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 22, 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.

On August 22, 2024, Liquidia Corporation, a Delaware corporation (the "Company") issued a press release announcing that (i) on August 21, 2024, the Company filed a lawsuit in the U.S. District Court of the District of Columbia (the "District Court") (Case No. 1:24-cv-02428) that challenges the recent decision by the U.S. Food and Drug Administration (the "FDA") to grant 3-year new clinical investigation exclusivity (NCI exclusivity) to Tyvaso DPI and (ii) on August 20, 2024, United Therapeutics voluntarily dismissed, without prejudice, the complaint it had filed against the FDA in the District Court, challenging the FDA's acceptance of Liquidia's amended New Drug Application for YUTREPIA (treprostinil) inhalation powder for review.

A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit
99.1	Press Release of Liquidia Corporation, dated August 22, 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.

August 22, 2024

Liquidia Corporation

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

Exhibit 99.1

Liquidia Files Litigation to Challenge Regulatory Exclusivity Blocking Access to YUTREPIA™ (treprostinil) inhalation powder for Patients Suffering with PAH and PH-ILD

MORRISVILLE, N.C., August 22,2024 - Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, announced today that it has filed litigation in the U.S. District Court of the District of Columbia (Case No. 1:24-cv-02428) that challenges the recent decision by the United States Food and Drug Administration (FDA) to grant 3-year new clinical investigation exclusivity (NCI exclusivity) to Tyvaso DPI®. FDA granted tentative approval of YUTREPIA™ (treprostinil) inhalation powder to treat pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) patients on August 16, 2024. As a result of the FDA's award of NCI exclusivity to Tyvaso DPI, the final approval of YUTREPIA™ (treprostinil) inhalation powder is currently delayed until after the expiration of the exclusivity on May 23, 2025.

Dr. Roger Jeffs, Ph.D., Chief Executive Officer of Liquidia, said: "The FDA's action improperly allows United Therapeutics to tack on yet another regulatory exclusivity, stifling competition and patient choice. This decision violates clear congressional intent to allow NCI exclusivity only for true innovations that are supported by new clinical studies that demonstrate safety and/or efficacy of the innovation. It is our strong belief that the FDA's decision to grant Tyvaso DPI this new NCI exclusivity should be vacated, and Liquidia should be allowed to bring YUTREPIA to market for the benefit of patients immediately."

In establishing NCI exclusivity, Congress sought to encourage innovation in drug development while also ensuring patient access to alternative drugs through competition. Accordingly, NCI exclusivity is only granted for a period of three years from the date of an FDA approval that is supported by certain types of clinical studies, expressly excluding bioavailability studies and clinical investigations that a drug sponsor has previously submitted to FDA. Additionally, NCI exclusivity is limited in scope to the innovative change supported by the new clinical investigation.

Separately, on August 20, 2024, United Therapeutics voluntarily dismissed, without prejudice, the complaint it had filed against the FDA in the U.S. District Court for the District of Columbia, challenging the FDA's acceptance of Liquidia's amended NDA for YUTREPIA for review. With the FDA's grant of tentative approval for YUTREPIA, the FDA decided that it was proper for Liquidia to add PH-ILD to the NDA for YUTREPIA via an amendment.

Liquidia remains committed to addressing the unmet needs of PAH and PH-ILD patients and is seeking final approval of YUTREPIA as soon as possible.

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 size 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 YUTREPIA™ (treprostinil) Inhalation Powder

YUTREPIA is an inhaled dry-powder formulation of treprostinil delivered through a convenient, low-effort, palm-sized device. 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 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.

Tyvaso® and Tyvaso DPI® are a 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 of our lawsuit against the FDA, 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 voluntary dismissal of a lawsuit without prejudice allows the underlying claims to be reasserted and does not address the merits of the underlying claims. 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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