



## Liquidia Corporation Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 8, 2025

- Awaiting FDA action on YUTREPIA™ NDA with a PDUFA goal date of May 24, 2025
- District Court dismissed cross claim filed by United Therapeutics challenging PH-ILD amendment
- Fully enrolled Cohort A of ASCENT study in patients with PH-ILD
- Further strengthened financial position via access of up to \$100 million from existing financing agreement with HealthCare Royalty
- Company to host webcast today at 8:30 a.m. ET

MORRISVILLE, N.C., May 08, 2025 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, today reported financial results for the first quarter ended March 31, 2025. The company will also host a webcast at 8:30 a.m. ET on May 8, 2025 to discuss its financial results and provide a corporate update.

Dr. Roger Jeffs, Liquidia's Chief Executive Officer, said: "With the FDA's PDUFA goal date on the YUTREPIA NDA just over two weeks away, we remain focused on ensuring that we are prepared to make YUTREPIA commercially available in the quickest time possible if granted full approval. We continue to believe that YUTREPIA has the potential to be the prostacyclin of first choice for patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD)."

### Corporate Updates

#### **Awaiting FDA action on NDA for YUTREPIA (treprostinil) inhalation powder**

On March 28, 2025, the U.S. Food and Drug Administration (FDA) accepted Liquidia's New Drug Application (NDA) resubmission for YUTREPIA (treprostinil) inhalation powder to treat PAH and PH-ILD as a complete Class 1 response to the previous action letter issued on August 16, 2024, which granted tentative approval of YUTREPIA. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of May 24, 2025, the day after regulatory exclusivity expires for Tyvaso DPI®.

#### **Court will not hear cross-claim that challenged the amendment to the YUTREPIA NDA to add the PH-ILD indication**

On May 2, 2025, Liquidia announced that the U.S. District Court for the District of Columbia (District Court) dismissed, without prejudice, the cross-claim filed by United Therapeutics (UTHR) that sought to challenge Liquidia's amendment to its NDA for YUTREPIA™ (treprostinil) inhalation powder, which added the treatment of PH-ILD to the proposed label for YUTREPIA. In its ruling, the District Court determined that UTHR's claim was unripe and that UTHR had failed to plausibly allege that it has standing. UTHR has the right to appeal the Court's ruling.

#### **Fully enrolled Cohort A of ASCENT study in PH-ILD patients**

In March 2025, Liquidia completed enrollment of Cohort A of the open-label ASCENT study evaluating the tolerability and titratability of YUTREPIA in PH-ILD, with more than 50 patients enrolled. An interim look at the dosing and tolerability profile in the first 20 patients to complete eight weeks of treatment was consistent with observations made in the INSPIRE study of PAH patients. To date, patients in Cohort A of ASCENT were able to titrate to doses that are three-times higher than the labelled target dose of nebulized Tyvaso, while showing positive trends on exploratory measures of efficacy, including 6-minute walk distance. Liquidia will present additional data from Cohort A of the ASCENT study during two poster sessions at the American Thoracic Society (ATS) 2025 International Conference on May 20, 2025.

#### **Strengthened financial position ahead of launch via amendment to Agreement with HealthCare Royalty**

On March 17, 2025, Liquidia entered into a sixth amendment to its agreement with HealthCare Royalty (HCR Agreement) to provide for up to an additional \$100 million of financing in three tranches. The company intends to use the proceeds to fund ongoing commercial development of YUTREPIA, continued development of YUTREPIA in other clinical trials, including but not limited to trials for pediatric patients and trials further evaluating the use of YUTREPIA in PAH and PH-ILD patients, clinical development of L606, a sustained-release formulation of treprostinil administered twice-daily with a next-generation nebulizer, and for general corporate purposes.

### First Quarter 2025 Financial Results

Cash and cash equivalents totaled \$169.8 million as of March 31, 2025, compared to \$176.5 million as of December 31, 2024.

Revenue was \$3.1 million for the three months ended March 31, 2025, compared to \$3.0 million for the three months

ended March 31, 2024. Revenue related primarily to the promotion agreement with Sandoz, Inc. pursuant to which we share profits from the sale of Treprostinil Injection in the United States (Promotion Agreement). The increase of \$0.1 million was primarily due to the impact of unfavorable gross-to-net returns adjustments recorded in the prior year offset by lower sales volumes in the current year.

