

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 19, 2025**

LIQUIDIA CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39724
(Commission
File Number)

85-1710962
(IRS Employer
Identification No.)

419 Davis Drive, Suite 100, Morrisville, North Carolina
(Address of principal executive offices)

27560
(Zip Code)

Registrant's telephone number, including area code: **(919) 328-4400**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock	LQDA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 19, 2025, Liquidia Corporation, a Delaware corporation, issued a press release announcing its financial results for the full year ended December 31, 2024, and also provided a corporate update. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit

No.	Exhibit
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99.1	Press Release of Liquidia Corporation, dated March 19, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* The information in Item 2.02 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

March 19, 2025

Liquidia Corporation

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer and Chief Operating Officer

Liquidia Corporation Reports Full Year 2024 Financial Results and Provides Corporate Update

- Targeting final FDA approval of YUTREPIA™ after expiration of regulatory exclusivity on May 23, 2025
- Advancing pipeline of inhaled treprostinil products in clinical studies
- Strengthened financial position by up to \$100 million via amendment to existing financing agreement with HealthCare Royalty Partners (HCRx)
- Company to host webcast today at 8:30 a.m. ET

MORRISVILLE, N.C., March 19, 2025 – Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, today reported financial results for the full year ended December 31, 2024. The company will also host a webcast at 8:30 a.m. ET on March 19, 2025 to discuss its financial results and provide a corporate update.

Dr. Roger Jeffs, Liquidia’s Chief Executive Officer, said: “Building on our progress this past year, Liquidia has strengthened its financial position, with up to an additional \$100 million available pursuant to an amendment to its existing financing agreement with HCRx, while remaining poised for the potential approval and commercialization of YUTREPIA after the expiration on May 23, 2025 of the regulatory exclusivity that is currently preventing final approval. We continue to have our sights set on fulfilling our promise to provide physicians and patients with what we believe can be a much-needed therapeutic alternative, and potentially the prostacyclin of first choice, for patients with PAH and PH-ILD.”

Corporate Updates**Potential for final FDA approval of YUTREPIA (treprostinil) inhalation powder after expiration of regulatory exclusivity on May 23, 2025**

On August 16, 2024, the United States Food and Drug Administration (FDA) granted tentative approval for YUTREPIA for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) and simultaneously determined that Tyvaso DPI® qualifies for a three-year New Clinical Investigation (NCI) exclusivity for the chronic use of dry powder formulations of treprostinil for the approved indications. The NCI exclusivity will expire on May 23, 2025, after which the FDA may grant final approval of YUTREPIA.

Continuing to advance the pipeline of inhaled treprostinil in the clinic

The open-label ASCENT study evaluating the tolerability and titratability of YUTREPIA in patients with PH-ILD is nearing enrollment completion. Observations to date have demonstrated tolerability and titratability of YUTREPIA in PH-ILD patients that is consistent with observations from the prior INSPIRE study in PAH patients.

Liquidia continues to progress clinical studies of L606 (liposomal treprostinil) inhalation suspension, an investigational sustained-release formulation of treprostinil administered twice-daily with a next-generation nebulizer. The U.S. open-label safety study of 28 patients with PAH and PH-ILD remains ongoing. To date, participants have safely titrated to the study’s maximum dose twice daily, which is comparable to 26-28 breaths of Tyvaso® administered four times per day. The FDA has confirmed that a single, placebo-controlled, global pivotal study in PH-ILD patients would support seeking approval to treat both PAH and PH-ILD patients.

Strengthened financial position by amending HCRx agreement to incrementally add up to \$100 million

In March 2025, Liquidia entered into an amendment to its agreement with HCRx (HCR Agreement) to provide for up to an additional \$100 million of financing in three tranches. Under the terms of the agreement, Liquidia received \$25.0 million at closing with the potential to receive two additional tranches of funding: \$50.0 million upon the first commercial sale of YUTREPIA following receipt of final FDA approval for the treatment of PAH and PH-ILD, so long as no injunction has been issued prohibiting Liquidia from commercializing YUTREPIA for either or both of PAH and PH-ILD, and \$25.0 million upon the mutual agreement of the parties after achieving aggregate net sales of YUTREPIA in excess of \$100 million any time on or prior to June 30, 2026.

