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): **October 2, 2024**

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.

First Amendment to License Agreement with Pharmosa Biopharm

As previously disclosed, on June 28, 2023, Liquidia Technologies, Inc., a Delaware corporation (the "Liquidia Technologies") and a wholly owned subsidiary of Liquidia Corporation, a Delaware corporation (the "Company"), entered into a License Agreement (as amended, the "License Agreement") with Pharmosa Biopharm Inc., a corporation incorporated under the laws of Taiwan ("Pharmosa"), which provided for, among other things, (i) 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 (ii) a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America (the "Non-Exclusive License").

On October 2, 2024 (the "Effective Date"), Liquidia Technologies and Pharmosa entered into a First Amendment to the License Agreement (the "First Amendment"). The First Amendment, among other things, (i) expands Liquidia Technologies' licensed territory beyond North America to include key markets in Europe, Japan and elsewhere, (ii) adds certain potential development milestone payments of up to $7.75 million tied to clinical development and approvals in PAH and/or PH-ILD outside North America, (iii) adds certain potential sales milestone payments of up to $150 million tied to commercial sales outside North America and (iv) limits Liquidia Technologies' ability to deduct certain portions of milestone and royalty payments due to manufacturers of devices for the administration of L606 from milestone payments and royalties payable by Liquidia Technologies to Pharmosa pursuant to the License Agreement.

In connection with the rights granted in the First Amendment and the Device License Agreement, the Company agreed to pay to Pharmosa $3.5 million within 30 days following Liquidia Technologies' receipt of an invoice from Pharmosa following the Effective Date. In addition to the $3.5 million initial fee, the Company will be responsible for certain royalties payable on global net sales of L606, which are unchanged from the License Agreement.

The foregoing description of the terms of the First Amendment is not complete and is qualified in its entirety by reference to the text of the First Amendment, which will be filed as an exhibit to the Company's next Quarterly Report on Form 10-Q.

Device License Agreement with Pharmosa Biopharm

Concurrently with the execution of the First Amendment, on the Effective Date, Liquidia Technologies and Pharmosa also entered into a Device License Agreement (the "Device License Agreement"). Pursuant to the terms of the Device License Agreement, Pharmosa will provide (i) an exclusive license to Liquidia Technologies for the right to develop, manufacture, use and commercialize Pharmosa's next-generation smart-technology nebulizers (the "Device") for use with L606 in most countries (subject to certain exceptions) (the "Territory") and (ii) a non-exclusive license to Liquidia Technologies for the right to develop, manufacture and use (but not commercialize) the Device outside of the Territory.

The Device License Agreement is effective upon signing and unless earlier terminated, the Device License Agreement will remain in effect on a country-by-country basis until the expiration of the License Agreement with respect to the Existing Product (as defined in the Device License Agreement) in such country. The Device 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 Device License Agreement).

The foregoing description of the terms of the Device License Agreement is not complete and is qualified in its entirety by reference to the text of the Device License Agreement, which will be filed as an exhibit to the Company's next Quarterly Report on Form 10-Q.

Item 8.01 Other Events.

On October 2, 2023, the Company issued a press release announcing the execution of the First Amendment and the Device 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 October 2, 2024.
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.

October 2, 2024

Liquidia Corporation

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer and Chief Operating Officer

Exhibit 99.1

Liquidia and Pharmosa Biopharm Expand Collaboration to Develop Sustained Release Inhaled Treprostinil (L606)

- Liquidia amends exclusive license to include key markets in Europe, Japan and elsewhere
- Liquidia also obtains rights to Pharmosa's next-generation nebulizers for use with L606
- Pharmosa to receive $3.5 million upfront and up to $157.75 million in additional development and sales milestones tied to commercial sales outside of North America

MORRISVILLE, N.C., October 2, 2024 – Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary diseases, and Pharmosa Biopharm (Pharmosa) today announced that they have amended the current exclusive licensing agreement for the development and commercialization 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). The amended agreement expands Liquidia's licensed territory beyond North America to include key markets in Europe, Japan and elsewhere. Pharmosa will retain certain territories, including China, Korea, Taiwan, Middle East, North Africa, Turkey and Southeast Asia.

