

**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 2, 2019**

LIQUIDIA TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-38601

(Commission
File Number)

20-1926605

(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.)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Common stock

Trading Symbol(s)

LQDA

Name of each exchange on which registered

Nasdaq Capital Market

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))

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 x

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. x

Item 2.02 Results of Operations and Financial Condition.

On May 2, 2019, Liquidia Technologies, Inc., a Delaware corporation, issued a press release announcing its financial results for the three months ended March 31, 2019 and also provided a corporate update. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Liquidia Technologies, Inc. Press Release, dated May 2, 2019.

* The information in Item 2.02 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURE

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 2, 2019

Liquidia Technologies, Inc.

By: /s/ Timothy Albury

Name: Timothy Albury

Title: Interim Chief Financial Officer



**Liquidia Technologies Reports First Quarter 2019
Financial Results and Provides Corporate Update**

*Recent Phase 3 Data Highlight Clinical Relevance of LIQ861 in Treating Pulmonary Arterial Hypertension
On Track for Planned New Drug Application (NDA) Submission for LIQ861 in Late 2019
Continued Pipeline Progress Leveraging Proprietary Print® Technology
Management to Host Webcast and Conference Call Today at 8:00 a.m. ET*

RESEARCH TRIANGLE PARK, NC — May 2, 2019 — Liquidia Technologies, Inc. (Nasdaq: LQDA) (“Liquidia”), a late-stage clinical biopharmaceutical company, today reported its financial results for the quarter ended March 31, 2019 and provided a corporate update.

“Liquidia has started the year strong, delivering on our clinical timelines and driving towards an NDA submission for LIQ861, our lead program to treat patients with pulmonary arterial hypertension (PAH),” stated Neal Fowler, Chief Executive Officer of Liquidia. “We met the primary endpoint of safety and tolerability in our pivotal Phase 3 clinical trial (INSPIRE). We have also started to present data on the patient benefits from LIQ861 as demonstrated by favorable functional and patient-reported outcomes measured in exploratory endpoints.

“Based on this data and our interactions with clinicians and patients, we believe LIQ861 is safe, well-tolerated and has utility as a first-line prostacyclin in PAH. If approved, LIQ861 will be the first-to-market inhaled dry powder treprostinil that can be delivered using a convenient, palm-sized device, with the potential to maximize the therapeutic benefits of treprostinil by safely delivering higher doses into the lungs,” concluded Mr. Fowler.

Recent Corporate Highlights

- **Met the primary endpoint of the INSPIRE study by demonstrating safety and tolerability of ‘861 at the two-month timepoint.** LIQ861 was observed to be well-tolerated in 109 patients, 60% of whom were naïve to prostacyclin therapy (Add-Ons) and 40% of whom transitioned from Tyvaso. Both patient groups remained on therapy with 93% of patients completing at least two months of treatment, thereby meeting the study’s primary endpoint. LIQ861 was evaluated at doses exceeding 150 mcg capsule strength with no study-drug related serious adverse events. Most treatment-related adverse events were mild to moderate, consistent with prostacyclin therapy, and observed in the first two weeks of treatment. Liquidia anticipates submitting the NDA for LIQ861 to the U.S. Food and Drug Administration (FDA) in late 2019.
 - **Presented data on LIQ861 from the INSPIRE trial highlighting safety and tolerability along with preliminary data on functional and patient outcomes.** The presentation at the 39th International Society for Heart & Lung Transplantation (ISHLT) Meeting in April 2019 provided detailed results by patient group on the adverse event profile, duration of treatment and two of the exploratory endpoints. Specifically, at the two-month timepoint, the functional measure of median “six-minute walk distance” was maintained or improved in both the Add-On and Tyvaso transition groups. Additionally, patients in both groups reported physical and emotional improvements in quality of life, as measured by the Minnesota Living with Heart Failure Questionnaire.
 - **Initiated Phase 2-enabling toxicology studies for LIQ865 in the first quarter of 2019.** Our second product candidate, LIQ865, is an injectable, non-opioid, sustained-release formulation of bupivacaine for the management of local post-operative pain.
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- **Raised \$34.5 million in additional capital through a public offering in the first quarter of 2019.** We completed an offering of 3,000,000 shares of our common stock for gross proceeds of \$34.5 million, or approximately \$31.7 million, net of underwriting discounts, commissions and offering expenses.

