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 4, 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 2.02 Results of Operations and Financial Condition.

On May 4, 2023, Liquidia Corporation, a Delaware corporation, issued a press release announcing its financial results for the quarter ended March 31, 2023, and also provided a corporate update. A copy of the press release is furnished herewith as Exhibit 99.1.*

On May 4, 2023, the Company held a conference call and online webcast in connection with the Company's announcement of its financial results for the quarter ended March 31, 2023. A copy of the script for such conference call and webcast is furnished as Exhibit 99.2 to this report. An archive of such conference call and webcast and the related question and answer session will be available online at https://liquidia.com/investors/events-and-presentations.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Exhibit
99.1	Press Release of Liquidia Corporation, dated May 4, 2023.
99.2	Liquidia Corporation script for the conference call and online webcast held on May 4, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* The information in Item 2.02 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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.

May 4, 2023

Liquidia Corporation

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

Liquidia Corporation Reports First Quarter 2023 Financial Results and Provides Corporate Update

MORRISVILLE, N.C., May 4, 2023 - Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) today reported financial results for the first quarter ended March 31, 2023. The Company will host a webcast at 8:30 a.m. ET to discuss the financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "We have heard from the physician community about the increasing demand for inhaled treprostinil to treat both pulmonary arterial hypertension (PAH) and pulmonary hypertension with interstitial lung disease (PH-ILD). With specific regard to PH-ILD, it is clear that the need for inhaled products to treat this previously underdiagnosed and untreated population will significantly surpass that of PAH. Based on conversations with physicians, we believe that patients with PH-ILD, who commonly suffer from lung restriction and impaired respiratory effort, may benefit from an inhaled formulation of treprostinil enabled by PRINT Technology and administered with a low-resistance dry powder inhaler. This enthusiastic feedback from physicians continues to strengthen our commitment to bring YUTREPIA™ (treprostinil) inhalation powder to patients as quickly as possible."

Corporate Updates

Secured access to additional capital with revenue interest financing. In January, HealthCare Royalty (HCRx) agreed to provide Liquidia an aggregate of up to $100 million upon certain events. To date, HCRx has funded $32.5 million, of which $22.2 million was used to repay the then existing debt obligations to Silicon Valley Bank (SVB), with excess proceeds of approximately $9.6 million funded to the Company after deduction of transaction costs. Liquidia may receive three additional tranches of funding: $7.5 million to support any acquisition of rights to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension; $35 million upon the earlier of regulatory approval of YUTREPIA or a favorable resolution of the ongoing patent litigation with United Therapeutics Corporation (UTC); and $25 million to be drawn upon the mutual agreement of the parties. In exchange for the total investment, HCRx will receive a tiered royalty on net revenue generated by YUTREPIA and other products marketed by Liquidia. The specific tiered royalty rates range between 0.36% to 10.0%, depending upon the total amount advanced to Liquidia and achievement of certain annual net sales thresholds. HCRx will also receive certain fixed quarterly payments. The aggregate payments to HCRx are capped at 175% of the total amounts advanced by HCRx, with the potential for a true-up payment to be made by Liquidia if HCRx's internal rate of return is less than 18% on the date the cap is reached.

Advanced appeals of legal rulings in Hatch-Waxman and PTAB litigation. On May 3, 2023, the Company presented oral arguments to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in the appeal of the decision of the District Court in the Hatch-Waxman litigation initiated by UTC. UTC is appealing the District Court's ruling related to U.S. Patent No. 9,593,066 (the '066 Patent) which found five of the six asserted claims of the '066 Patent are invalid and that the remaining asserted claim is not infringed by Liquidia. Liquidia is appealing the District Court's decision with respect to U.S. Patent No. 10,716,793 (the '793 Patent) which found that all of the claims of the '793 Patent were valid and infringed by Liquidia based on the arguments that were presented by Liquidia in the Hatch-Waxman Litigation.

