

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): **May 24, 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 May 24, 2021, Liquidia Corporation, a Delaware corporation (the “Company”), issued a press release announcing that Sandoz Treprostinil Injection, a generic form of Remodulin®, is now also available for subcutaneous administration to treat patients diagnosed with pulmonary arterial hypertension. 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 May 24, 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.

May 24, 2021

Liquidia Corporation

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer



Liquidia Announces Generic Treprostinil Injection Now Also Available for Subcutaneous Route of Administration

Sandoz Generic Treprostinil Injection now available for both routes of administration, subcutaneous and intravenous

MORRISVILLE, N.C., May 24, 2021 - Liquidia Corporation (NASDAQ: LQDA) (“Liquidia” or the “Company”) today announced that Sandoz Treprostinil Injection, a generic form of Remodulin®, is now also available for subcutaneous (“SC”) administration to treat patients diagnosed with pulmonary arterial hypertension (“PAH”).

Sandoz Treprostinil Injection was the first fully-substitutable AP rated generic version of Remodulin. Both options for intravenous and SC administration of Sandoz generic Treprostinil Injection are now available at the same specialty pharmacy that dispenses the brand name medicine.

On May 21, 2021, Liquidia PAH’s manufacturing partner, Chengdu Shifeng Medical Technologies LTD (“Chengdu”) began selling the RG 3ml Medication Cartridge, which may be used to supply medications to PAH patients. Liquidia had previously announced the FDA’s clearance of Chengdu’s 510(k) supporting the use of the cartridge with the CADD-MS 3 pump manufactured by Smiths Medical, which has been used for the SC administration of Remodulin for more than 10 years.

Scott Moomaw, Liquidia’s Senior Vice President of Commercial, said: “We are excited to provide a new option in the parenteral use of Treprostinil Injection. Patients who need and depend on subcutaneously administered treprostinil will now, for the first time, have access to a lower cost generic treprostinil. Through our agreement with Sandoz, we will continue to provide the same level of high-touch support and services to our patients, but at a lower cost compared to the branded product.”

Since commercial launch two years ago, Sandoz Treprostinil Injection has only been used for intravenous administration. The cartridges required to operate the CADD-MS 3 pump were not available to patients using generic Treprostinil Injection due to restrictions imposed by other companies. The introduction of the RG 3ml Medication Cartridge has enabled the use of SC administration of Sandoz Treprostinil Injection for the first time.

Keren Haruvi, President, Sandoz Inc. said: “The FDA clearance of a path to bring additional new cartridges required for subcutaneous administration of this medicine means another option for patients who need access to this life-enhancing pulmonary arterial hypertension medicine. Sandoz has a strong track record for manufacturing high-quality generic medicines and supplying them reliably to the patients who need them.”

Remodulin® (treprostinil) is a registered trademark of United Therapeutics Corporation.

CADD-MS® 3 is a registered trademark of Smiths Medical ASD, Inc.

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 Sandoz, Inc., 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 is developing LIQ861, an inhaled dry powder formulation of treprostinil for the treatment of PAH. Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as Sandoz Treprostinil Injection.

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 our response to the Complete Response Letter received in November 2020, the potential for eventual FDA approval of the NDA for LIQ861, 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, 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) 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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