Anticipated Upcoming Milestones

- Report LIQ861 bioavailability and pharmacokinetic properties of treprostinil in the second quarter of 2019;
- Initiate an additional clinical trial in Europe that explores the effects of LIQ861 on acute and chronic hemodynamic measurements and right heart function in PAH patients to help inform the medical community and support clinical development;
- Submit an NDA to the FDA for LIQ861 in late 2019;
- Present longitudinal data on LIQ861 at key medical conferences, including at the American Thoracic Society International Conference May 17-22, Dallas, TX; and
- Complete toxicology studies that support LIQ865 as a Phase 2-ready program by the end of the year.

First Quarter 2019 Financial Highlights

- **Revenues:** We reported no revenue for the quarter ended March 31, 2019, compared to \$0.9 million for the quarter ended March 31, 2018. Our revenue has been primarily derived from collaborating and licensing our proprietary PRINT® technology to pharmaceutical companies. There were no research and development services performed for other pharmaceutical companies during the quarter ended March 31, 2019 as we prioritize the development of our own pharmaceutical products.
- **Research and Development (R&D):** R&D expenses were \$10.7 million for the quarter ended March 31, 2019, compared to \$7.6 million for the quarter ended March 31, 2018. The increase in R&D expenses was primarily due to our ongoing INSPIRE Phase 3 clinical trial for LIQ861, which commenced in December 2017.
- **General and Administrative (G&A):** G&A expenses were \$3.0 million for the quarter ended March 31, 2019, compared to \$2.1 million for the quarter ended March 31, 2018. The increase was primarily due to employee-related expenditures, including stock-based compensation, and public company costs, partially offset by a decrease in professional fees.
- **Interest Expense:** Interest expense was \$0.2 million for the three months ended March 31, 2019, compared to \$17.9 million for the three months ended March 31, 2018. The decrease was primarily due to lower levels of debt during the three months ended March 31, 2019 as a result of the conversion of convertible notes into shares of Series D preferred stock in February 2018.
- **Net Loss:** The net loss for the first quarter of 2019 was \$13.8 million, compared to \$27.5 million for the quarter ended March 31, 2018. The change was primarily due to a decrease in revenues and an increase in R&D and G&A expenses, offset by lower interest expense.
- **Cash Position:** Cash totaled \$60.8 million as of March 31, 2019.
- **Shares Outstanding:** There were 18,637,012 shares of common stock outstanding as of March 31, 2019.

Webcast and Conference Call

Liquidia's management team will host a webcast and conference call at 8:00 a.m. ET today to discuss the financial results and provide a corporate update. The live call may be accessed by dialing 1-877-707-8711

(domestic) and 1-857-270-6219 (international) and entering the conference code: 5995454. A live and archived webcast of the call will be available on the Events & Presentations page of Liquidia's website.

About Liquidia Technologies

Liquidia Technologies 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. Being evaluated in a Phase 3 clinical trial (INSPIRE), LIQ861 is designed to improve the therapeutic profile of treprostinil by enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies by using a convenient, palm-sized, disposable 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. For more information visit Liquidia's website at www.liquidia.com.

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 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 an NDA for LIQ861, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The words "anticipate," "believe," "continue," "estimate," "expect," "intend," "may," "will" 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 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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-Financial Tables Follow-