Concurrently, in April 2023, UTC initiated an appeal to the Federal Circuit of the decision by the Patent Trial and Appeal Board (PTAB) to invalidate the ‘793 patent. The PTAB found in July 2022 that all claims of the ‘793 Patent are unpatentable based on obviousness. In February 2023, the PTAB reaffirmed that decision when it denied UTC’s request for a rehearing. Should the Federal Circuit affirm the PTAB’s decision, the PTAB’s decision would override any finding in the Hatch-Waxman litigation that Liquidia has breached any valid claims of the ‘793 Patent.

Liquidia continues to anticipate that it will reach final legal resolution in late 2023 or the first half of 2024.

First Quarter 2023 Financial Results

Cash totaled $94.4 million as of March 31, 2023. During the three months ended March 31, 2023, the Company received $31.8 million net proceeds from the revenue interest financing agreement net of costs, of which $22.2 million was used to repay the Amended and Restated Loan and Security Agreement with SVB (the A&R SVB LSA) entered into in January 2022.

Revenue was $4.5 million for the three months ended March 31, 2023, compared to $3.5 million for the three months ended March 31, 2022. Revenue related primarily to the Promotion Agreement. The increase of $1.0 million was primarily due to increased quantities and favorable gross-to-net rebate adjustments.

Cost of revenue was $0.7 million for both the three months ended March 31, 2023 and 2022. Cost of revenue related to the Promotion Agreement as noted above.

Research and development expenses were $5.3 million for the three months ended March 31, 2023, compared with $4.7 million for the three months ended March 31, 2022. The increase of $0.6 million or 12% was primarily due to a $0.5 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA.

General and administrative expenses were $7.8 million for the three months ended March 31, 2023, compared with $12.5 million for the three months ended March 31, 2022. The decrease of $4.7 million or 38% was primarily due to a $4.0 million decrease in legal fees related to ongoing YUTREPIA-related litigation and a $1.8 million decrease in stock-based compensation expense driven by an option modification charge recorded in 2022. These decreases were offset by a $1.1 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA.

Other expenses, net was $2.5 million for the three months ended March 31, 2023, compared with $1.5 million for the three months ended March 31, 2022. The three months ended March 31, 2023 included a $2.3 million loss on extinguishment of debt related to repayment of the A&R SVB LSA in January 2023. The three months ended March 31, 2022 included a $1.0 million loss on extinguishment of debt related to the refinance of long-term debt with SVB during January 2022.

Net loss for the three months ended March 31, 2023, was $11.7 million, or $0.18 per basic and diluted share, compared to a net loss of $15.9 million, or $0.30 per basic and diluted share, for the three months ended March 31, 2022.

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 optimal 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 Treprostinil Injection

Treprostinil Injection is the first-to-file, fully substitutable generic treprostinil for parenteral administration. Treprostinil Injection contains the same active ingredient, same strengths, same dosage form and same inactive ingredients as Remodulin® (treprostinil) and is offered to patients and physicians with the same level of service and support, but at a lower price than the branded drug. Liquidia PAH promotes the appropriate use of Treprostinil Injection for the treatment of PAH in the United States in partnership with its commercial partner, who holds the Abbreviated New Drug Application (ANDA) with the FDA.

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). 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 IPRs for the ’793 and ‘901 patents and of the District Court 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) pandemic 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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Liquidia Corporation
Select Consolidated Balance Sheet Data
(in thousands)

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 94,412	$ 93,283
Total assets	$ 128,922	$ 129,198
Total liabilities	$ 47,279	38,776
Accumulated deficit	$ (362,341)	(350,596)
Total stockholders' equity	$ 81,643	90,422

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	2022
Revenue	$ 4,493	$ 3,492
Costs and expenses:		
Cost of revenue	654	694
Research and development	5,278	4,728
General and administrative	7,793	12,542
Total costs and expenses	13,725	17,964
Loss from operations	(9,232)	(14,472)
Other income (expense):		
Interest income	922	4
Interest expense	(1,124)	(478)
Loss on extinguishment of debt	(2,311)	(997)
Total other expense, net	(2,513)	(1,471)
Net loss and comprehensive loss	$ (11,745)	$ (15,943)
Net loss per common share, basic and diluted	$ (0.18)	$ (0.30)
Weighted average common shares outstanding, basic and diluted	64,656,424	52,465,283

Exhibit 99.2

LIQUIDIA FIRST QUARTER 2023 FINANCIAL RESULTS AND CORPORATE UPDATE CONFERENCE CALL

Thursday May 4, 2023 at 8:30 AM ET

OPERATOR:

Good morning and welcome everyone to the Liquidia Corporation First Quarter 2023 Financial Results and Corporate Update conference call. My name is Lisa and I will be your conference operator today. Currently, all participants are in a listen-only mode. Following the presentation, we will conduct a question-and-answer session. Instructions will be provided at that time for you to queue up for questions. I would like to remind everyone that this conference call is being recorded.

