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): **March 17, 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 March 17, 2022, Liquidia Corporation, a Delaware corporation, issued a press release announcing its financial results for the full year ended December 31, 2021 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 March 17, 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.

March 17, 2022

Liquidia Corporation

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

Exhibit 99.1

Liquidia Corporation Reports Full-Year 2021 Financial Results and Provides Corporate Update

- *Received tentative FDA approval of YUTREPIA™ (treprostinil) inhalation powder*
- *Expanded use of Treprostinil Injection to include subcutaneous administration*
- *Preparing to launch YUTREPIA in late-2022 pending final FDA approval*
- *Company to host webcast and conference call today at 8:30 a.m. ET*

MORRISVILLE, N.C., March 17, 2022 - Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today reported financial results for full-year ended December 31, 2021. The Company will host a webcast and conference call at 8:30 a.m. ET to discuss the 2021 financial results and provide a corporate update.

Roger Jeffs, Liquidia's Chief Executive Officer, said: "Last year, we achieved every goal we set by increasing sales of Treprostinil Injection, securing tentative approval of YUTREPIA, advancing our legal position in the ongoing Hatch-Waxman case, and strengthening our balance sheet. I am sincerely grateful for the team who has positioned the company for its next stage of dramatic growth. We are excited about the opportunity to offer YUTREPIA to PAH patients in 2022, especially as the demand for inhaled treprostinil expands into a potential market opportunity of over $1 billion in the near future."

Corporate Updates

Completed first full year as a fully integrated, research, development, and commercial organization with immediate focus on treating pulmonary hypertension. In November 2020, Liquidia Technologies, Inc. and RareGen, LLC (now known as Liquidia PAH, LLC) became wholly owned operating subsidiaries of Liquidia Corporation. The new corporate entity includes commercialization capabilities and expertise in pulmonary arterial hypertension (PAH) in support of Treprostinil Injection, the first-to-file generic formulation of Remodulin® (treprostinil) from Sandoz Inc. Strategically, the combined entity reinforced Liquidia's commitment to PAH patients and the medical community in preparation for the launch of YUTREPIA™ (treprostinil) inhalation powder upon potential final approval by the United Stated Food and Drug Administration (FDA) and favorable resolution of the Hatch-Waxman litigation.

Received tentative FDA approval of YUTREPIA™ (treprostinil) inhalation powder to treat PAH, validating the application of PRINT® Technology. In November 2021, the FDA issued a tentative approval of YUTREPIA which indicated that the New Drug Application (NDA) had met all the requirements for final approval but cannot yet be marketed pending resolution of Hatch-Waxman litigation commenced by United Therapeutics on in June 2020. In support of the approval decision, the FDA completed an on-site Pre-Approval Inspection of the Morrisville, North Carolina, facility over 5-days with no Form 483 Inspectional Observations issued.

Removed barriers to increase adoption of generic Treprostinil Injection by patients, physicians, and payers. In May 2021, Liquidia PAH's manufacturing partner, Chengdu Shifeng Medical Technologies LTD began selling the RG 3ml Medication Cartridge, which may be used to supply treprostinil to PAH patients using the CADD-MS 3 pump for subcutaneous administration. As a result, unit sales of Treprostinil Injection increased dramatically in 2021 across intravenous and subcutaneous routes of administration, more than doubling the number of patients being treated as compared to the first half of 2021. The Company remains confident that the inventory of pumps and cartridges held by specialty pharmacies is sufficient to support the treatment of all PAH patients requiring parenteral administration of Treprostinil Injection.

Continued to advance legal proceedings to allow for final approval of YUTREPIA. In support of YUTREPIA, the Company is actively involved in Hatch-Waxman litigation brought by United Therapeutics Corporation ("UTC") in June 2020 involving three U.S. patents: No. 9,604,901 (the '901 Patent), 9,593,066 (the '066 Patent) and 10,716,793 (the '793 Patent). During 2021, Liquidia secured several favorable legal rulings in proceedings at the District Court of Delaware and through *inter partes* review (IPR) at the U.S. Patent Office. In August, the U.S. Patent Trial and Appeal Board (PTAB) instituted *inter partes* review (IPR) against the '793 Patent, stating that Liquidia demonstrated a reasonable likelihood of prevailing in its assertion that all of the claims of the '793 patent are unpatentable as obvious over the combination of certain prior art cited by Liquidia in its petition to the PTAB. In October, the PTAB found that found that seven of the nine claims in the '901 Patent were unpatentable, leaving only the narrower dependent claims 6 and 7 remaining, both of which require actual storage at ambient temperature of treprostinil sodium. In December, UTC stipulated to Liquidia's non-infringement of the '901 Patent. Trial in the Hatch-Waxman litigation is scheduled for March 28-31, and a final written decision in the IPR for the '793 Patent is expected in August 2022.

