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): **July 27, 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 1.01 Entry Into a Material Definitive Agreement.

Third Amendment to Revenue Interest Financing Agreement

As previously disclosed, on January 9, 2023, Liquidia Technologies, Inc., a Delaware corporation (the "Liquidia Technologies") and a wholly owned subsidiary of Liquidia Corporation (the "Company") entered into a Revenue Interest Financing Agreement with HealthCare Royalty Partners IV, L.P. and HealthCare Royalty Management, LLC (collectively, "HCR"), as amended by that certain Amendment to Revenue Interest Financing Agreement, dated April 17, 2023, and as further amended by that certain Second Amendment to Revenue Interest Financing Agreement, dated June 28, 2023, by and among Liquidia Technologies and HCR (as amended, the "Financing Agreement").

On July 27, 2023, Liquidia Technologies and HCR entered into a Third Amendment to the Financing Agreement (the "Third Amendment"), pursuant to which, among other things, (i) HCR agreed to make payment of the $10 million second tranche under the Financing Agreement on July 27, 2023, (ii) the Financing Agreement was amended to provide that funding of the third and fourth tranches under the Financing Agreement would be subject to the mutual agreement of the parties, and (iii) the Financing Agreement was amended to base certain existing obligations to make, and calculations of, certain quarterly fixed payments and included product payment amounts under the Financing Agreement on the date of the closing of the third tranche rather than the date of the first commercial sale of YUTREPIA.

The foregoing description of the terms of the Third Amendment is not complete and is qualified in its entirety by reference to the text of the Third Amendment, which will be filed as an exhibit to the Company's next Quarterly Report on Form 10-Q.

Item 8.01 Other Events.

On July 27, 2023, the Company issued a press release announcing that it submitted an amendment to the tentatively approved new drug application (the "NDA") for YUTREPIA (treprostinil) inhalation powder to add the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD). If approved by the U.S. Food and Drug Administration (the "FDA"), YUTREPIA would be indicated for the treatment of both PH-ILD and pulmonary arterial hypertension (PAH). The FDA can grant final approval of the PH-ILD indication in the YUTREPIA label after the new clinical investigation exclusivity granted to Tyvaso® expires on March 31, 2024.

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 July 27, 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.

July 27, 2023

Liquidia Corporation

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

Exhibit 99.1

Confidential Information

Liquidia Submits Amendment to Add PH-ILD Indication to Tentatively Approved NDA for YUTREPIA™ (treprostinil) Inhalation Powder

Confidential Information

- No new clinical data is required to add PH-ILD indication as per FDA correspondence
- Recertified that YUTREPIA does not infringe any valid patents listed in the Orange Book for Tyvaso
- Preparing for potential launch of YUTREPIA between end of 2023 to mid-2024

MORRISVILLE, N.C., July 26, 2022 - Liquidia Corporation (NASDAQ: LQDA) announced today the submission of an amendment to the tentatively approved new drug application (NDA) for YUTREPIA™ (treprostinil) inhalation powder to add the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD). The U.S. Food and Drug Administration (FDA) has previously confirmed in writing that the addition of the PH-ILD indication will not require any new clinical information. Upon acceptance of the amendment, the FDA will confirm the type of resubmission as Class 1 or Class 2. If approved by FDA, YUTREPIA would be indicated for the treatment of both PH-ILD and pulmonary arterial hypertension (PAH). The FDA can grant final approval of the PH-ILD indication in the YUTREPIA label after the new clinical investigation exclusivity granted to Tyvaso® expires on March 31, 2024.

Concurrent with the amendment, Liquidia recertified under 21 U.S.C. 355(b)(2)(A)(iv), also referred to as paragraph IV certification, that the patents listed for Tyvaso® in the FDA's publication of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, are invalid and/or not infringed by YUTREPIA. All Orange Book patents previously asserted by United Therapeutics have already been found to be invalid or not-infringed as decided by U.S. District Court, confirmed on appeal, or by the Patent Trial and Appeal Board (PTAB), pending appeal.

Dr. Roger Jeffs, Chief Executive Officer of Liquidia, said: "We have submitted this request to ensure that patients may access YUTREPIA for both the PAH and PH-ILD indications as soon as possible. We continue to hear from the community that alternative inhaled products are needed, especially for those patients who may benefit from a low resistance dry powder inhaler that can be easily titrated to optimal therapeutic effect like YUTREPIA. This feedback reinforces our undeterred commitment to deliver on the full potential of YUTREPIA to improve patients' lives."

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, which is indicated 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. The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) 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.

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 appeals arising from our patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at the PTAB, 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 in the IPR for the ’793 patent and of the Court and CAFC in the Hatch-Waxman litigation are not determinative of the outcome of any appeal of those 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, 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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