I will now hand the call over to Jason Adair, Senior Vice President, Corporate Development & Strategy.

JASON ADAIR:

Thank you Lisa. It is my pleasure to welcome everyone to Liquidia's First Quarter 2023 Financial Results and Corporate Update Conference Call Joining the call today are:

- Chief Executive Officer…Roger Jeffs
- Chief Financial Officer…Michael Kaseta
- Chief Medical Officer…Rajeev Saggar
- Chief Commercial Officer…Scott Moomaw
- And General Counsel …Rusty Schundler

Before we begin, please note that today's conference call will contain forward-looking statements, including those statements regarding future results, unaudited and forward-looking financial information as well as the company's future performance and/or achievements. These statements are subject to known and unknown risks and uncertainties, which may cause our actual results or performance to be materially different from any future results or performance expressed or implied on this call. For additional information, including a detailed discussion of our risk factors, please refer to the company's documents filed with the Securities and Exchange Commission, which can be accessed on our website.

I would now like to turn the call over to Roger for our prepared remarks after which he will open the call up for your questions.

R. Jeffs, CEO:

Good morning, everyone and thank you for joining us.

As we said just 7 weeks ago, our confidence remains high…our balance sheet is strong…our legal team continues to have success in the courts… and the market opportunity for YUTREPIA, our dry-power inhaled formulation of treprostinil, continues to expand as physicians gain better exposure to the benefits of inhaled prostacyclins in treating PAH and PH-ILD patients.

This PH-ILD opportunity is especially intriguing because it seems that the medical and investor community at-large is quickly catching up to the true value that can be created by finally offering an option to this previously untreated group. It's helpful to see the increasing demand for inhaled treprostinil and the increased diagnosis and treatment of PH-ILD. It should accelerate adoption of YUTREPIA given the clear benefits of tolerability, titratability and over-all patient experience with a low-resistance device. While we wait for the opportunity to launch the product, we look forward to further defining YUTREPIA's beneficial product profile in an open-label study in PH-ILD patients that we intend to initiate later this year.

One of the reasons we decided to move up our earnings this quarter is to offer near real-time feedback on the most recent legal events that are gating to the potential approval and launch of YUTREPIA. I'd like to hand the call over to Rusty, who was just in Federal Circuit Court yesterday for the oral arguments of the Hatch-Waxman appeals. Rusty…

R. SCHUNDLER, GC:

Thank you, Roger.

As a reminder, the Company is an active party to two separate ongoing appeal proceedings at the Court of Appeals for the Federal Circuit, either of which could open the path to final FDA approval of YUTREPIA if ruled in Liquidia's favor. Broadly speaking, the appeals relate to two patents asserted by United Therapeutics, the '066 patent and the '793 patent.

The first, and most advanced, ongoing appeal proceeding relates to the District Court's decision last August in the Hatch-Waman Litigation. In this proceeding, UTC is appealing the District Court's ruling related to the '066 Patent which found five of the six asserted claims of the '066 Patent are invalid and that the remaining asserted claim is not infringed by Liquidia. And Liquidia is appealing the District Court's decision with respect to the '793 Patent, which found that all of the claims were valid and infringed by Liquidia based on the arguments that were presented during the Hatch-Waxman Litigation.

Yesterday, the Federal Circuit conducted oral arguments in this appeal. The majority of the argument time was spent addressing Liquidia's appeal of the District Court's decision with respect to the '793 patent, with only a few questions from the judges and a couple minutes spent on UTC's appeal of the District Court's decision with respect to the '066 patent. Although it is premature to speculate as to the outcome of the appeal, we hope to receive a decision from the court within the next few months.

