Liquidia Corporation Reports Third Quarter 2024 Financial Results and Provides Corporate Update

November 13, 2024

- Received tentative approval from the FDA for YUTREPIA™ (treprostinil) inhalation powder for both pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD)
- U.S. Supreme Court rejected final appeal of '793 patent decision, marking victories with respect to three patents originally asserted final and not subject to further appeal
- Strengthened balance sheet by raising approximately $100 million in additional capital

MORRISVILLE, N.C., Nov. 13, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, today reported financial results for the third quarter ended September 30, 2024. The company will host a webcast at 8:30 a.m. ET on November 13, 2024, to discuss the financial results and provide a corporate update.

Dr. Roger Jeffs, Liquidia's Chief Executive Officer, said: "This quarter we achieved our goal of adding pulmonary hypertension associated with interstitial lung disease (PH-ILD) to the indication statement for YUTREPIA™. While the FDA decision to grant three-year exclusivity to TYVASO DPI®, which will expire on May 23, 2025, currently gates our launch, we will exhaust every effort to bring YUTREPIA to market sooner, as evidenced by our litigation against the FDA to contest what we believe to be the improper grant of exclusivity to TYVASO DPI. In the interim, we will use this pre-launch period to further advance knowledge of the clinical profile of YUTREPIA in PH-ILD patients through our ASCENT study, where we hope to show YUTREPIA's clear advantages related to the tolerability, titratability and durability in this underserved patient population."

Corporate Updates

Received tentative approval from the FDA for YUTREPIA (treprostinil) inhalation powder
In August, the FDA granted tentative approval for YUTREPIA for the treatment of patients with pulmonary arterial hypertension (PAH) and PH-ILD. At present, final approval of YUTREPIA is delayed until after expiration on May 23, 2025, of the new clinical investigation (NCI) exclusivity that was granted to TYVASO DPI.

Commenced litigation to challenge regulatory exclusivity blocking final approval of YUTREPIA
In August, Liquidia filed a lawsuit in the U.S. District Court of the District of Columbia (Case No. 1:24-cv-02428) that challenges the decision by the U.S. Food and Drug Administration (FDA) to grant 3-year NCI exclusivity to Tyvaso DPI. Liquidia and the FDA have agreed to an expedited briefing schedule in anticipation of a hearing on the parties' respective motions for summary judgment on December 5, 2024.

Favorable decisions related to three patents originally asserted against Liquidia are now final and not subject to further appeal
In October, the U.S. Supreme Court rejected the petition filed by United Therapeutics (UTHR) for a writ of certiorari, seeking to appeal prior decisions which found that all claims of U.S. Patent No. 10,716,793 ('793 Patent) are unpatentable. As a result, all disputes regarding the three patents originally asserted by UTHR have now been fully resolved. No valid claims of any of the three patents originally asserted by UTHR are infringed by Liquidia, and all of the decisions are now final and not subject to further appeal. With this decision, UTHR now has no remaining claims in which it is contesting approval of YUTREPIA for the treatment of PAH after the expiration of NCI exclusivity in May 2025.

With the final resolution of the litigation related to the three patents originally asserted against Liquidia by UTHR, the sole remaining patent asserted by UTHR against Liquidia is U.S. Patent No. 11,826,327 ('327 Patent) related to the treatment of PH-ILD patients. In May 2024, the U.S. District Court of the District of Delaware denied UTHR's request for a preliminary injunction with respect to the '327 Patent. A trial in the '327 Patent lawsuit is currently scheduled for June 2025.

Expanded collaboration with Pharmosa Biopharm to develop L606 (liposomal treprostinil) inhalation suspension
In October, Liquidia and Pharmosa amended an exclusive licensing agreement for the development and commercialization of L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of PAH and PH-ILD. The amendment expands Liquidia's licensed territory beyond North America to include key markets in Europe, Japan and elsewhere. In addition, Liquidia has obtained rights to Pharmosa's next-generation nebulizers for use with L606. As part of the amendment, Pharmosa received a $3.5 million initial payment following execution of the amendment and may receive up to $157.75 million in additional development and sales milestones tied to activities in territories outside of North America. Liquidia continues to treat patients with L606 in the ongoing open-label U.S. study.

Strengthened financial position by approximately $100 million through equity raise and advance from financing agreement

In September, Liquidia closed on an underwritten public offering and a concurrent private placement with total gross proceeds of $67.5 million, before deducting underwriting discounts and commissions, and transaction-related expenses. Liquidia also entered into a fifth amendment to the Revenue Interest Financing Agreement (RIFA) with HealthCare Royalty (HCRx) for HCRx to fund an additional $32.5 million to the company. With this amendment, HCRx has funded the full $100 million in non-dilutive capital as originally contemplated under the RIFA entered into in January 2023.

Third Quarter 2024 Financial Results

Cash and cash equivalents totaled $204.4 million as of September 30, 2024, compared to $83.6 million as of December 31, 2023.

Revenue was $4.4 million for the three months ended September 30, 2024, compared to $3.7 million for the three months ended September 30, 2023. Revenue related primarily to the promotion agreement with Sandoz, Inc. (Sandoz) pursuant to which we share profits from the sale of Treprostinil Injection in the United States (the Promotion Agreement). The increase of $0.7 million was primarily due to the impact of higher sales quantities in the current year as compared to the same period in the prior year.

