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 19, 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 19, 2024, the Company issued a press release announcing that the U.S. Food and Drug Administration (i) granted tentative approval of YUTREPIA (treprostinil) inhalation powder for patients with pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"), and (ii) simultaneously determined that Tyvaso DPI, approved on May 23, 2022, qualifies for a three-year new dosage form exclusivity for the chronic use of dry powder formulations of treprostinil for the approved indications. As a result, final approval of YUTREPIA for PAH and PH-ILD is delayed until after expiry of the three-year regulatory exclusivity for Tyvaso DPI on May 23, 2025.

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 19, 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 19, 2024

Liquidia Corporation

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

Exhibit 99.1

U.S. FDA Grants Tentative Approval of YUTREPIA™ (treprostinil) Inhalation Powder for Patients with Pulmonary Arterial Hypertension (PAH) and Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD)

- FDA confirmed that the amendment to add PH-ILD to the YUTREPIA NDA was proper and that application otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act
- Final Approval of YUTREPIA for PAH and PH-ILD may occur after expiration of 3-year regulatory exclusivity for Tyvaso DPI on May 23, 2025
- FDA's tentative approval is based upon all information submitted in the NDA, including the status of good manufacturing practices of the facilities used in the manufacture and testing of YUTREPIA

MORRISVILLE, N.C., August 19,2024 - Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, announced today that the U.S. Food and Drug Administration (FDA) has granted tentative approval of YUTREPIA™ (treprostinil) inhalation powder to treat adults with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). Tentative approval indicates that YUTREPIA has met all regulatory standards for quality, safety and efficacy required for approval in the United States but must await the expiration of regulatory exclusivity of a competing product before final approval can be granted.

Dr. Roger Jeffs, Ph.D., Chief Executive Officer of Liquidia, said: "We are pleased that the FDA agreed that our NDA amendment last July was proper, providing a clear path to full approval of YUTREPIA in both PAH and PH-ILD. However, we are disappointed and disagree with the FDA's decision to simultaneously grant regulatory exclusivity to United Therapeutics for Tyvaso DPI that encompasses chronic use of essentially any dry-powder formulation of treprostinil in the approved indications for a three-year period for its new dosage form approved on May 23, 2022. We plan to take quick action to challenge the FDA's broad grant of regulatory exclusivity and defend the ability for patients to have access to YUTREPIA with the least delay possible."

The tentative approval of YUTREPIA is based on findings from the Phase 3 INSPIRE trial which evaluated patients who were naïve to treprostinil, as well as those transitioning to YUTREPIA from nebulized treprostinil. YUTREPIA was shown to be safe and well-tolerated regardless of a patient's previous exposure to treprostinil. Results from the INSPIRE study were published in the Pulmonary Circulation Journal in 2022 and the Vascular Pharmacology Journal in 2021. The FDA's approval also confirms that the supporting information related to the manufacturing, testing and supply chain of YUTREPIA meets regulatory standards for quality and safety in accordance with Good Manufacturing Practices (GMP).

Liquidia remains committed to addressing the unmet needs of PAH and PH-ILD patients and will seek final approval of YUTREPIA as early 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® is a registered trademark 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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