the Promotion Agreement.

Cost of revenue was $2.9 million for the year ended December 31, 2022, compared with $3.0 million for the year ended December 31, 2021. Cost of revenue related to the Promotion Agreement as noted above and included (i) the cost of employing a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of PAH, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection and (ii) amortization of the intangible asset associated with the Promotion Agreement.

Research and development expenses were $19.4. million for the year ended December 31, 2022, compared with $20.5 million for the year ended December 31, 2021. The decrease of $1.1 million or 5% was primarily due to a $0.9 million decrease in personnel, consulting, and stock-based compensation expenses. During the year ended December 31, 2022, we incurred $7.0 million related to our YUTREPIA program compared to a total of $6.7 million during the year ended December 31, 2021.

General and administrative expenses were $32.4 million for the year ended December 31, 2022, compared with $23.1 million for the year ended December 31, 2021. The increase of $9.3 million or 40% was primarily due to a $4.2 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA and a $3.1 million increase in stock-based compensation expense driven by an option modification charge recorded in the first quarter of 2022.

Other expenses, net were $2.2 million for the year ended December 31, 2022, compared with $0.8 million for the year ended December 31, 2021. The increase of $1.4 million was primarily due to a $1.0 million loss on extinguishment of debt related to the refinance of our long-term debt during January 2022 and a $1.6 million increase in interest expense due to a higher debt balance and higher interest rate on our debt from the A&R SVB LSA, offset by a $1.1 million increase in interest income from higher cash and cash equivalents balances.

Net loss for during the year ended December 31, 2022, was $41.0 million, or $0.67 per basic and diluted share, compared to a net loss of $34.6 million, or $0.70 per basic and diluted share, for the year ended December 31, 2021.

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. The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) without additional clinical studies. 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 optimal 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.

Tyvaso® is a registered trademark of United Therapeutics Corporation.

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 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 the potential for final FDA approval of the NDA for YUTREPIA, the timeline or outcome related to appeals arising from our patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at 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 favorable decisions of the PTAB in the IPRs for the '793 and '901 patents and of the District Court in the Hatch-Waxman Litigation are not determinative of the outcome of any appeal of those decisions. 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.

Contact Information

Media & Investors:
Jason Adair
Senior Vice President, Corporate Development and Strategy
919.328.4400
jason.adair@liquidia.com

Liquidia Corporation
Select Balance Sheet Data

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 93,283	$ 57,494
Total assets	$ 129,198	$ 93,729
Total liabilities	$ 38,776	$ 28,464
Accumulated deficit	$ (350,596)	$ (309,581)
Total stockholders' equity	$ 90,422	$ 65,265

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2022	2021
Revenue	$ 15,935	$ 12,853
Costs and expenses:		
Cost of revenue	2,859	3,023
Research and development	19,435	20,517
General and administrative	32,411	23,110
Total costs and expenses	54,705	46,650
Loss from operations	(38,770)	(33,797)
Other income (expense):		
Interest income	1,090	33
Interest expense	(2,338)	(762)
Loss on extinguishment of debt	(997)	(53)
Total other income (expense), net	$ (2,245)	$ (782)
Net loss and comprehensive loss	$ (41,015)	$ (34,579)
Net loss per common share, basic and diluted	$ (0.67)	$ (0.70)
Weighted average common shares outstanding, basic and diluted	60,958,862	49,677,737

Source: Liquidia Corporation