Liquidia Corporation Reports Full Year 2023 Financial Results and Provides Corporate Update

March 13, 2024

- Preparing to launch YUTREPIA™ (treprostinil) inhalation powder upon final FDA approval
- Federal Circuit rejected request by United Therapeutics for rehearing of earlier decision finding '793 Patent invalid
- Advancing industry leading portfolio for inhaled treprostinil with YUTREPIA and sustained-release program L606
- Company to host webcast today at 8:30 a.m. ET

MORRISVILLE, N.C., March 13, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) today reported financial results for the full year ended December 31, 2023. The Company will host a webcast at 8:30 a.m. ET to discuss the 2023 financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "Based on our success last year, we are preparing to become a full-scale commercial entity in 2024 and initiate meaningful change to the lives of patients diagnosed with PAH and PH-ILD. Given recent favorable court decisions, we have positioned the Company to be ready for launch of YUTREPIA in both indications following the expiration of Tyvaso's market exclusivity on March 31, 2024. Once on the market, we are confident that the medical community will see first-hand that YUTREPIA has the potential to not only be the best-in-class inhaled product, but also the prostacyclin of first choice given its convenient, low-effort delivery and wide dosing range enabled by our proprietary PRINT Technology."

Corporate Updates

Invalidity of sole patent supporting injunction was affirmed in appeal proceedings at the Federal Circuit. In December 2023, the previous ruling by the Patent Trial and Appeal Board (PTAB) that all of the claims in U.S. Patent No. 10,716,793 ('793 Patent) are invalid was affirmed by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit). On March 12, 2024, the Federal Circuit rejected United Therapeutics' request for a rehearing of the ruling in December. Liquidia has submitted these Federal Circuit rulings to Judge Andrews and requested that he set aside the injunction preventing final regulatory approval of YUTREPIA that he entered in 2022, which is based solely on the '793 Patent.

Awaiting final FDA approval of YUTREPIA to treat PAH and PH-ILD after March 31, 2024. In September 2023, the U.S. Food and Drug Administration (FDA) accepted for review the Company's amendment to the tentatively approved new drug application (NDA) for YUTREPIA to include the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD) to the label. The FDA tentatively approved YUTREPIA to treat pulmonary arterial hypertension (PAH) in November 2021 and confirmed that the addition of the PH-ILD indication would not require any new clinical studies. The FDA may grant final approval of YUTREPIA for both PAH and PH-ILD after the new clinical investigation exclusivity granted to Tyvaso® expires on March 31, 2024 and after Judge Andrews sets aside his injunction.

Advancing industry leading portfolio for inhaled treprostinil between YUTREPIA and sustained-release program, L606. In December 2023, the Company opened enrollment in the ASCENT study, an open-label prospective multicenter study to evaluate safety and tolerability of YUTREPIA in patients diagnosed with PH-ILD. Liquidia plans to complete enrollment of all 60 patients in 2024 and will share interim data at upcoming conferences. Also in December 2023, the FDA confirmed that a single Phase 3 placebo-controlled efficacy trial in PH-ILD patients would be required to support approval of L606 for the treatment of both PAH and PH-ILD under the 505(b)(2) regulatory pathway. The Company is preparing to initiate the global PH-ILD study by the end of 2024. In addition, an on-going, open-label study of L606 in U.S. patients with PAH and PH-ILD is more than one-third enrolled and includes some patients who have been successfully treated with L606 for longer than one year and at doses comparable to 25 to 27 breaths of Tyvaso, four times daily.

Full Year 2023 Financial Results

Cash and cash equivalents totaled $83.7 million as of December 31, 2023. In the first week of January, Liquidia closed two transactions that brought an additional $100 million of gross proceeds into the Company. Liquidia and an affiliate of Patient Square Capital entered into a common stock purchase agreement for the private placement of common stock that yielded gross proceeds of approximately $75.0 million. That same week, HealthCare Royalty Partners (HCRx) and Liquidia entered a fourth amendment to the Revenue Interest Financing Agreement (RIFA) to fund an additional $25.0 million. HCRx has now invested $67.5 million in non-dilutive capital from the $100 million originally contemplated from four tranches under the RIFA.

Revenue was $17.5 million for the year ended December 31, 2023, compared with $15.9 million for the year ended December 31, 2022. Revenue related primarily to the sale of Treprostinil Injection under the Promotion Agreement with Sandoz Inc. The increase of $1.6 million was primarily due to favorable gross-to-net chargeback, rebate, and managed care adjustments offset by the impact of lower sales quantities as compared to the prior year.

Cost of revenue was $2.9 million for both the year ended December 31, 2023 and the year ended December 31, 2022. Cost of revenue related to the Promotion Agreement as noted above. During the fourth quarter of 2024 our sales force expanded in size, however, this increase was offset by a decrease in amortization.