Liquidia has also obtained certain rights to Pharmosa's next-generation smart-technology nebulizers for use with its proprietary liposomal drug formulations. Unlike current nebulized treatments for PAH and PH-ILD, these palm-sized, lightweight, virtually silent nebulizers provide portability like a dry-powder inhaler and rapidly deliver a dose using breath-actuated smart technology that adapts to a patient's normal breathing pattern.

Dr. Rajeev Saggar, Chief Medical Officer of Liquidia, stated: "This is a great example of our approach to research and development in pulmonary hypertension. This partnership has the potential to be transformational for people living with PAH and PH-ILD, as it will combine Liquidia's expertise as a leader in the field of pulmonary hypertension with Pharmosa's deep experience in inhaled liposomal formulations. We are delighted by the interest from the global medical and patient communities, many of which lack access to inhaled formulations of treprostinil, as we prepare to initiate the L606 pivotal study in PH-ILD later this year. We are also encouraged by the recent scientific advice from the European Medicines Agency that supports our plan to proceed with the study as designed."

Pei Kan, Ph.D., President of Pharmosa, added: "This expanded partnership with Liquidia is a strong endorsement for our L606 programs and our contribution to the fight against pulmonary hypertension including PAH and PH-ILD. With more than 100,000 PAH and PH-ILD patients in the major countries outside North America, improvements of the treatment strategies in this region are essential since there is no approved treatment for PH-ILD outside the U.S. We believe Liquidia's commitment to move quickly and execute its global clinical program will accelerate the potential for long-term value creation for both parties in this partnership."

Consistent with the agreement from June 2023, Liquidia will be responsible for the development, regulatory and commercial activities of L606 in the expanded territory. Pharmosa will continue to manufacture clinical and commercial supplies of L606. In consideration for these incremental exclusive rights, Liquidia will pay Pharmosa an upfront payment of $3.5 million and up to $157.75 million in additional milestone payments for the development of PAH and PH-ILD indications and commercial sales outside of North America. Royalties payable by Liquidia to Pharmosa on global net sales of L606 have not changed and remain two tiers of low, double-digit royalties as set forth in the original agreement.

Clinically, L606 continues to generate encouraging data in an open-label safety study in the United States in both PAH and PH-ILD. As reported in a poster presentation at the 2024 American Thoracic Society International Conference, the tolerability and titratability profile of L606 observed to date has been favorable up to the maximum dose allowed in the study of 378 mcg twice daily, a dosage comparable to 26 to 28 breaths of Tyvaso administered four times daily. Pharmacokinetic studies in healthy volunteers demonstrated therapeutic levels of L606 up to 12 hours and 7-times lower peak plasma concentration compared to Tyvaso®. The increased apparent half-life of L606, in concert with comparable systemic exposure and clearance rate, suggests that L606 provides controlled, continuous drug coverage during sleeping and waking hours, and supports twice-daily administration using a breath-actuated, smart-technology nebulizer.

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 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 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 developing innovative therapies for patients with rare cardiopulmonary disease. The company's current focus spans the development and commercialization of products in pulmonary hypertension and other applications of its proprietary PRINT® Technology. PRINT enabled the creation of Liquidia's lead candidate, YUTREPIA™ (treprostinil) inhalation powder, an investigational drug for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The company is also developing L606, an investigational sustained-release formulation of treprostinil administered twice-daily with a next-generation nebulizer, and currently markets generic Treprostinil Injection for the treatment of PAH. To learn more about Liquidia, please visit https://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.

Tyvaso® is a registered trademark of United Therapeutics Corporation

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, 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, 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.

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