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): **May 13, 2024**

LIQUIDIA CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-39724**	**85-1710962**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

419 Davis Drive, Suite 100, Morrisville, North Carolina	**27560**
(Address of principal executive offices)	(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 May 13, 2024, Liquidia Corporation, a Delaware corporation, issued a press release announcing its financial results for the quarter ended March 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
99.1	Press Release of Liquidia Corporation, dated May 13, 2024.
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.

May 14, 2024

Liquidia Corporation

By: /s/ Michael Kaseta
Name: Michael Kaseta
Title: Chief Financial Officer and Chief Operating Officer

Exhibit 99.1

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

MORRISVILLE, N.C., May 13, 2024 – Liquidia Corporation (NASDAQ: LQDA) today reported financial results for the first quarter ended March 31, 2024. The company will host a webcast at 8:30 a.m. ET on May 14, 2024 to discuss the financial results and provide a corporate update.

Dr. Roger Jeffs, Liquidia's chief executive officer, said: "We continue to vigorously pursue final agency action for YUTREPIA's approval for pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). And as we have shown, we will remain relentless in the defense of our freedom to go to market despite the myriad of legal filings by our competitor. At our core is our steadfast commitment to deliver YUTREPIA to patients with PAH and PH-ILD. We feel YUTREPIA can provide an important and differentiated alternative to address lingering unmet needs that continue to limit the optimal delivery of inhaled treprostinil."

Corporate Updates

Removed all legal barriers for FDA to issue final action on the amended NDA for YUTREPIA. As of April 1, 2024, there is no further legal impediment preventing the U.S. Food and Drug Administration (FDA) from granting final approval of YUTREPIA for both PAH and PH-ILD. In late March 2024, Judge Andrews set aside the injunction issued in the original Hatch Waxman litigation that had prevented FDA approval of the NDA for YUTREPIA. In addition, the FDA regulatory exclusivity granted to Tyvaso® for the treatment of PH-ILD expired on March 31, 2024.

Progressing the ASCENT study of YUTREPIA in PH-ILD. The company continues to enroll up to 60 subjects into the ASCENT study, an open-label prospective multicenter study to evaluate safety and tolerability of YUTREPIA in patients diagnosed with PH-ILD. Patients to date have titrated to known therapeutics doses of at least 79.5 mcg and up to 318 mcg, a range comparable to 9 to 36 breaths of Tyvaso. The company intends to present data at medical conferences later in the year.

Continuing to treat PAH and PH-ILD patients with L606. The sustained-release liposomal formulation of treprostinil is being evaluated in an open-label study in PH-ILD and PAH patients. To date, patients have safely titrated to doses up to 378 mcg administered twice daily, a dosage that would be comparable to 26 to 28 breath equivalents of Tyvaso administered four times daily. Liquidia will share additional safety and dosing data from the on-going L606 study in a poster presentation at the American Thoracic Society 2024 International Conference in San Diego on May 22, 2024.

Awaiting ruling from District Court on preliminary injunction in new patent infringement lawsuit filed by United Therapeutics. United Therapeutics filed a new patent infringement lawsuit against the company in Delaware District Court (Case No. 1:23-cv-00975-RGA) alleging that YUTREPIA infringes U.S. Patent No. 11,826,327 ('327 patent), which issued in November 2023. UTHR has filed a motion for preliminary injunction to block Liquidia from launching YUTREPIA for PH-ILD. Judge Andrews heard oral arguments from both parties regarding the motion for preliminary injunction on April 23, 2024, and the matter is fully briefed. The parties are awaiting the Court's decision.

Court denied United Therapeutics' Request for Injunctive Relief in Lawsuit Against FDA. UTHR filed a separate lawsuit against FDA in the U.S. District Court for the District of Columbia (Case No. 1:24-cv00484-JDB), and a motion for a temporary restraining order and preliminary injunction, seeking to require FDA to reject the amendment to Liquidia's NDA to add PH-ILD to the label for YUTREPIA. Judge Bates, who is presiding over this lawsuit, denied UTHR's motion on the basis that the FDA had not yet taken final agency action with respect to Liquidia's NDA. However, the Court has ordered that FDA provide the Court and the parties with at least three business days' advance notice prior to issuance of any decision on Liquidia's NDA. The FDA has since filed a motion to dismiss the lawsuit, and briefing on the motion to dismiss is in progress.

