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): **November 8, 2022**

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 November 8, 2022, Liquidia Corporation, a Delaware corporation, issued a press release announcing its financial results for the quarter ended September 30, 2022, and also provided a corporate update. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Exhibit
99.1	Press Release of Liquidia Corporation, dated November 8, 2022.
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.

November 8, 2022

Liquidia Corporation

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

Exhibit 99.1

Liquidia Reports Third Quarter 2022 Financial Results and Provides Corporate Update

- *Company to host webcast and conference call today at 8:30 a.m. ET*

MORRISVILLE, N.C., November 8, 2022 - Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for the third quarter ended September 30, 2022. The Company will host a webcast and conference call at 8:30 a.m. ET to discuss the third quarter 2022 financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "The third quarter marked a critical juncture in our mission to provide YUTREPIA™ (treprostinil) inhalation powder to patients with PAH and PH-ILD. We have now demonstrated in at least one legal forum that each of the patent claims asserted against us is invalid or not infringed. We will continue our relentless efforts to affirm these decisions in their respective appeals so that YUTREPIA can be provided as an important new treatment option for physicians, patients and payors . The feedback from physicians and patients that we have received continues to demonstrate a continuing need for a product with YUTREPIA's profile and strengthens our resolve to launch YUTREPIA as soon as possible."

Corporate Updates

Further clarity on path to launching YUTREPIA with key legal wins. In 2020, United Therapeutics Corporation (UTC) filed litigation in the United States District Court for the District of Delaware (the Court) under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) that alleged Liquidia infringes U.S. Patent No. 9,593,066 ('066 Patent), U.S. Patent No. 10,716,793 ('793 Patent) and U.S. Patent No. 9,604,901 ('901 Patent). Since that time, the Company has demonstrated, either through proceedings in the Court or in parallel *inter partes* review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB), that each of the claims asserted by UTC against the Company is invalid or not infringed. To summarize:

'793 Patent: In July 2022, the PTAB found in favor of Liquidia in the '793 IPR stating that all the claims of the '793 Patent have been shown to be unpatentable based on the preponderance of the evidence. While the Court in the Hatch-Waxman litigation ruled against Liquidia based on the arguments presented at trial, finding that the '793 Patent is valid and infringed, that ruling will be overridden by the PTAB decision in the event it is affirmed on appeal. UTC has requested a rehearing with respect to the PTAB's decision in the '793 IPR. UTC has publicly stated that, if the rehearing request is denied, it intends to appeal the PTAB's decision.

‘066 Patent: In August 2022, the Court ruled in Liquidia’s favor with respect to the ‘066 Patent, finding that five of the six asserted claims of the '066 Patent are invalid and that the remaining asserted claim is not infringed by Liquidia.

‘901 Patent: In December 2021, UTC stipulated that, based on the Court’s construction of the claims in the ‘901 Patent, Liquidia does not infringe any of the asserted claims.

YUTREPIA launch timing. While the decisions of the Court and the PTAB are all subject to ongoing rehearing requests and appeals, unless UTC is successful in overturning at least one of the decisions that have been rendered, the Company will be able to launch YUTREPIA following completion of the appeals process. Based on the current status of the various appeals and rehearing requests, it is likely that the timeline for a prospective launch will be primarily governed by the resolution of UTC’s expected appeal of the ‘793 IPR decision. If the PTAB denies the rehearing request, we anticipate that the timeline for the completion of the appeal to the Court of Appeals for the Federal Circuit could be approximately 12-14 months from the date on which the rehearing request is denied. However, in the event the briefing schedule is accelerated, oral argument occurs earlier than expected or if the decision of the PTAB is summarily affirmed, the appeals process may be completed within a shorter time period.

Continued to share long-term clinical data and other studies related to YUTREPIA. Data from the completed INSPIRE study were published in the journal *Pulmonary Circulation*, highlighting observations from patients treated for an average of one year. YUTREPIA was safely dosed from 26.5 mcg to 212 mcg, which are comparable to 3 to 24 breaths of nebulized Tyvaso® per session. Patients maintained or improved in exploratory measures of clinical efficacy, whether prostacyclin naïve or transitioning from Tyvaso. The ongoing open-label extension study will provide up to three years of long-term safety and clinical effectiveness data as patients continue to titrate to higher doses as needed, with some patients having now reached a dose of 238.5 mcg, administered four times daily. To that point, the Company presented data at the CHEST 2022 Annual Meeting hosted by the American College of Chest Physicians supporting the conclusions that (i) increasing YUTREPIA dose trends with improvements in six-minute-walk-distance (6MWD) and New York Heart Association (NYHA) Functional Class and (ii) the aerosol performance of YUTREPIA is not affected by real-world patient misuse scenarios such as varying the inhalation orientation or dropping the device.

