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

August 10, 2023

MORRISVILLE, N.C., Aug. 10, 2023 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) today reported financial results for the second quarter ended June 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: "This quarter saw Liquidia significantly advance our mission to become the leading inhaled treprostinil provider for pulmonary hypertension patients. Achievements of note include: 1) the affirmation by the U.S. Court of Appeals for the Federal Circuit (CAFC) that all claims of the No. 9,593,066 ('066 patent) are invalid or not infringed, 2) the filing of an amendment to add PH-ILD to the YUTREPIA label, and 3) the license of L606 from Pharmosa Biopharm to develop and commercialize a sustained-release liposomal formulation of treprostinil for twice-daily nebulization. With these achievements in mind, we we will continue to prepare for a potential launch of YUTREPIA in the near future, both for PAH and subsequently PH-ILD."

Corporate Updates

Advanced litigation with United Therapeutics. With the decision of the CAFC issued in July with respect to the Hatch-Waxman litigation between Liquidia and United Therapeutics Corporation (UTHR), only one of the three patents originally asserted against Liquidia in Hatch-Waxman litigation, U.S. Patent No. 10,716,793 ('793 Patent), remains gating to final approval for YUTREPIA. In July 2022, the Patent Trial and Appeal Board (PTAB) found the '793 Patent to be unpatentable due to the existence of prior art as cited in the *inter partes* review filed by Liquidia. The PTAB then re-affirmed that decision in February 2023, and UTHR appealed the decision to the CAFC. Briefing in the appeal should be completed in fourth quarter 2023 and oral arguments will be heard on the next available date in the oral argument calendar, expected to be late fourth quarter 2023 to early 2024. 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. If affirmed by the CAFC, the PTAB's decision would override any earlier finding of infringement, and Liquidia would immediately seek final regulatory approval for YUTREPIA.

Submitted amendment to add PH-ILD indication to tentatively approved new drug application (NDA) for YUTREPIA. The U.S. Food and Drug Administration (FDA) had previously confirmed that the additional PH-ILD indication would not require any new clinical efficacy data. If approved, YUTREPIA would be indicated for the treatment of both 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 also 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. All Orange Book patents previously asserted by United Therapeutics have already been found to be invalid or not-infringed as decided by U.S. District Court, confirmed on appeal, or by the PTAB, pending the appeal described above.

Expanded pipeline through partnership with Pharmosa Biopharm to develop L606 in North America. In June, Liquidia acquired an exclusive license to develop and commercialize L606, an inhaled, sustained-release, liposomal formulation of treprostinil currently being evaluated in a Phase 3 open-label clinical trial for the treatment of PAH and PH-ILD. L606 offers potential advantages of (a) less frequent dose administrations, (b) more consistent drug exposure over 24 hours, including sleeping hours, (c) improved tolerability via lower peak exposure, and (d) improved portability via a modern, next-gen nebulizer. Liquidia will be responsible for development, regulatory and commercial activities of L606 in North America, while Pharmosa will manufacture clinical and commercial supplies of L606 and support Liquidia's effort to establishing a redundant global supply chain. Pending input from the FDA from a planned Type B meeting later this year, Liquidia intends to initiate a Phase 3 randomized, placebo-controlled study in 2024 to evaluate treatment of PH-LD patients with L606.

Second Quarter 2023 Financial Results

Cash totaled $88.2 million as of June 30, 2023, compared to $93.3 million as of December 31, 2022.

Revenue was $4.8 million for the three months ended June 30, 2023, compared to $3.9 million for the three months ended June 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 increase of $0.9 million was primarily due to favorable gross-to-net chargeback and rebate adjustments.

Cost of revenue was $0.7 million for both the three months ended June 30, 2023, and 2022. Cost of revenue related to the promotion agreement as noted above.

Research and development expenses were $17.7 million for the three months ended June 30, 2023, compared to $5.2 million for the three months ended June 30, 2022. The increase of $12.5 million or 239% was primarily due to a $10.0 million upfront payment owed to Pharmosa for the exclusive license in North America to develop and commercialize L606. Additionally, there was a $2.2 million increase in expenses related to our YUTREPIA program driven by higher manufacturing and supply costs.

General and administrative expenses were $9.2 million for the three months ended June 30, 2023, compared to $6.9 million for the three months ended June 30, 2022. The increase of $2.3 million or 33% was primarily due to a $1.3 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA, a $0.7 million increase in legal fees related to our ongoing YUTREPIA-related litigation, and a $0.6 million increase in stock-based compensation expense.

Total other expense, net was $0.7 million for the three months ended June 30, 2023, compared with $0.5 million for the three months ended June 30, 2022. Liquidia incurred an increase of $0.9 million in 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 a $0.7 million increase in interest income attributable to higher money market yields.

Net loss for the three months ended June 30, 2023, was $23.5 million, or $0.36 per basic and diluted share, compared to a net loss of $9.4 million, or $0.15 per basic and diluted share, for the three months ended June 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, 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 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, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer. The L606 suspension uses Pharmosa Biopharma'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.

Tyvaso® is a 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 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 IPR for the '793 patent and of the Court and CAFC 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) 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)

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 88,196	$ 93,283
Total assets	$ 121,597	$ 129,198
Total liabilities	$ 60,940	38,776
Accumulated deficit	$ (385,858)	(350,596)
Total stockholders' equity	$ 60,657	90,422

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

	Three Months Ended June 30,	
	2023	2022
Revenue	$ 4,786	$ 3,918
Costs and expenses:		
Cost of revenue	671	731
Research and development	17,695	5,219
General and administrative	9,245	6,938
Total costs and expenses	27,611	12,888
Loss from operations	(22,825)	(8,970)
Other income (expense):		
Interest income	734	65
Interest expense	(1,426)	(542)
Loss on extinguishment of debt	—	—
Total other expense, net	(692)	(477)
Net loss and comprehensive loss	$ (23,517)	$ (9,447)
Net loss per common share, basic and diluted	$ (0.36)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	64,788,482	62,179,305

Source: Liquidia Corporation