Liquidia Corporation Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 7, 2023

- Oral arguments in appeal of '793 PTAB decision set for December 4, 2023
- PDUFA goal date to add PH-ILD indication to YUTREPIA label is January 24, 2024
- Hired sales force in preparation of potential positive legal and regulatory outcomes

MORRISVILLE, N.C., Nov. 07, 2023 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) today reported financial results for the third quarter ended September 30, 2023. The Company will host a webcast at 8:30 a.m. ET to discuss the financial results and provide a corporate update.

Dr. Roger Jeffs, Liquidia's Chief Executive Officer, said: "We continue to make great strides in advancing our mission to help patients with pulmonary hypertension breathe easier and live longer. We are looking forward to upcoming key events that will help unlock the value of YUTREPIA® (treprostinil) inhalation powder, with pivotal legal arguments set in early December and potential label expansion of YUTREPIA for PH-ILD in late January. In anticipation of potential successful resolution of the ongoing legal dispute with United Therapeutics and receiving final FDA approval, we have expanded our top-tier sales force, all of whom are deeply skilled in the commercialization of rare disease products. If successful, we look forward to promoting the benefits of YUTREPIA's unmatched product profile, specifically its tolerability, titratability, and durability, all delivered via a patient-friendly low-effort device enabled by our proprietary PRINT technology."

Corporate Updates

Received PDUFA goal date to add PH-ILD indication to YUTREPIA label. The U.S. Food and Drug Administration (FDA) accepted the amendment to the New Drug Application (NDA) for YUTREPIA to add the indication of pulmonary hypertension associated with interstitial lung disease (PH-ILD) to the label and has set a Prescription Drug User Fee Act (PDUFA) goal date of January 24, 2024. If approved, YUTREPIA would be indicated for the treatment of both pulmonary arterial hypertension (PAH) and PH-ILD, though final approval of the PH-ILD indication cannot occur until the new clinical investigation exclusivity granted to Tyvaso® expires on March 31, 2024. Concurrent with this amendment, Liquidia submitted a paragraph IV certification indicating that the patents listed for Tyvaso® in the FDA's publication commonly known as the Orange Book are invalid and/or not infringed by YUTREPIA. In September 2023, United Therapeutics (UTHR) filed a second complaint for patent infringement against the Company under the Hatch-Waxman Act in the U.S. District Court for the District of Delaware (District Court), asserting infringement of U.S. Patent No. 10,716,793 ('793 Patent). This second complaint is tied to the same '793 patent previously ruled invalid by Patent Trial and Appeal Board (PTAB).

Oral arguments for appeal of PTAB ruling of '793 Patent invalidity scheduled for December 4, 2023. Final regulatory approval of YUTREPIA is currently barred by an order from earlier Hatch-Waxman proceedings in the District Court in which the '793 Patent was found to be valid and infringed. However, in a parallel proceeding before the PTAB, the '793 Patent was found to be invalid. If the PTAB's decision is affirmed by the Court of Appeals for the Federal Circuit (CAFC), then the PTAB's decision would override the decision from the District Court proceeding, thereby creating the opportunity for the Company to seek final FDA approval for YUTREPIA. Once argued, the CAFC could rule within a few days, in the case of summary affirmance, or within a few months after oral argument if a full written opinion is issued. Additionally, if the CAFC upholds the PTAB decision in Liquidia's favor, then such ruling would have precedential effect in the second lawsuit recently filed by UTHR alleging infringement of the '793 Patent in connection with the amendment of YUTREPIA's NDA to add the PH-ILD indication.

Fully transitioned clinical development of L606 from Pharmosa to Liquidia for the North American territory. In June, Liquidia acquired an exclusive license to develop and commercialize L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a Phase 3 open-label clinical trial for the treatment of PAH and PH-ILD. Compared to current inhaled options, L606 offers potential advantages of more consistent drug exposure over 24 hours, including during sleeping hours, with twice-daily dosing and improved tolerability via a modern, next-gen nebulizer. Liquidia has assumed full responsibility for the investigational new drug (IND) and is preparing for a Type C meeting with the FDA in December to discuss the registration pathway for PAH and PH-ILD.