Third Quarter 2022 Financial Results

Cash totaled $98.3 million as of September 30, 2022, compared to $57.5 million as of December 31, 2021.

Revenue was $3.2 million for the three months ended September 30, 2022, compared to $3.2 million for the three months ended September 30, 2021. Revenue related primarily to the Promotion Agreement. During the three months ended September 30, 2022, the profit split percentage we received under the Promotion Agreement was 50%, whereas during the three months ended September 30, 2021, the profit split percentage decreased from 80% to 50% as a result of achievement of predetermined cumulative sales thresholds. This decrease in profit split percentage was offset by an increase in the number of units sold.

Cost of revenue was $0.7 million for the three months ended September 30, 2022, compared to $0.9 million for the three months ended September 30, 2021. Cost of revenue related to the Promotion Agreement as noted above.

Research and development expenses were $4.5 million for the three months ended September 30, 2022, compared with $4.5 million for the three months ended September 30, 2021. During the three months ended September 30, 2022, we incurred $1.5 million related to YUTREPIA compared to $1.4 million during the three months ended September 30, 2021. Research and development expenses for the three months ended September 30, 2022 and 2021 also included personnel and consulting costs of $2.0 million and $2.1 million, respectively, including stock-based compensation of $0.3 million in each year.

General and administrative expenses were $6.7 million for the three months ended September 30, 2022, compared with $4.9 million for the three months ended September 30, 2021. The increase of $1.8 million or 38% was primarily due to a $2.2 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA offset by a $0.9 million decrease in legal fees related to our ongoing YUTREPIA-related litigation.

Other Expenses net total was $0.3 million for the three months ended September 30, 2022, compared with $0.2 million for the three months ended September 30, 2021. The increase of $0.1 million was primarily due to a $0.4 million increase in interest expense due to a higher debt balance and interest rate on our debt from the Amended and Restated Loan and Security Agreement dated as of January 7, 2022 with Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P., offset by increased interest income from higher cash and cash equivalents balances.

Net loss for the three months ended September 30, 2022, was $9.1 million, or $0.14 per basic and diluted share, compared to a net loss of $7.3 million, or $0.14 per basic and diluted share, for the three months ended September 30, 2021.

Tyvaso® is a registered trademark of United Therapeutics Corporation.

About YUTREPIA™ (treprostinil) inhalation powder

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a proven, convenient, 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. 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 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 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 or rehearing requests 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, 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 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 for Media & Investors
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Liquidia Corporation
Select Consolidated Balance Sheet Data
(in thousands)

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 98,320	$ 57,494
Total assets	$ 132,568	$ 93,729
Total liabilities	$ 37,534	$ 28,464
Accumulated deficit	$ (344,063)	$ (309,581)
Total stockholders' equity	$ 95,034	$ 65,265

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

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2022	2021	2022	2021
Revenue	$ 3,165	$ 3,179	$ 10,575	$ 9,638
Costs and expenses:				
Cost of revenue	740	890	2,165	2,297
Research and development	4,512	4,487	14,459	15,136
General and administrative	6,744	4,882	26,224	14,640
Total costs and expenses	11,996	10,259	42,848	32,073
Loss from operations	(8,831)	(7,080)	(32,273)	(22,435)
Other income (expense):				
Interest income	359	4	428	30
Interest expense	(620)	(205)	(1,640)	(558)
Loss on extinguishment of debt	—	—	(997)	(53)
Total other income (expense), net	(261)	(201)	(2,209)	(581)
Net loss and comprehensive loss	$ (9,092)	$ (7,281)	$ (34,482)	$ (23,016)
Net loss per common share, basic and diluted	$ (0.14)	$ (0.14)	$ (0.58)	$ (0.47)
Weighted average common shares outstanding, basic and diluted	64,458,741	52,081,497	59,745,042	48,822,303