First Quarter 2024 Financial Results

Cash and cash equivalents totaled $157.9 as of March 31, 2024, compared to $83.7 million as of December 31, 2023. In the first week of January, Liquidia closed two transactions that brought an additional $100 million of gross proceeds into the company. Liquidia and an affiliate of Patient Square Capital entered into a common stock purchase agreement for the private placement of common stock that yielded gross proceeds of $75.0 million. That same week, HealthCare Royalty Partners (HCRx) and Liquidia entered a fourth amendment to the Revenue Interest Financing Agreement (RIFA) to fund an additional $25.0 million. HCRx has now invested $67.5 million in non-dilutive capital from the $100 million originally contemplated from four tranches under the RIFA.

Revenue was $3.0 million for the three months ended March 31, 2024, compared to $4.5 million for the three months ended March 31, 2023. Revenue related primarily to the promotion agreement with Sandoz pursuant to which we share profits from the sale of Treprostinil Injection in the United States (the Promotion Agreement). The decrease from the prior year was primarily due to favorable gross-to-net rebate adjustments recorded in the prior year and the impact of lower sales quantities in the current year as compared to the same period in the prior year.

Cost of revenue was $1.5 million for the three months ended March 31, 2024, compared to $0.7 million for the three months ended March 31, 2023. Cost of revenue related to the Promotion Agreement. 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 $10.1 million for the three months ended March 31, 2024, compared to $5.3 million for the three months ended March 31, 2023. The increase of $4.8 million or 91% was primarily due to a $2.0 million increase in personnel expenses (including stock-based compensation) related to higher headcount, and a $1.7 million increase in clinical expenses related to our L606 program. Additionally, there was a $1.3 million increase in expenses related to our YUTREPIA program driven by higher clinical and supply expenses related to our ASCENT study, which was initiated in the second half of 2023.

General and administrative expenses were $20.2 million for the three months ended March 31, 2024, compared to $7.8 million for the three months ended March 31, 2023. The increase of $12.4 million or 160% was primarily due to a $3.1 million increase in legal fees related to our ongoing YUTREPIA-related litigation, a $5.9 million increase in personnel expenses (including stock-based compensation), and a $2.2 million increase in commercial and consulting expenses in preparation for the potential commercialization of YUTREPIA.

Total other expenses, net was $12.1 for the three months ended March 31, 2024, compared with $2.5 million for the three months ended March 31, 2023. The increase of $9.6 million was primarily due to driven by a $9.2 million increase in loss on extinguishment of debt resulting from the Fourth Amendment to the RIFA, which was executed in January 2024, and a $1.4 million increase in interest expense attributable to the higher borrowings under the RIFA compared to the prior year. These increases were offset by a $1.0 million increase in interest income attributable to higher money market balances.

Net loss for the three months ended March 31, 2024, was $40.9 million or $0.54 per basic and diluted share, compared to a net loss of $11.7 million, or $0.18 per basic and diluted share, for the three-month ended March 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. The FDA previously issued tentative approval of YUTREPIA for the PAH indication in November 2021. In July 2023, Liquidia filed an amendment to its New Drug Application for YUTREPIA, seeking to add PH-ILD to the label. 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, with the objective of informing YUTREPIA's dosing and tolerability profile in patients with PH-ILD. 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 and potentially mitigating local and systemic side effects. 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, Inc. (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 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 PAH and PH-ILD. Liquidia Technologies is also developing L606, an investigational liposomal formulation of treprostinil administered twice-daily with a 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.

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 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.

Contact Information

Investors:
Jason Adair
Chief Business Officer
919.328.4350
jason.adair@liquidia.com

Media:
Patrick Wallace
Director, Corporate Communications
919.328.4383
patrick.wallace@liquidia.com

Liquidia Corporation
Select Condensed Consolidated Balance Sheet Data (unaudited)
(in thousands)

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 157,858	$ 83,679
Total assets	$ 197,116	$ 118,332
Total liabilities	$ 110,856	$ 71,039
Accumulated deficit	$ (470,026)	$ (429,098)
Total stockholders' equity	$ 86,260	$ 47,293

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

	Three Months Ended March 31,	
	2024	**2023**
Revenue	$ 2,972	$ 4,493
Costs and expenses:		
Cost of revenue	1,467	654
Research and development	10,057	5,278
General and administrative	20,249	7,793
Total costs and expenses	31,773	13,725
Loss from operations	(28,801)	(9,232)
Other income (expense):		
Interest income	1,880	922
Interest expense	(2,542)	(1,124)
Loss on extinguishment of debt	(11,483)	(2,311)
Total other expense, net	(12,127)	(2,513)
Net loss and comprehensive loss	$ (40,928)	$ (11,745)
Net loss per common share, basic and diluted	$ (0.54)	$ (0.18)
Weighted average common shares outstanding, basic and diluted	75,393,907	64,656,424