Full Year 2024 Financial Results

Cash and cash equivalents totaled \$176.5 million as of December 31, 2024, compared to \$83.7 million as of December 31, 2023.

Revenue was \$14.0 million for the year ended December 31, 2024, compared to \$17.5 million for the year ended December 31, 2023. 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 decrease of \$3.5 million was primarily due to lower sales quantities, driven by limitations on the availability of pumps used to administer Treprostinil Injection subcutaneously. Sales quantities will continue to be impacted until alternative pumps are available.

Cost of revenue was \$5.9 million for the year ended December 31, 2024, compared to \$2.9 million for the year ended December 31, 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 \$47.8 million for the year ended December 31, 2024, compared to \$43.2 million for the year ended December 31, 2023. The increase of \$4.6 million or 11% was primarily due to (i) a \$6.1 million increase in expenses related to our L606 program, (ii) a \$5.3 million increase in expenses related to YUTREPIA research and development activities, including the ASCENT trial, (iii) a \$5.1 million increase in personnel expenses (including stock-based compensation) related to increased headcount, and (iv) a \$3.5 million upfront license fee due to Pharmosa for the exclusive license in Europe to develop and commercialize L606 recorded during the year ended December 31, 2024, offset by (i) \$5.1 million lower commercial manufacturing expenses reflecting the impact of expensing YUTREPIA inventory costs in the prior year and (ii) a \$10.0 million upfront license fee due to Pharmosa for the exclusive license in North America to develop and commercialize L606 recorded during the year ended December 31, 2023.

General and administrative expenses were \$81.6 million for the year ended December 31, 2024, compared to \$44.7 million for the year ended December 31, 2023. The increase of \$36.9 million or 82% was primarily due to (i) a \$19.7 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, (ii) a \$7.9 million increase in legal fees related to our ongoing YUTREPIA-related litigation, and (iii) a \$6.8 million increase in commercial expenses in preparation for the potential commercialization of YUTREPIA.

Total other expense, net was \$9.1 million for the year ended December 31, 2024, compared to \$5.1 million for the year ended December 31, 2023. The increase of \$4.0 million was primarily driven by a \$2.0 million increase in the net loss on extinguishment of debt resulting from the Fourth and Fifth Amendments to the HCR Agreement, which were executed in January 2024 and September 2024, respectively. Additionally, there was a \$6.2 million increase in interest expense attributable to the higher borrowings under the HCR Agreement compared to the prior year and a \$4.2 million increase in interest income attributable to higher money market balances.

Net loss for the year ended December 31, 2024, was \$130.4 million or \$1.66 per basic and diluted share, compared to a net loss of \$78.5 million, or \$1.21 per basic and diluted share, for the year ended December 31, 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.

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, 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, 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 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)

	December 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 176,479	\$ 83,679
Total assets	\$ 230,313	\$ 118,332
Total liabilities	\$ 153,038	\$ 71,039
Accumulated deficit	\$ (559,492)	\$ (429,098)
Total stockholders' equity	\$ 77,275	\$ 47,293

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

	Full Year Ended December 31,	
	2024	2023
Revenue	\$ 13,996	\$ 17,488
Costs and expenses:		
Cost of revenue	\$ 5,879	\$ 2,888
Research and development	\$ 47,842	\$ 43,242
General and administrative	\$ 81,569	\$ 44,742
Total costs and expenses	\$ 135,290	\$ 90,872
Loss from operations	\$ (121,294)	\$ (73,384)
Other income (expense):		
Interest income	\$ 7,654	\$ 3,466
Interest expense	\$ (12,486)	\$ (6,273)
Gain (loss) on extinguishment of debt	\$ (4,268)	\$ (2,311)
Total other expense, net	\$ (9,100)	\$ (5,118)
Net loss and comprehensive loss	\$ (130,394)	\$ (78,502)
Net loss per common share, basic and diluted	\$ (1.66)	\$ (1.21)
Weighted average common shares outstanding, basic and diluted	\$ 78,707,503	\$ 64,993,476