The second ongoing appeal proceeding was initiated by United Therapeutics in April, after the PTAB rejected their rehearing request and reaffirmed its previous decision which found that all of the claims in the '793 patent were unpatentable. We currently anticipate that briefing in this appeal will conclude by early in the 4th quarter, and expect oral argument to be scheduled either late this year or in the first half of 2024. We will not know the scheduled date for oral arguments until after briefing is complete. Once argued, we would then anticipate that a decision could be rendered by the Court as early as a few days after oral argument, if the Court issues a summary affirmance, or within a few months after oral argument if a full written opinion is issued.

When these appeals are taken together, if all of the original decisions are affirmed on appeal, then we will be clear to seek final approval of Yutrepia.

I'll now pass the call on to Mike for an overview of our financial reporting, Mike…

M. KASETA, CFO

Thank you, Rusty, and good morning everyone.

From a financial perspective, the company has never been stronger or its future brighter. The combination of cash on-hand and access to future funds through our revenue-financing agreement provides a solid foundation from which we can build our presence in the PH community. We have recently initiated a hiring effort to support our commercial and medical affairs team. At the same time, our operations team continues to ramp production of commercial inventory and will be prepared whenever we get the green-light to launch YUTREPIA.

Turning to our first quarter 2023 financial results, which can be found in the press release issued today, you will see that:

- Revenue was $4.5 million for the three months ended March 31, 2023, compared to $3.5 million for the same quarter in 2022. Revenue related primarily to the sale of Treprostinil Injection under the profit-split agreement with Sandoz, and the increase of $1.0 million was primarily due to increased quantities and favorable gross-to-net rebate adjustments.

- Cost of revenue was $0.7 million for the quarter, which was the same compared to first quarter 2022

- Research and development expenses were $5.3 million for the quarter, compared to $4.7 million for the first quarter 2022. The increase of $0.6 million or 12% was primarily due to a $0.5 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA.

- General and administrative expenses were $7.8 million in the first quarter 2023 compared with $12.5 million for the comparable quarter in 2022. The decrease of $4.7 million or 38% was primarily due to a $4.0 million decrease in legal fees related to ongoing YUTREPIA-related litigation and a $1.8 million decrease in stock-based compensation expense driven by an option modification charge recorded in 2022. These decreases were offset by a $1.1 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA.

- Other Expenses in the quarter totaled $2.5 million, an increase of $1.0 million over the same quarter last year, and included a $2.3 million loss on extinguishment of debt related to repayment of our loan with SVB in January 2023.

- All totaled, we incurred a net loss in the first quarter of 2023 of $11.7 million, or 18 Cents per basic and diluted share, compared to a net loss of $15.9 million, or 30 Cents per basic and diluted share, for the first quarter 2022.

- On the balance sheet, we ended the first quarter with cash and cash equivalents totaling $94.4 million and feel well prepared to execute on our objectives for the year ahead.

I would now like to turn the call back over to Roger.

R. JEFFS, CEO:

Thank you, Mike.

Finally, I want to briefly address a comment that was made by United Therapeutics in its earnings call yesterday in which it compared emitted dose calculations between Yutrepia and Tyvaso DPI. This is a red herring. Patients and physicians don't care about emitted dose calculations – they only care about the actual dose received. As confirmed in our registration studies, and validated by the FDA in their granting of tentative approval, Yutrepia reliably and precisely delivers doses to patients that are comparable to all of the treprostinil doses in the Tyvaso DPI label, as well as doses above and beyond those that are in the Tyvaso DPI label.

Patients also care about the comfort and usability of the treatment. And we believe that our low-resistance device, its ease of use, and robustness will be strongly favored by patients and their providers.

As you can tell ….our excitement and confidence is rapidly escalating as we prepare for the potential launch of YUTREPIA.

At this time, I would now like to open it up for questions. Operator, first question please…..

AFTER Q&A SESSION, ROGER WILL CLOSE WITH:

With no further questions, again we thank you for joining us today and look forward to reporting on our continued progress in the coming quarters.