**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 1, 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 1.01 Entry Into a Material Definitive Agreement.**

On December 1, 2022, Liquidia PAH, LLC, a Delaware limited liability company ("Liquidia PAH"), a wholly-owned subsidiary of Liquidia Corporation, a Delaware corporation (the "Company"), entered into a Device Development and Supply Agreement (the "Pump Development Agreement") with Mainbridge Health Partners, LLC ("Mainbridge") and Sandoz Inc. ("Sandoz").

The Pump Development Agreement provides for the cooperation between Liquidia PAH, Sandoz and Mainbridge to develop a new pump that is suitable for the subcutaneous administration of treprostinil. Mainbridge will perform all development, validation and testing activities required for the pump and related consumables.

Under the Pump Development Agreement, Liquidia PAH and Sandoz will provide Mainbridge with product requirements for the pump and related consumables, and have the right to review proposed protocols for verification testing and human factor testing and the results of all such testing.

The Pump Development Agreement also provides that the parties anticipate submitting a 510(k) clearance application for the pump to the U.S. Food and Drug Administration in 2023.

Liquidia PAH and Sandoz will split all development costs and milestone payments under the Pump Development Agreement in accordance with the terms and conditions set forth therein.

The foregoing description of the Pump Development Agreement does not purport to be complete and is qualified in its entirety by reference to the complete terms and conditions of the Pump Development Agreement to be filed as an exhibit to the Company's next Form 10-K to be filed with the Securities and Exchange Commission (the "SEC").

**Item 8.01 Other Events.**

On December 5, 2022, Liquidia Corporation, a Delaware corporation (the "Company"), issued a press release announcing the collaboration between the Company, Sandoz and Mainbridge to develop the new pump for the subcutaneous administration of treprosinil pursuant to the Pump Development Agreement. 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 5, 2022. |
| 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 5, 2022

Liquidia Corporation

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

**Exhibit 99.1**

**Liquidia Announces Collaboration to Develop a New Infusion Pump for Subcutaneous Delivery of Treprostinil Injection to Treat Pulmonary Arterial Hypertension (PAH)**

- Liquidia and Sandoz will collaborate with Mainbridge Health Partners to develop a new infusion pump

- Liquidia and Sandoz have also extended the term of their promotion agreement for Treprostinil Injection until 2032

**MORRISVILLE, N.C., December 5, 2022** - Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) announced today a collaboration with Sandoz Inc. (Sandoz) and Mainbridge Health Partners LLC (Mainbridge) to support the development of a new subcutaneous pump for infusion of Treprostinil Injection, a generic form of Remodulin®, for which Liquidia has the exclusive rights to promote and commercialize with Sandoz.

Scott Moomaw, Senior Vice President of Commercial at Liquidia, stated: “Liquidia remains committed to addressing unmet needs in the administration of treprostinil, whether it be inhaled or infused. In order to alleviate the single-source dependence on the existing CADD-MS 3 system, Sandoz and Liquidia have found a great partner in Mainbridge with the skills and know-how to efficiently develop a new infusion pump using technology that has been previously approved by the U.S. Food and Drug Administration (FDA) for delivery of insulin. Our goal is to ensure the widespread availability of our trusted and proven Treprostinil Injection to the benefit of physicians, payors and patients in the PAH community.”

To enable the collaboration, Sandoz and Liquidia will enter into a joint agreement with Mainbridge (Pump Agreement). Mainbridge will perform all development, validation and testing activities required for the pump and related consumables. The parties anticipate submitting a 510(k) in 2023 for FDA clearance. Sandoz and Liquidia will split equally the development costs. In connection with the execution of the Pump Agreement, Liquidia and Sandoz also agreed to extend their promotion agreement for Treprostinil Injection by another five years until December 31, 2032.

**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 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.

Remodulin ® and Tyvaso® are registered trademarks of United Therapeutics Corporation.
CADD-MS 3® is a registered trademark of Smiths Medical MD, Inc.

**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.

**About Mainbridge Health Partners**

Mainbridge Health Partners is an infusion technology and solutions company focused on creation and development of software, process, and products for better outcomes. Mainbridge embraces industry changing discoveries which improve patient care with proven, leading-edge technology to significantly enhance both domestic and global healthcare products and services. Mainbridge developed FUSEBOX™, a platform that runs ambulatory infusion centers and suites. For more information, please visit www.mainbridgehp.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 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, 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 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) 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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