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): **December 20, 2023**

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, in January 2021, Liquidia Corporation, a Delaware Corporation (the "Company") filed a petition with the Patent Trial and Appeal Board ("PTAB") for *inter partes* review of U.S. Patent No. 10,716,793 (the "'793 Patent"), seeking a determination that the claims in the '793 Patent are invalid. In July 2022, the PTAB ruled in our favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable due to the existence of prior art cited by the Company in the *inter partes* review proceedings. In August 2022, United Therapeutics Corporation ("United Therapeutics") submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '793 Patent. The rehearing request was denied in February 2023. In April 2023, United Therapeutics appealed the decision of the PTAB with respect to the '793 Patent to the United States Court of Appeals for the Federal Circuit. Oral argument on the appeal was held on December 4, 2023.

On December 20, 2023, the Company issued a press release announcing that the United States Court of Appeals for the Federal Circuit affirmed the earlier decision of the PTAB. As a result of the decision, the Company will immediately seek to set aside the injunction issued by the U.S. District Court for the District of Delaware in the lawsuit filed by United Therapeutics under the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act") and pursue final regulatory approval of YUTREPIA by the U.S. Food and Drug Administration.

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 December 20, 2023.
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.

December 20, 2023

Liquidia Corporation

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

Exhibit 99.1

U.S. Federal Circuit Affirms Earlier PTAB Decision to Invalidate All Claims of United Therapeutics Patent No. 10,716,793 (‘793 Patent)

- Liquidia will pursue final FDA approval for YUTREPIA™ (treprostinil) inhalation
- Liquidia will immediately request that District Court set aside injunction tied to ‘793 patent

MORRISVILLE, N.C., December 20, 2023 - Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) announced that the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) today affirmed the earlier decision by the Patent Trial and Appeal Board (PTAB) which found all claims of U.S. Patent No. 10,716,793 (‘793 Patent) to be unpatentable due to the existence of prior art cited by Liquidia in *inter partes* review (IPR) proceedings. As a result of today’s decision, Liquidia will immediately seek to set aside the injunction issued by the U.S. District Court for the District of Delaware (District Court) in the lawsuit filed by United Therapeutics (UTHR) under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) and pursue final regulatory approval of YUTREPIA by the U.S. Food and Drug Administration (FDA).

Roger Jeffs, Chief Executive Officer of Liquidia, stated: “We are thrilled with the court’s swift decision. We now have rulings from the Federal Circuit confirming that YUTREPIA does not infringe any valid claim in any of the three patents that were initially asserted by United Therapeutics. We will now direct our attention towards the more important goal of improving patients’ lives and addressing unmet needs by seeking final FDA approval of YUTREPIA to treat PAH and, subsequently, PH-ILD.”

As a result of today’s decision, Liquidia will also seek to dismiss all claims related to the ‘793 patent in the second Hatch-Waxman lawsuit filed by UTHR in association with Liquidia’s amended New Drug Application (NDA) to add the indication to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD) to the YUTREPIA label. On November 30, 2023, UTHR filed an amended complaint in Hatch-Waxman litigation adding allegations that the Company infringes a newly issued patent, U.S. Patent No. 11,826,327 (’327 Patent). Because neither the ’793 Patent nor the ’327 Patent was issued prior to the filing of the original NDA for YUTREPIA, the Company believes UTHR is not entitled to a statutory 30-month stay with respect to either of these patents. The Company intends to vigorously defend itself against these allegations, so that patients suffering from PAH and PH-ILD can have the potential to access the Company’s products.

The FDA tentatively approved YUTREPIA to treat pulmonary arterial hypertension (PAH) in November 2021. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of January 24, 2024, for the PH-ILD indication.

About YUTREPIA™(treprostinil) inhalation powder

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-resistance, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. In July 2023, Liquidia filed an amendment to its NDA for YUTREPIA, seeking to add pulmonary hypertension with interstitial lung disease (PH-ILD) to the label. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of January 24, 2024 for the amendment. Previously, the FDA has confirmed that YUTREPIA may add the treatment of PH-ILD to the label for YUTREPIA without additional clinical studies. 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 was previously referred to as LIQ861 in investigational studies.

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 pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (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 the commercialization for 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 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, including 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 the PTAB with respect to the '793 patent is not determinative of the outcome of the appeal of the decision. 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, including the impact of the coronavirus (COVID-19) outbreak on our Company and our financial condition and results of operations, 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

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