Third Quarter 2023 Financial Results

Cash totaled $76.2 million as of September 30, 2023, compared to $93.3 million as of December 31, 2022.

Revenue was $3.7 million for the three months ended September 30, 2023, compared to $3.2 million for the three months ended September 30, 2022. Revenue related primarily to the promotion agreement between Liquidia PAH and Sandoz Inc, sharing profit derived from the sale of Sandoz's substitutable generic treprostinil injection (Treprostinil Injection) in the United States (the Promotion Agreement). The increase from the prior year was primarily due to favorable gross-to-net managed care and chargeback adjustments offset by the impact of lower sales quantities as compared to the same period in the prior year.

Cost of revenue was $0.6 million for the three months ended September 30, 2023, compared to $0.7 million for the three months ended September 30, 2022. Cost of revenue related to the Promotion Agreement as noted above. The decrease from the prior year was primarily due to lower intangible asset amortization due to an extension of the term of the Promotion Agreement during the fourth quarter of 2022.

Research and development expenses were $7.4 million for the three months ended September 30, 2023, compared to $4.5 million for the three months ended September 30, 2022. The increase of $2.9 million or 65% was primarily due to a $1.5 million increase in expenses related to our YUTREPIA program driven by higher manufacturing and pre-launch commercial supply costs, a $0.7 million increase in consulting and personnel expenses related to higher headcount, and a $0.4 million increase in clinical expenses related to our L606 open label study.

General and administrative expenses were $10.6 million for the three months ended September 30, 2023, compared to $6.7 million for the three

months ended September 30, 2022. The increase of $3.9 million or 57% was primarily due to a $1.4 million increase in legal fees related to our ongoing YUTREPIA-related litigation, a $0.9 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA, a $0.7 million increase in commercial expenses, and a $0.6 million increase in stock-based compensation expense.

Total other expense, net was $0.9 million for the three months ended September 30, 2023, compared with $0.3 million for the three months ended September 30, 2022. The increase of $0.6 million was driven by $1.1 million higher interest expense attributable to the higher borrowings under the Revenue Interest Financing Agreement with HealthCare Royalty Partners as compared to balances outstanding under the Amended and Restated Loan and Security Agreement with Silicon Valley Bank and offset by a $0.5 million increase in interest income attributable to higher money market yields.

Net loss for the three months ended September 30, 2023, was $15.8 million, or $0.24 per basic and diluted share, compared to a net loss of $9.1 million, or $0.14 per basic and diluted share, for the three months ended September 30, 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 NDA for YUTREPIA, seeking to add pulmonary hypertension with interstitial lung disease (PH-ILD) to the label. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of January 24, 2024 for the amendment. 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.

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 pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (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)

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 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. and Liquidia PAH, LLC. 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 the commercialization for pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

Remodulin® and Tyvaso® are registered trademarks of United Therapeutics Corporation.

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 or *inter partes* review proceedings conducted at the PTAB, including 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 the PTAB with respect to the '793 patent is not determinative of the outcome of the appeal of the decision. 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.

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Liquidia Corporation
Select Consolidated Balance Sheet Data
(in thousands)

	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 76,225	$ 93,283
Total assets	$ 111,641	$ 129,198
Total liabilities	$ 63,635	$ 38,776
Accumulated deficit	$ (401,648)	$ (350,596)
Total stockholders' equity	$ 48,006	$ 90,422

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

	Three Months Ended September 30,	
	2023	2022
Revenue	$ 3,678	$ 3,165
Costs and expenses:		
Cost of revenue	570	740
Research and development	7,440	4,512
General and administrative	10,559	6,744
Total costs and expenses	18,569	11,996
Loss from operations	(14,891)	(8,831)
Other income (expense):		
Interest income	862	359
Interest expense	(1,761)	(620)
Loss on extinguishment of debt	—	—
Total other expense, net	(899)	(261)
Net loss and comprehensive loss	$ (15,790)	$ (9,092)
Net loss per common share, basic and diluted	$ (0.24)	$ (0.14)
Weighted average common shares outstanding, basic and diluted	64,857,508	64,458,741

Source: Liquidia Corporation