Liquidia Technologies, Inc.
Balance Sheets

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
Assets		
Current assets:		
Cash	\$ 60,809,779	\$ 39,534,985
Accounts receivable	10,486	272,557
Prepaid expenses and other current assets	302,945	219,057
Total current assets	<u>61,123,210</u>	<u>40,026,599</u>
Property, plant and equipment, net	7,525,450	8,130,708
Operating lease right-of-use assets, net	3,909,054	—
Prepaid expenses and other assets	1,162,199	1,260,951
Total assets	<u>\$ 73,719,913</u>	<u>\$ 49,418,258</u>
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 5,987,577	\$ 3,235,949
Accrued expenses	1,749,748	1,459,182
Accrued compensation	944,192	2,515,519
Deferred rent	—	268,599
Current portion of operating lease liabilities	477,008	—
Current portion of finance lease liabilities	899,512	452,703
Current portion of long-term debt	924,505	316,906
Total current liabilities	<u>10,982,542</u>	<u>8,248,858</u>
Long-term operating lease liabilities	6,102,448	—
Long-term finance lease liabilities	1,349,180	376,082
Long-term deferred rent	—	2,406,084
Long-term deferred revenue	8,071,920	8,071,920
Long-term debt	9,896,576	11,627,643
Total liabilities	<u>36,402,666</u>	<u>30,730,587</u>
Stockholders' equity (deficit):		
Common stock — \$0.001 par value, 40,000,000 and 40,000,000 shares authorized as of March 31, 2019 and December 31, 2018, respectively, 18,637,012 and 15,519,469 issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	18,637	15,520
Additional paid-in capital	218,721,394	185,726,048
Accumulated deficit	(181,422,784)	(167,053,897)
Total stockholders' equity (deficit)	<u>37,317,247</u>	<u>18,687,671</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 73,719,913</u>	<u>\$ 49,418,258</u>

Liquidia Technologies, Inc.
Statements of Operations and Comprehensive Loss

	Three Months Ended	
	March 31,	
	2019	2018
Revenues	\$ —	\$ 925,970
Costs and expenses:		
Cost of sales	—	27,049
Research and development	10,664,302	7,626,701
General and administrative	3,021,581	2,149,725
Total costs and expenses	13,685,883	9,803,475
Loss from operations	(13,685,883)	(8,877,505)
Other income (expense):		
Interest income	137,785	—
Interest expense	(218,691)	(17,876,795)
Derivative and warrant fair value adjustments	—	(753,887)
Total other income (expense), net	(80,906)	(18,630,682)
Net loss	(13,766,789)	(27,508,187)
Other comprehensive loss	—	—
Comprehensive loss	\$ (13,766,789)	\$ (27,508,187)
Net loss per common share:		
Basic	\$ (0.86)	\$ (44.33)
Diluted	(0.87)	(44.33)
Weighted average common shares outstanding:		
Basic	16,037,767	620,530
Diluted	15,892,619	620,530

Liquidia Technologies, Inc.
Statements of Cash Flows

	Three Months Ended March 31,	
	2019	2018
Operating activities		
Net loss	\$ (13,766,789)	\$ (27,508,187)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	886,985	341,314
Depreciation and amortization	609,034	324,854
Amortization of discount on long-term debt and convertible notes	—	17,550,541
Non-cash interest expense	16,559	227,186
Warrant fair value adjustment	—	753,887
Non-cash rent (income) expense	—	(51,465)
Changes in operating assets and liabilities:		
Accounts receivable	262,071	1,004,778
Prepaid expenses and other current assets	(83,888)	(178,326)
Other non-current assets	481,177	(5,433)
Accounts payable	2,867,151	(566,020)
Accrued expenses	190,672	(404,408)
Accrued compensation	(1,571,327)	(1,207,382)
Deferred revenue	—	(281,600)
Net cash used in operating activities	<u>(10,108,355)</u>	<u>(10,000,261)</u>
Investing activities		
Purchases of property, plant and equipment	(245,319)	(257,067)
Net cash used in investing activities	<u>(245,319)</u>	<u>(257,067)</u>
Financing activities		
Principal payments on finance leases	(220,933)	(151,430)
Refund of principal payments on long-term debt	—	588,889
Principal payments on long-term debt	—	(912,011)
Payments for debt issuance costs	—	(392,000)
Proceeds from issuance of Series D preferred stock, net of issuance costs	—	25,206,742
Proceeds from public offering of common stock, net of underwriting fees and commissions	32,047,576	—
Payments for deferred offering costs	(262,077)	(58,734)
Proceeds from exercise of stock options and warrants	63,902	150,689
Net cash provided by (used in) financing activities	<u>31,628,468</u>	<u>24,432,145</u>
Net increase (decrease) in cash	21,274,794	14,174,817
Cash, beginning of period	39,534,985	3,418,979
Cash, end of period	<u>\$ 60,809,779</u>	<u>\$ 17,593,796</u>