

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): **March 30, 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 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 March 30, 2021, Liquidia Corporation, a Delaware corporation (the “Company”), issued a press release announcing that the U.S. Food and Drug Administration cleared the 510(k) application submitted by Liquidia PAH’s manufacturing partner, Chengdu Shifeng Medical Technologies LTD, for the RG 3ml Medication Cartridge which is indicated for use with the CADD-MS 3 pump. 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
<u>99.1</u>	<u>Press Release of Liquidia Corporation, dated March 30, 2021.</u>
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.

March 30, 2021

Liquidia Corporation

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer



Liquidia Corporation
 419 Davis Drive, Suite 100
 Morrisville, NC 27560
 www.liquidia.com

Liquidia Announces Generic Treprostinil Injection Will Be Available for Subcutaneous Route of Administration

- *Addressable market for generic Treprostinil Injection more than doubles*
- *FDA cleared 510(k) for RG 3ml Medication Cartridge for use with CADD-MS® 3 pump*

RESEARCH TRIANGLE PARK, N.C., March 30, 2021 - Liquidia Corporation (NASDAQ: LQDA) (“Liquidia” or the “Company”) today announced that Treprostinil Injection, a generic form of Remodulin®, will soon be available for subcutaneous (“SC”) administration to treat patients diagnosed with pulmonary arterial hypertension (“PAH”).

On March 26, 2021, the U.S. Food and Drug Administration (“FDA”) cleared the 510(k) application submitted by Liquidia PAH’s manufacturing partner, Chengdu Shifeng Medical Technologies LTD (“Chengdu”) for the RG 3ml Medication Cartridge which is indicated for use with the CADD-MS 3 pump. Manufactured by Smiths Medical, the CADD-MS 3 pump has been used for the SC administration of Remodulin for more than 10 years.

Damian deGoo, Liquidia’s Chief Executive Officer, said: “We are very thankful for the effort and support Chengdu has demonstrated to enable the subcutaneous administration of Treprostinil Injection. We worked hard to overcome this obstacle, and we can now offer generic Treprostinil Injection to more than double the number of PAH patients. We will continue to offer patients, prescribers and payers the same high-touch services and support but at a lower cost compared to the branded product.”

Since commercial launch two years ago, Treprostinil Injection has only been used for intravenous administration. The cartridges required to operate the only subcutaneous pump that could deliver treprostinil injection (CADD-MS 3) were not made available to patients using generic treprostinil injection. The introduction of the RG 3ml Medication Cartridge will enable the launch of SC administration of Treprostinil Injection for the first time.

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 its commercial partner, who holds the Abbreviated New Drug Application (ANDA) with the FDA.



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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 two product candidates: LIQ861, an inhaled dry powder formulation of treprostinil for the treatment of PAH, and LIQ865, an injectable, sustained-release formulation of bupivacaine for the management of local post-operative pain for three to five days after a procedure. Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as 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 anticipate submission contents and timelines, including our potential 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 its *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 risk that the expected benefits and synergies from the Merger Transaction are not realized, 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.



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Liquidia Corporation is headquartered in Research Triangle Park, NC. For more information, please visit www.liquidia.com.

Contact Information

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