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): **August 7, 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 August 7, 2024, Liquidia Corporation, a Delaware corporation, issued a press release announcing its financial results for the quarter ended June 30, 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 August 7, 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.

August 7, 2024

Liquidia Corporation

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

Exhibit 99.1

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

MORRISVILLE, N.C., August 7, 2024 -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, today reported financial results for the second quarter ended June 30, 2024. The company will host a webcast at 8:30 a.m. ET on August 7, 2024 to discuss the financial results and provide a corporate update.

Dr. Roger Jeffs, Liquidia's Chief Executive Officer, said: "We continue to face no legal impediments for the FDA approval of YUTREPIA for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), and our commercial team stands ready to launch YUTREPIA contingent on the FDA's final approval. If approved, we firmly believe that the ease of administration and broad dosage spectrum of YUTREPIA will drive the treatment to become the preferred prostacyclin therapy of choice."

Corporate Updates

Progressed litigation, maintaining a clear legal path to full approval of YUTREPIA

On May 31, Judge Andrews of the U.S. District Court for the District of Delaware denied the motion for preliminary injunction filed by United Therapeutics (UTHR) in its lawsuit alleging that YUTREPIA infringes U.S. Patent No. 11,826,327 ('327 patent).

In addition, on March 29, the U.S. District Court for the District of Columbia has denied motions for a temporary restraining order and preliminary injunction requested by UTHR in its suit against the U.S. Food and Drug Administration (FDA). On May 7, both Liquidia and FDA filed motions to dismiss UTHR's complaint.

While both lawsuits are continuing forward, these rulings reinforce the clear legal path for FDA to issue a final decision on the amended New Drug Application (NDA) for YUTREPIA for the treatment of both PAH and PH-ILD.

Progressed clinical studies in YUTREPIA and presented new posters at the World Symposia on Pulmonary Hypertension

During the World Symposia on Pulmonary Hypertension in Barcelona this summer, Liquidia presented two live thematic poster sessions and five encore presentations covering the company's investigational products, YUTREPIA™ (treprostinil) inhalation powder and L606 (liposomal treprostinil) inhalation suspension. The two new posters entitled: "Exploratory Efficacy Analysis of INSPIRE Open Label Extension Study with Inhaled Treprostinil (YUTREPIA™)" and "High Resolution Computed Tomography (HRCT) Chest Scans to Examine the Association Between Regional Drug Deposition of LIQ861 (YUTREPIA™) and Vasodilation in PH-ILD Population," along with the five encore presentations, can be found on the Publications section of Liquidia's website.

Progressed L606 in clinic and presented summary of safety and dosing poster at the American Thoracic Society 2024 International Conference (ATS)

In May at the ATS Conference in San Diego, Liquidia presented data related to the investigational use of L606 (liposomal treprostinil) inhalation suspension in patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD).

The Phase 3, 2-part, open-label, multicenter study aims to demonstrate the safety and tolerability of L606 in patients with PAH or PH-ILD in the short-term and long-term. The trial is enrolling patients in two groups, a transition group and a naïve group. The transition group is comprised of participants with PAH or PH-ILD who transitioned from nebulized Tyvaso or Tyvaso DPI to L606. The naïve group is comprised of participants with PAH who have not previously received treprostinil therapy and added L606 to no more than two non-prostacyclin oral therapies.

Second Quarter 2024 Financial Results

Cash and cash equivalents totaled $133.1 million as of June 30, 2024, compared to $83.7 million as of December 31, 2023.

Revenue was $3.7 million for the three months ended June 30, 2024, compared to $4.8 million for the three months ended June 30, 2023. Revenue related primarily to our 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 of $1.1 million was primarily due to 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 June 30, 2024, compared to $0.7 million for the three months ended June 30, 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 $9.4 million for the three months ended June 30, 2024, compared to $17.7 million for the three months ended June 30, 2023. The decrease of $8.3 million or 47% was primarily due to a $10 million upfront license fee due to Pharmosa for the exclusive license in North America to develop and commercialize L606 recorded during the three months ended June 30, 2023. Additionally, there was a $1.4 million decrease in expenses related to our YUTREPIA program driven by expensing prelaunch inventory costs in the prior year. These decreases were offset by a $1.7 million increase in clinical expenses related to our L606 program and a $1.5 million increase in personnel expenses (including stock-based compensation) related to increased headcount.

General and administrative expenses were $20.0 million for the three months ended June 30, 2024, compared to $9.2 million for the three months ended June 30, 2023. The increase of $10.8 million or 116% was primarily due to a $6.3 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, a $2.2 million increase in commercial and consulting expenses in preparation for the potential commercialization of YUTREPIA, and a $0.9 million increase in legal fees related to our ongoing YUTREPIA-related litigation.

Total other expenses, net was $0.7 million for both the three months ended June 30, 2024 and 2023. There was a $1.2 million increase in interest expenses attributable to the higher borrowings under the company's Revenue Interest Financing Agreement (RIFA) with HealthCare Royalty Partners (HCRx) as compared to the prior year, and a $1.1 million increase in interest income attributable to higher money market balances.

Net loss for the three months ended June 30, 2024, was $27.9 million or $0.37 per basic and diluted share, compared to a net loss of $23.5 million, or $0.36 per basic and diluted share, for the three-month ended June 30, 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 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, 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.

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

	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 133,093	$ 83,679
Total assets	$ 177,361	$ 118,332
Total liabilities	$ 114,639	$ 71,039
Accumulated deficit	$ (497,968)	$ (429,098)
Total stockholders' equity	$ 62,722	$ 47,293

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

	Three Months Ended June 30,	
	2024	**2023**
Revenue	$ 3,659	$ 4,786
Costs and expenses:		
Cost of revenue	1,493	671
Research and development	9,420	17,695
General and administrative	19,943	9,245
Total costs and expenses	30,856	27,611
Loss from operations	(27,197)	(22,825)
Other income (expense):		
Interest income	1,855	734
Interest expense	(2,600)	(1,426)
Total other expense, net	(745)	(692)
Net loss and comprehensive loss	$ (27,942)	$ (23,517)
Net loss per common share, basic and diluted	$ (0.37)	$ (0.36)
Weighted average common shares outstanding, basic and diluted	76,435,831	64,788,482