Research and development expenses were $43.2 million for the year ended December 31, 2023 compared with $19.4 million for the year ended December 31, 2022. The increase of $23.8 million or 122% was driven largely by the $10.0 million upfront license fee payment to Pharmosa for the exclusive license in North America to develop and commercialize L606. We incurred an additional $2.6 million in expenses related to our L606 program during the year ended December 31, 2023. Expenses related to our YUTREPIA program increased by $6.3 million from $6.7 million during the year ended December 31, 2022 to $13.0 million during the year ended December 31, 2023 primarily due to increased manufacturing activities

related to pre-launch commercial supply and the startup of our ASCENT study during 2023. Personnel and consulting expenses, including stock compensation expense, increased $5.1 million primarily due to increased headcount to support the potential commercialization of YUTREPIA.

General and administrative expenses were $44.7 million for the year ended December 31, 2023, compared with $32.4 million for the year ended December 31, 2022. The increase of $12.3 million or 38% was primarily due to a $9.8 million increase in personnel and consulting expenses, including stock-based compensation, and a $1.4 million increase in commercial expenses in preparation for the potential commercialization of YUTREPIA.

Total other expense, net was $5.1 million for the year ended December 31, 2023, compared with $2.2 million for the year ended December 31, 2022. The increase of $2.9 million was primarily due to a $3.9 million increase in interest expense attributable to the higher borrowings under the RIFA as compared to balances outstanding under the Amended and Restated Loan and Security Agreement with Silicon Valley Bank (A&R SVB LSA) and a $1.3 million increase in loss on extinguishment of debt due offset by a $2.4 million increase in interest income attributable to higher money market yields. The year ended December 31, 2023 included a $2.3 million loss on extinguishment of debt related to repayment of the A&R SVB LSA in January 2023. The year ended December 31, 2022 included a $1.0 million loss on extinguishment of debt related to the refinance of our long-term debt with SVB in January 2022.

Net loss for the year ended December 31, 2023 was $78.5 million, or $1.21 per basic and diluted share, as compared to a net loss of $41.0 million, or $0.67 per basic and diluted share, for the year ended December 31, 2022.

About YUTREPIA™(treprostinil) inhalation powder
YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-resistance, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA 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. In July 2023, Liquidia filed an amendment to its New Drug Application for YUTREPIA, seeking to add PH-ILD to the label. Previously, the FDA has confirmed that YUTREPIA may add the treatment of PH-ILD to the label for YUTREPIA 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 enhanced 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 L606 (liposomal treprostinil) inhalation suspension
L606 is an investigational, sustained-release formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer. The L606 suspension uses Pharmosa Biopharm's proprietary liposomal formulation to encapsulate treprostinil which can be released slowly at a controlled rate into the lung, enhancing drug exposure over an extended period of time and reducing local irritation of the upper respiratory tract. L606 is currently being evaluated in an open-label study in the United States for treatment of PAH and PH-ILD with a planned pivotal study for the treatment of PH-ILD.

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 pulmonary arterial hypertension (PAH)
PAH is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death. Currently, an estimated 45,000 patients are diagnosed and treated in the United States. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression, and improve quality of life.

About pulmonary hypertension associated with interstitial lung disease (PH-ILD)
Pulmonary hypertension (PH) associated with interstitial lung disease (ILD) includes a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis, chronic hypersensitivity pneumonitis, connective tissue disease related ILD, and chronic pulmonary fibrosis with emphysema (CPFE) among others. Any level of PH in ILD patients is associated with poor 3-year survival. A current estimate of PH-ILD prevalence in the United States is greater than 60,000 patients, though population growth in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until March 2021, when inhaled treprostinil was first approved for this indication.

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. (Liquidia Technologies) and Liquidia PAH, LLC (Liquidia PAH). Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). Liquidia Technologies is also developing L606, an investigational liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, for use in North America. Liquidia PAH provides for the commercialization of 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 patent

litigation in the U.S. District Court for the District of Delaware, inter partes review proceedings conducted at the PTAB or other litigation instituted by United Therapeutics or others, including rehearings or appeals of decisions in any such proceedings, 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 courts or other tribunals are not determinative of the outcome of the appeals or rehearings of the 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, 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

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 83,679	$ 93,283
Total assets	$ 118,332	$ 129,198
Total liabilities	$ 71,039	$ 38,776
Accumulated deficit	$ (429,098)	$ (350,596)
Total stockholders' equity	$ 47,293	$ 90,422

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2023	2022
Revenue	$ 17,488	$ 15,935
Costs and expenses:		
Cost of revenue	2,888	2,859
Research and development	43,242	19,435
General and administrative	44,742	32,411
Total costs and expenses	90,872	54,705
Loss from operations	(73,384)	(38,770)
Other income (expense):		
Interest income	3,466	1,090
Interest expense	(6,273)	(2,338)
Loss on extinguishment of debt	(2,311)	(997)
Total other income (expense), net	(5,118)	(2,245)
Net loss and comprehensive loss	$ (78,502)	$ (41,015)
Net loss per common share, basic and diluted	$ (1.21)	$ (0.67)
Weighted average common shares outstanding, basic and diluted	64,993,476	60,958,862

Liquidia

Source: Liquidia Corporation