

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): **June 28, 2023**

LIQUIDIA CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39724
(Commission
File Number)

85-1710962
(IRS Employer
Identification No.)

419 Davis Drive, Suite 100, Morrisville, North Carolina
(Address of principal executive offices)

27560
(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.

License Agreement with Pharmosa Biopharm

On June 28, 2023, Liquidia Technologies, Inc., a Delaware corporation (the “Liquidia Technologies”) and a wholly owned subsidiary of Liquidia Corporation (the “Company”), entered into a License Agreement with Pharmosa Biopharm Inc., a corporation incorporated under the laws of Taiwan (“Pharmosa”).

The License Agreement provides for, among other things, an exclusive licensing agreement between Pharmosa and the Company for the development and commercialization in North America of L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) and a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America.

Under the terms of the License Agreement, the Company will be responsible for development, regulatory and commercial activities of L606 in North America. Pharmosa will manufacture clinical and commercial supplies of the liposomal formulation through its global supply chain and support Liquidia in establishing a redundant global supply chain. In consideration for these exclusive rights, the Company will pay Pharmosa an upfront payment of \$10 million, potential development milestone payments tied to PAH and PH-ILD indications of up to \$30 million, potential sales milestones of up to \$185 million and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a \$10 million milestone payment for each additional indication approved after PAH and PH-ILD and each additional product approved under the license. The Company also retains the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the License Agreement.

The License Agreement is effective upon signing and unless earlier terminated, the License Agreement will remain in effect on a country-by-country and Product-by-Product basis until the date on which the Royalty Term (as defined in the License Agreement) in such country with respect to such Product (as defined in the License Agreement) expires. The License Agreement may be terminated by mutual agreement or by either party for a material breach by the other party, subject to notice and cure provisions, or by either party in a Bankruptcy Event (as defined in the License Agreement).

Concurrently with the execution of the License Agreement, Pharmosa and Liquidia Technologies also entered into an Asset Transfer Agreement (the “Asset Transfer Agreement”) pursuant to which Pharmosa will transfer its inventory of physical materials to the Company (as set forth on the terms and conditions therein) in order for the Company and Pharmosa to perform the necessary actions contemplated under the License Agreement.

In each of the License Agreement and the Asset Transfer Agreement, Pharmosa and the Company made customary representations and warranties and agreed to customary covenants, including, without limitation, with respect to indemnification, for transactions of this type.

The foregoing descriptions of the terms of the License Agreement and Asset Transfer Agreement are not complete and are qualified in their entirety by reference to the text of the License Agreement and Asset Transfer Agreement, which will be filed as exhibits to the Company’s next Quarterly Report on Form 10-Q.

Second Amendment to Revenue Interest Financing Agreement

As previously disclosed, on January 9, 2023, Liquidia Technologies 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, by and among Liquidia Technologies and HCR (as amended, the “Financing Agreement”).

On June 28, 2023, Liquidia Technologies and HCR entered into a Second Amendment to the Financing Agreement (the “Second Amendment”), pursuant to which, HCR will move \$2.5 million from the fourth tranche to the second tranche under the Financing Agreement. As a result, HCR will fund a total of \$10 million (as the second tranche under the Financing Agreement), which will be used for the upfront payment owed to Pharmosa in connection with the transactions contemplated by the License Agreement. The Second Amendment does not impact the \$35 million third tranche under the Financing Agreement that will be available to the Company upon favorable resolution of the ongoing patent litigation with United Therapeutics Corporation.

The foregoing description of the terms of the Second Amendment is not complete and is qualified in its entirety by reference to the text of the Second 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 June 28, 2023, the Parent issued a press release announcing the execution of the License Agreement with Pharmosa. 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 June 28, 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.

June 28, 2023

Liquidia Corporation

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer



Liquidia Corporation and Pharmosa Biopharm Announce Collaboration for Sustained-Release Inhaled Treprostinil Product in North America

- Liquidia exclusively licenses North American rights to L606, an inhaled formulation of treprostinil administered twice-daily with a short duration, next-generation nebulizer
- Liquidia funds \$10 million upfront payment from finance agreement with HealthCare Royalty
- Pharmosa to receive up to \$215 million in development and sales milestones for PAH and PH-ILD indications, \$10 million for each additional approved indication and additional product, and royalties on net sales of L606
- Creates industry leading portfolio in rapidly expanding market for inhaled treprostinil
- Liquidia to host webcast today at 8:30 a.m. Eastern Time

MORRISVILLE, N.C., June 28, 2023 – Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) and Pharmosa Biopharm (Pharmosa) today announced that they have entered into an exclusive licensing agreement for the development and commercialization in North America of L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD).