Cost of revenue was \$1.5 million for each of the three months ended March 31, 2025 and 2024. Cost of revenue related to the Promotion Agreement as noted above.

Research and development expenses were \$7.0 million for the three months ended March 31, 2025, compared to \$10.1 million for the three months ended March 31, 2024. The decrease of \$3.1 million or 31% was primarily due to a \$3.6 million decrease in personnel expenses (including stock-based compensation) due to a shift from activities related to research and development to preparation for the potential commercialization of YUTREPIA. These decreases were offset by a \$1.7 million increase in clinical expenses related to our L606 program, and a \$0.4 million decrease in expenses related to our YUTREPIA research and development activities.

General and administrative expenses were \$30.1 million for the three months ended March 31, 2025, compared to \$20.2 million for the three months ended March 31, 2024. The increase of \$9.9 million or 48% was primarily due to a \$8.1 million increase in personnel expenses (including stock-based compensation) driven by higher headcount and a shift from activities related to research and development to preparation for the potential commercialization of YUTREPIA, a \$0.6 million increase in legal fees related to our ongoing YUTREPIA-related litigation, and a \$0.6 million increase in facilities and infrastructure expenses.

Total other expense, net was \$2.9 million for the three months ended March 31, 2025, compared with \$1.3 million for the three months ended March 31, 2024. The increase of \$1.6 million was primarily driven by a \$1.5 million increase in interest expense attributable to the higher borrowings under the HCR Agreement.

Net loss for the three months ended March 31, 2025, was \$38.4 million or \$0.45 per basic and diluted share, compared to a net loss of \$30.1 million, or \$0.40 per basic and diluted share, for the three months ended March 31, 2024.

#### **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<sup>®</sup> Technology. PRINT enabled the creation of Liquidia's lead candidate, YUTREPIA<sup>™</sup> (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](http://www.liquidia.com).

Remodulin<sup>®</sup> and Tyvaso<sup>®</sup> 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, 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 between Liquidia and 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, the potential for additional funding under the HCR Agreement, our anticipated use of net proceeds funded under the HCR Agreement, our estimates regarding future expenses, capital requirements and needs for additional financing, and potential revenue and profitability of YUTREPIA, if approved, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The receipt of tentative approval of an NDA from the FDA is not determinative as to whether or when the FDA will grant final approval. 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.

### **Financial Statement Revision**

During the three months ended March 31, 2025, we identified immaterial errors in our accounting treatment of the fourth and fifth amendments to the HCR Agreement. We voluntarily revised our previously issued 2024 annual consolidated financial statements to correct the immaterial errors and disclosed the impacts to our quarterly financial statements for the respective 2024 interim periods in our Current Report on Form 8-K filed on May 8, 2025. As a result of the revision, the loss on extinguishment has been eliminated and an adjustment to interest expense resulting from the modifications has been recorded, with corresponding adjustments to the long-term debt and accumulated deficit accounts. The financial statement line items as of and for the three months ended March 31, 2024 in the financial statements presented in this press release reflect such revisions.

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**Liquidia Corporation**

**Select Condensed Consolidated Balance Sheet Data (unaudited)  
(in thousands)**

	March 31	December 31
	,	,
	<b>2025</b>	<b>2024</b>
Cash and cash equivalents	\$ 169,758	\$ 176,479
Total assets	\$ 227,429	\$ 230,313
Total liabilities	\$ 177,716	\$ 150,935
Accumulated deficit	\$ (595,756)	\$ (557,389)
Total stockholders' equity	\$ 49,713	\$ 79,378

**Liquidia Corporation**

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

	Three Months Ended March 31,	
	<b>2025</b>	<b>2024</b>
Revenue	\$ 3,120	\$ 2,972
Costs and expenses:		
Cost of revenue	1,517	1,467
Research and development	6,966	10,057
General and administrative	30,062	20,249
Total costs and expenses	38,545	31,773
Loss from operations	(35,425)	(28,801)
Other income (expense):		
Interest income	1,728	1,880
Interest expense	(4,670)	(3,162)
Total other expense, net	(2,942)	(1,282)
Net loss and comprehensive loss	\$ (38,367)	\$ (30,083)
Net loss per common share, basic and diluted	\$ (0.45)	\$ (0.40)
Weighted average common shares outstanding, basic and diluted	85,172,696	75,393,907

