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 31, 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 8.01 Other Events.

As previously disclosed, United Therapeutics Corporation ("United Therapeutics") filed a lawsuit against Liquidia Technologies, Inc., a Delaware corporation ("Liquidia Technologies") and a wholly owned subsidiary of Liquidia Corporation, a Delaware corporation (the "Company"), in Delaware District Court (Case No. 23-975) alleging that YUTREPIA (treprostinil) inhalation powder ("YUTREPIA") would infringe U.S. Patent No. 11,826,327, which was issued in November 2023. Thereafter, United Therapeutics filed a motion for a preliminary injunction to block Liquidia Technologies from launching YUTREPIA to treat pulmonary hypertension associated with interstitial lung disease ("PH-ILD").

On June 3, 2024, the Company issued a press release announcing that, on May 31, 2024, Judge Andrews denied United Therapeutics' motion for a preliminary injunction to block the launch of YUTREPIA to treat PH-ILD.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit
99.1	Press Release of Liquidia Corporation, dated June 3, 2024.
104	Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

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.

June 3, 2024

Liquidia Corporation

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

Exhibit 99.1

District Court Issues Favorable Ruling and Denies United Therapeutics' Request to Block YUTREPIA™ Launch

- On May 31, Judge Andrews denied United Therapeutics' motion for a preliminary injunction to block the launch of YUTREPIA in the PH-ILD indication

- Ruling reinforces the clear path for FDA to issue final decision on amended NDA for YUTREPIA to treat both PAH and PH-ILD

MORRISVILLE, N.C., June 3, 2024 – Liquidia Corporation (NASDAQ: LQDA) announced today that on May 31, Judge Andrews of the U.S. District Court for the District of Delaware (District Court) denied the motion for preliminary injunction filed by United Therapeutics (UTHR) that sought to block the launch of Liquidia's YUTREPIA™ (treprostinil) inhalation powder to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD). The ruling reinforces the clear path for the U.S. Food and Drug Administration (FDA) to issue a final decision on the amended New Drug Application (NDA) for YUTREPIA.

Dr. Roger Jeffs, Chief Executive Officer of Liquidia, said: "We are pleased that Judge Andrews ruled that United Therapeutics' request for an injunction failed on critical grounds, including UTHR's failure to show our obviousness challenge lacks substantial merit and UTHR's failure to show that the public interest weighs in favor of an injunction. While we await a final FDA action, we will continue to intensify our commercial preparations as we work to make this important treatment option available to pulmonary arterial hypertension (PAH) and PH-ILD patients."

The motion for preliminary injunction was filed in the lawsuit (Case No. 23-975) filed by UTHR in September 2023 in which it has alleged YUTREPIA would infringe U.S. Patent No. 11,826,327 ('327 patent). While this ruling maintains the status quo in which there is no legal impediment to the FDA granting final approval to YUTREPIA, this lawsuit will continue forward to trial, which is currently scheduled for June 2025.

Friday's ruling follows earlier legal rulings from multiple bodies finding that YUTREPIA does not infringe any valid claim of the patents previously asserted by UTHR, including the decision by the Patent Trial and Appeal Board, affirmed by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), that all claims of U.S. Patent No. 10,716,793 ('793 Patent) to be unpatentable. UTHR has stated that it plans to appeal the Federal Circuit's affirmation of the invalidity of the '793 Patent to the United States Supreme Court. Separately, UTHR has also appealed Judge Andrews' ruling to set aside an injunction that he had previously issued blocking the launch of YUTREPIA based solely on the '793 Patent.

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. 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 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. (Liquidia Technologies) and Liquidia PAH, LLC (Liquidia PAH). 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 short-duration, next-generation nebulizer, for use in North America. Liquidia PAH provides for the commercialization of pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

Tyvaso® is a registered trademark of United Therapeutics.

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, 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. Similarly, favorable decisions of courts with respect to motions for preliminary injunctions or other preliminary relief in a lawsuit are not determinative of the final outcome of the lawsuit. 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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