Cost of revenue was $1.6 million for the three months ended September 30, 2024, compared to $0.6 million for the three months ended September 30, 2023. Cost of revenue related to the Promotion Agreement as noted above. The increase from the prior year was primarily due to our sales force expansion during the fourth quarter of 2023.

Research and development expenses were $11.9 million for the three months ended September 30, 2024, compared to $7.4 million for the three months ended September 30, 2023. The increase of $4.5 million or 60% was primarily due to a $2.1 million increase in personnel expenses (including stock-based compensation) related to increased headcount, a $1.3 million increase in clinical expenses related to our L606 program, and a $2.5 million increase in expenses related to YUTREPIA research and development activities, including the ASCENT trial, offset by $1.5 million lower commercial manufacturing expenses reflecting the impact of expensing YUTREPIA inventory costs in the prior year.

General and administrative expenses were $20.2 million for the three months ended September 30, 2024, compared to $10.6 million for the three months ended September 30, 2023. The increase of $9.6 million or 91% was primarily due to a $6.7 million increase in personnel expenses (including stock-based compensation) driven by higher headcount and expansion of our sales force in the fourth quarter of 2023, a $1.5 million increase in legal fees related to our ongoing YUTREPIA-related litigation, and a $0.5 million increase in commercial expenses in preparation for the potential commercialization of YUTREPIA.

Total other income, net was $6.0 million for the three months ended September 30, 2024, compared with total other expense, net of $0.9 million for the three months ended September 30, 2023. The variance was primarily driven by a $7.2 million gain on extinguishment of debt resulting from the Fifth Amendment to the RIFA, which was executed in September 2024. Additionally, there was a $1.2 million increase in interest expense attributable to the higher borrowings under the RIFA as compared to the prior year and a $1.0 million increase in interest income attributable to higher money market balances.

Net loss for the three months ended September 30, 2024, was $23.2 million or $0.30 per basic and diluted share, compared to a net loss of $15.8 million, or $0.24 per basic and diluted share, for the three months ended September 30, 2023.

About YUTREPIA™ (treprostinil) Inhalation Powder
YUTREPIA is an investigational, inhaled dry-powder formulation of treprostinil delivered through a convenient, low-effort, palm-sized device. In August 2024, the FDA issued tentative approval of YUTREPIA for the PAH and PH-ILD indications. 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 is currently being studied in the ASCENT trial, an Open-Label Prospective Multicenter Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in Pulmonary Hypertension, to evaluate the safety and tolerability of YUTREPIA in PH-ILD patients. YUTREPIA was previously referred to as LIQ861 in investigational studies.

About L606 (liposomal treprostinil) Inhalation Suspension
L606 is an investigational, sustained-release formulation of treprostinil administered twice-daily with a 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. L606 is currently being evaluated in an open-label study in the United States for treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) with a planned global pivotal placebo-controlled efficacy 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, Sandoz, who holds the Abbreviated New Drug Application (ANDA) with the FDA.

About Pulmonary Arterial Hypertension (PAH)
Pulmonary arterial hypertension (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 actual prevalence 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 developing innovative therapies for patients with rare cardiopulmonary disease. The company's current focus spans the development and commercialization of products in pulmonary hypertension and other applications of its proprietary PRINT® Technology. PRINT enabled the creation of Liquidia's lead candidate, YUTREPIA™ (treprostinil) inhalation powder, an investigational drug for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The company is also developing L606, an investigational sustained-release formulation of treprostinil administered twice-daily with a next-generation nebulizer, and currently markets generic Treprostinil Injection for the treatment of PAH. To learn more about Liquidia, please visit www.liquidia.com.

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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, which may occur after the expiration of the exclusivity period of TYVASO DPI, if at all, the timelines or outcomes related to patent litigation with United Therapeutics in the U.S. District Court for the District of Delaware, litigation with United Therapeutics and FDA in the U.S. District Court for the District of Columbia 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 Condensed Consolidated Balance Sheet Data (unaudited)
(in thousands)

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 204,368	$ 83,679
Total assets	$ 252,886	$ 118,332
Total liabilities	$ 142,368	$ 71,039
Accumulated deficit	$ (521,123)	$ (429,098)
Total stockholders' equity	$ 110,518	$ 47,293

Liquidia Corporation
Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September,	
	2024	2023
Revenue	$ 4,448	$ 3,678
Costs and expenses:		
Cost of revenue	$ 1,565	$ 570
Research and development	$ 11,890	$ 7,440
General and administrative	$ 20,182	$ 10,559
Total costs and expenses	$ 33,637	$ 18,569
Loss from operations	$ (29,189)	$ (14,891)
Other income (expense):		
Interest income	$ 1,815	$ 862
Interest expense	$ (2,996)	$ (1,761)
Gain on extinguishment of debt	$ 7,215	$ —
Total other expense, net	$ 6,034	$ (899)
Net loss and comprehensive loss	$ (23,155)	$ (15,790)
Net loss per common share, basic and diluted	$ (0.30)	$ (0.24)
Weighted average common shares outstanding, basic and diluted	$ 78,316,820	$ 64,857,508

Source: Liquidia Corporation