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): **January 24, 2020**

LIQUIDIA TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38601**	**20-1926605**
(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	Nasdaq Capital Market

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 January 24, 2020, Liquidia Technologies, Inc. (the "Company") submitted a new drug application, or NDA, to the U.S. Food and Drug Administration for LIQ861, an inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension, or PAH. On January 27, 2020, the Company issued a press release announcing the NDA submission. The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Exhibit
99.1	Press Release of Liquidia Technologies, Inc., dated January 27, 2020.

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.

January 27, 2020

Liquidia Technologies, Inc.

By: /s/ Richard D. Katz, M.D.
Name: Richard D. Katz, M.D.
Title: Chief Financial Officer

Exhibit 99.1

Liquidia Submits New Drug Application for LIQ861 (treprostinil) inhalation powder to U.S. Food and Drug Administration for the Treatment of Pulmonary Arterial Hypertension (PAH)

RESEARCH TRIANGLE PARK, NC – Jan 27, 2020 – Liquidia Technologies, Inc. (Nasdaq:LQDA) ("Liquidia"), a late-stage clinical biopharmaceutical company focused on the development of products using its proprietary PRINT® technology, today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for 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).

The NDA has been submitted under the 505(b)(2) regulatory pathway and includes data from three clinical studies to establish the safety, tolerability and pharmacokinetic profile of LIQ861. The open-label Phase 3 study, known as INSPIRE (Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil) (NCT03399604), included 121 PAH patients who transitioned from stable doses of the reference listed drug or added LIQ861 to no more than two approved non-prostacyclin oral PAH therapies. The company also completed pharmacokinetic studies to establish the bioavailability of LIQ861 relative to the bioavailability of the reference listed drug.

Neal Fowler, Chief Executive Officer of Liquidia, said, "The submission of the NDA for LIQ861 in the U.S. is a significant milestone for our company and our goal to address an important unmet need in the delivery of inhaled therapy for PAH patients. We would like to sincerely thank the patients, their families and the clinical investigators for their participation in the LIQ861 clinical program, and we look forward to working closely with the FDA during the review process."

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 ("DPI") for the treatment of pulmonary arterial hypertension (PAH). PRINT® technology enables development of drug particles that are precise and uniform in size, shape, weight and composition 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

Liquidia is a late-stage clinical biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary PRINT® technology to transform the lives of patients. Currently, Liquidia is focused on the development of two product candidates using its PRINT particle engineering platform: LIQ861 for the treatment of pulmonary arterial hypertension and LIQ865 for the treatment of local post-operative pain. Having been evaluated in a phase 3 clinical trial (INSPIRE), LIQ861 is designed to improve the therapeutic profile of treprostinil with the goal of enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies by using a convenient, palm-sized dry powder inhaler. LIQ865, for which Liquidia has completed two phase 1 clinical trials, is designed to deliver sustained-release particles of bupivacaine, a non-opioid anesthetic, to treat local post-operative pain for three to five days through a single administration.

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 timelines, including the filing of the New Drug Application (NDA) for LIQ861 or FDA acceptance of the NDA submission and potential approval thereof, 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, including but not limited to whether the conditions for the closing of the private placement will be satisfied. These forward-looking statements are subject to a number of risks discussed in our filings with the Securities and Exchange Commission, 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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