Roger Jeffs, Chief Executive Officer of Liquidia, stated: “L606 is the perfect life-cycle complement to our pipeline and furthers our mission to provide innovative treatment options that improve the lives of patients suffering from PAH or PH-ILD. As already observed in the ongoing Phase 3 open-label study of PAH patients, Pharmosa’s novel liposomal formulation offers potential to improve patient convenience and compliance with twice-daily dosing using a short-duration, next-generation nebulizer. More importantly, we believe that the inhaled drug-device combination may provide best-in-class treprostinil exposure over a 24-hour period, including during sleeping hours, which could translate to improved efficacy, tolerability, and patient outcomes. Our investment in this collaboration, alongside our continued preparation for a potential launch of YUTREPIA™ (treprostinil) inhalation powder, are clear examples of Liquidia’s long-term commitment to addressing unmet needs in treating pulmonary hypertension and enabling choice based on patients’ preferences and circumstances.”

Pei Kan, Ph.D., President of Pharmosa, added: “Liquidia is the ideal partner to bring L606 to the North American market. Liquidia has shown an unflinching determination to bring novel products to patients, and provides clear synergies with their commercial effort, clinical expertise and deep relationships with key opinion leaders. Pharmosa will focus on advancing its sustained-release liposomal technology which has demonstrated in L606 the ability to dramatically reduce maximum systemic drug concentrations while significantly increasing local concentrations deep in the lung.”

Under the agreement, Liquidia will be responsible for development, regulatory and commercial activities of L606 in North America. Pharmosa will manufacture clinical and commercial supplies of L606 and support Liquidia in establishing a redundant global supply chain. In consideration for these exclusive rights, Liquidia will pay Pharmosa an upfront payment of \$10 million, potential development and sales milestone payments of up to \$215 million tied to PAH and PH-ILD indications, and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a \$10 million milestone payment for each additional indication and additional product approved. Liquidia retains the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the license agreement.

Liquidia intends to seek first regulatory approval of L606 in the United States under the 505(b)(2) regulatory pathway. The planned New Drug Application (NDA) is expected to include: (i) the completed Phase 1 trial demonstrating tolerability and comparable pharmacokinetics to nebulized Tyvaso (treprostinil) inhalation solution; (ii) clinical data from the on-going, open-label Phase 3 study in the United States in PAH and PH-ILD patients; and (iii) clinical data from a double-blind, randomized, placebo-controlled study to evaluate treatment of PH-LD patients with L606. Liquidia intends to initiate the PH-ILD trial in first half of 2024.

In support of today's announcement, HealthCare Royalty (HCRx) will fund Liquidia \$10.0 million from the Revenue Interest Financing Agreement (RIFA) announced in January 2023. The RIFA included a \$7.5 million financing tranche at Liquidia's discretion to support any acquisition of rights to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension. In connection with the transaction with Pharmosa, HCRx has agreed to advance an additional \$2.5 million from the \$25 million fourth tranche under the RIFA, which was to be funded upon the mutual election of both Liquidia and HCRx. Today's announcement does not impact the \$35 million tranche that will be available to Liquidia upon favorable resolution of the ongoing patent litigation with United Therapeutics Corporation. Total proceeds funded to Liquidia by HCRx are now \$42.5 million of the up to \$100 million contemplated by the RIFA. As previously announced, HCRx will receive a tiered royalty on net revenue generated by YUTREPIA and other products marketed by Liquidia. 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.

Conference Call

Liquidia will host a webcast call today at 8:30 a.m. Eastern Time. To listen to the webcast, please visit <https://liquidia.com/investors/events-and-presentations>.

About L606 (liposomal treprostinil) inhalation suspension

L606 is an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer. The L606 suspension uses Pharmosa's proprietary liposomal formulation to encapsulate treprostinil which can be released slowly at a controlled rate into the lung, enhancing drug exposure over an extended period of time and reducing local irritation of the upper respiratory tract. L606 is currently being evaluated in an open-label study in the United States for treatment of pulmonary arterial hypertension (PAH) with a planned pivotal study for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD).

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 sarcoidosis among others. Any level of PH in ILD patients is associated with poor 3-year survival between 30 to 35%. 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 with inhaled treprostinil.

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 Pharmosa Biopharm

Pharmosa Biopharm Inc. (PBI) is a Taiwan-based biotechnology company focused on developing new drugs by exploiting its proprietary liposomal formulations and manufacturing technology. With regional and global strategic partnerships, PBI develops products through 505(b)(2) or hybrid applications to regulatory authorities with the intent to expand the clinical potential of existing drugs by exploiting innovative delivery formulations and medical devices. For more information, please visit <https://www.pharmosa.com.tw>

About HealthCare Royalty

HCRx is a leading royalty acquisition company focused on commercial or near-commercial stage biopharmaceutical products. HCRx has \$6.3 billion in cumulative capital commitments with offices in Stamford (CT), San Francisco, Boston and London. For more information, visit www.hcrx.com. HEALTHCARE ROYALTY[®] and HCRx[®] are registered trademarks of HealthCare Royalty Management, LLC.

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