

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 2, 2021**

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 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 8.01 Other Events.

On June 2, 2021, Liquidia Corporation, a Delaware corporation (the “Company”), issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) has accepted the Company’s New Drug Application resubmission for LIQ861 (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension and set a PDUFA goal date of November 7, 2021. A copy of the press release is filed as Exhibit 99.1 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 2, 2021.](#)

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 2, 2021

Liquidia Corporation

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer



Liquidia Announces FDA Acceptance of New Drug Application Resubmission for LIQ861 (treprostinil) Inhalation Powder

MORRISVILLE, N.C., June 2, 2021 - Liquidia Corporation (NASDAQ: LQDA) announced today that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) resubmission for LIQ861 (treprostinil) inhalation powder to treat pulmonary arterial hypertension (PAH). The FDA confirmed that the resubmission was a complete, class 2 response to the previous action letter issued on November 24, 2020. The FDA set a PDUFA goal date of November 7, 2021.

If the FDA determines, following its substantive review of the NDA, that all requirements for approval have been met, the FDA may issue tentative approval on a timeline generally informed by the PDUFA goal date. Any final FDA approval of the NDA for LIQ861 would be subject to the resolution of the pending Hatch-Waxman litigation commenced by United Therapeutics, and also subject to the FDA's consideration of developments that may have occurred since the time of the tentative approval. The FDA may not issue a final approval until the expiration of a 30-month regulatory stay in October 2022 or an earlier judgment unfavorable to United Therapeutics by the court. A new drug product may not be marketed until the date of final approval which is confirmed by the FDA at the time of final submission.

About LIQ861

LIQ861 is an investigational inhaled dry powder formulation of treprostinil designed using Liquidia's PRINT® technology with the goal of enhancing deep-lung delivery using a convenient, palm-sized dry powder inhaler for the treatment of pulmonary arterial hypertension (PAH). PRINT® technology 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 believes LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs. Liquidia has completed an open-label, multi-center phase 3 clinical study of LIQ861 in patients diagnosed with PAH known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of 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 is developing LIQ861, an inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

Contact Information

Media & Investors:

Jason Adair
Vice President, Corporate Development and Strategy
919.328.4400
jason.adair@liquidia.com