Strengthened the balance sheet to drive value though key legal milestones and regulatory events. Over the year, the Company initiated actions to significantly reduce net annual spending in 2021 compared to 2020 to extend the cash runway. The cost-cutting measures were complemented by $12.9 million in revenue from the profit derived from sales of Treprostinil Injection in Liquidia PAH's partnership with Sandoz. In January 2022, the Company increased its existing credit facility with Silicon Valley Bank, providing access to up to $40.0 million in term loans of which the first $20.0 million was funded in 2022. The net impact of these financial measures positions the Company to drive value through key legal and regulatory events as it prepares to launch YUTREPIA pending final FDA approval.

Full Year 2021 Financial Results

Cash totaled $57.5 million as of December 31, 2021. There were 52.3 million shares outstanding as of December 31, 2021.

Revenue was $12.9 million for the year ended December 31, 2021, compared with $0.7 million for the year ended December 31, 2020. 2021 includes a full year of revenue related to the Promotion Agreement following the acquisition of Liquidia PAH in November 2020. Revenue is net of $2.7 million in amortization of the contract acquisition costs associated with the Promotion Agreement with Sandoz.

Cost of revenue was $3.0 million for the year ended December 31, 2021, compared with $0.2 million for the year ended December 31, 2020. 2021 includes a full year of Cost of revenue related to the Promotion Agreement following the acquisition of Liquidia PAH in November 2020 and included (i) the cost of employing a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of PAH, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection and (ii) amortization of the intangible asset associated with the Promotion Agreement.

Research and development expenses were $20.5 million for the year ended December 31, 2021, compared with $32.2 million for the year ended December 31, 2020, a decrease of $11.7 million or 36.3%. The decrease primarily related to lower expenses from our YUTREPIA clinical program, which was substantially completed prior to filing the NDA in April 2020, and lower employee and consulting expenses.

General and administrative expenses were $23.1 million for the year ended December 31, 2021, compared with $27.4 million for the year ended December 31, 2020. The decrease of $4.3 million, or 15.6%, was due to a $9.1 million decrease in consulting expenses and professional fees associated with corporate activities, a $1.1 million decrease in personnel expenses, and a $0.5 million decrease in commercial and marketing expenses. These decreases were offset by a $5.1 million increase in legal fees related to our ongoing YUTREPIA-related litigation and a $2.0 million increase in stock-based compensation expenses driven by the accelerated vesting of equity awards upon tentative FDA approval of YUTREPIA in November 2021.

Net loss for during the year ended December 31, 2021, was $34.6 million, or $0.70 per basic and diluted share, compared to a net loss of $59.8 million, or $1.76 per basic and diluted share, for the year ended December 31, 2020.

Remodulin® (treprostinil) 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 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 our patent litigation pending in the U.S. District Court for the District of Delaware or our *inter partes* review with the PTAB or any related appeals, 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 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 Balance Sheet Data

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 57,493,933	$ 65,316,481
Total assets	$ 93,729,219	$ 99,531,760
Total liabilities	$ 28,463,678	$ 28,445,922
Accumulated deficit	$ (309,580,867)	$ (275,002,219)
Total stockholders' equity	$ 65,265,541	$ 71,085,838

Liquidia Corporation
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,	
	2021	2020
Revenue	$ 12,853,345	$ 739,628
Costs and expenses:		
Cost of revenue	3,022,911	237,712
Research and development	20,516,948	32,222,393
General and administrative	23,110,529	27,368,653
Total costs and expenses	46,650,388	59,828,758
Loss from operations	(33,797,043)	(59,089,130)
Other income (expense):		
Interest income	33,435	184,359
Interest expense	(815,040)	(857,998)
Total other income (expense), net	(781,605)	(673,639)
Net loss and comprehensive loss	$ (34,578,648)	$ (59,762,769)
Net loss per common share, basic and diluted	$ (0.70)	$ (1.76)
Weighted average common shares outstanding, basic and diluted	49,677,737	33,888,434