
**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): **October 30, 2018**

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.)

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 October 31, 2018, Liquidia Technologies, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the three months ended September 30, 2018. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 8.01 Other Events.

On October 30, 2018, the Board of Directors of the Company (the “Board”) appointed Dr. Stephen Bloch as Chairman of the Board, effective immediately, following Dr. Seth Rudnick’s request to step down as Chairman of the Board. Dr. Rudnick will continue to serve as a member of the Board and as a member of the Company’s Compensation Committee and Nominating and Corporate Governance Committee and Chairman of the Company’s Research and Development Committee.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Liquidia Technologies, Inc. Press Release, dated October 31, 2018.

* 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.

October 31, 2018

Liquidia Technologies, Inc.

By: /s/ Kevin Gordon

Name: Kevin Gordon

Title: President and Chief Financial Officer



Liquidia Technologies Reports Third Quarter 2018 Financial Results and Provides Corporate Update

- Completed enrollment of the safety portion of our Ph3 LIQ861 (INSPIRE) clinical trial
- Two-week safety Ph3 LIQ861 data readout anticipated in the first quarter of 2019
 - Dr. Stephen Bloch appointed as Chairman of the Board
 - Management to host webcast and conference call today at 8 a.m. ET

RESEARCH TRIANGLE PARK, NC — October 31, 2018 — Liquidia Technologies, Inc. (Nasdaq:LQDA) (“Liquidia”), a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using its proprietary PRINT® technology to transform the lives of patients, today reports its financial results for the quarter ended September 30, 2018 and provides a corporate update.

“We have made significant progress in the second half of 2018 with the closing of our IPO in July and the recent completion of enrollment for the safety portion of our pivotal Phase 3 clinical trial, INSPIRE, evaluating LIQ861 for the treatment of pulmonary arterial hypertension. Based on feedback from the U.S. FDA, we believe that this trial will support the NDA filing for LIQ861, which we are targeting to submit in late 2019,” stated Neal Fowler, Chief Executive Officer of Liquidia. “We are keenly focused on execution and we believe we are well-positioned to meet important milestones, including the anticipated readout of the two-week safety data for LIQ861 in the first quarter of 2019.”

“With today’s news, we also announced the appointment of Dr. Bloch as Chairman of the Board. Dr. Bloch has been on the board of Liquidia since 2009 and as such, is well-prepared to guide the company through its next stage of growth,” added Neal Fowler. “Dr. Seth Rudnick’s contributions over the last 10 years have been instrumental to the evolution of Liquidia and I am pleased that he will continue to serve as a valued member of Liquidia’s board. I want to thank them both for their support and guidance over the last several years.”

Corporate Highlights

- **Completed enrollment of the safety portion of our single, open-label Phase 3 clinical trial (INSPIRE) evaluating LIQ861, an inhaled dry powder formulation of treprostinil, for the treatment of pulmonary arterial hypertension (PAH).** As of October 24, 2018, 109 patients have enrolled in our INSPIRE trial and Liquidia has completed enrollment for the safety portion of the trial. We are currently focusing our efforts on completing patient enrollment in our one-directional crossover sub-study to compare bioavailability and pharmacokinetics (PK) of treprostinil as the patients transition from Tyvaso® to LIQ861. The primary objective of the INSPIRE study is to evaluate the long-term safety and tolerability of LIQ861. Of the total enrolled patient population, as of October 24, 2018, 104 patients have received at least two weeks of LIQ861. We expect to report two-week safety data in the first quarter of 2019 followed by PK results anticipated in the second quarter of 2019. We are targeting a new drug application (NDA) submission to the U.S. Food and Drug Administration (FDA) in late 2019.
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- **Completed initial public offering.** In July and August, Liquidia closed an initial public offering (IPO) of 4,833,099 shares of common stock at a public offering price of \$11.00 per share, including 287,644 shares sold pursuant to the partial exercise of the underwriters' over-allotment option to purchase additional shares. Liquidia received \$49.4 million in net proceeds, which included underwriting discounts and commissions, but prior to the payment of other offering expenses.
- **Closed on new credit facility and repaid certain existing debt.** On October 26, 2018, Liquidia and Pacific Western Bank (PWB) entered into an Amended and Restated Loan and Security Agreement (the "A&R LSA") that resulted in the extinguishment of Liquidia's \$8.0 million in outstanding indebtedness under the Loan and Security Agreement with PWB and the repayment in full of the promissory note issued to the University of North Carolina at Chapel Hill in the amount of \$1.8 million. The A&R LSA provides for an initial tranche of \$11.0 million received by Liquidia at closing and a second tranche of up to \$5.0 million available to be drawn through June 30, 2019, subject to the achievement of certain clinical milestones. The A&R LSA provides for interest-only payments through December 31, 2019, bears interest at the greater of the prime rate or 5% and has a four-year term.
- **Appointed Dr. Stephen Bloch as Chairman of the Board.** Dr. Bloch has been appointed Chairman of the Board, effective immediately, following Dr. Seth Rudnick's request to step down as Chairman of the Board. Dr. Rudnick will continue to serve as a member of the Board.

Anticipated Upcoming Milestones

- Present Phase 1a safety, PK and pharmacodynamic results in healthy volunteers for our second product candidate, LIQ865, at the American Society of Regional Anesthesia and Pain Medicine, being held November 15-17 in San Antonio, TX
- Initiate Phase 2-enabling toxicology studies for LIQ865, currently being evaluated for the treatment of local post-operative pain, in the fourth quarter of 2018
- Report LIQ861 Phase 3 two-week safety data from the INSPIRE study in the first quarter of 2019
- Enroll the first patient in the first quarter of 2019 in an additional clinical trial that explores the effects of LIQ861 on acute and chronic hemodynamic measurements and right heart function in PAH patients; this clinical trial is not required by the FDA
- Report LIQ861 Phase 3 PK results from our one-directional crossover sub-study in the second quarter of 2019
- NDA submission to the FDA for LIQ861 in late 2019

Third Quarter 2018 Financial Highlights

- **Revenues:** Revenues for the third quarter of 2018 were \$0.2 million, compared to \$1.8 million for the third quarter of 2017. Currently, our revenue is primarily derived from collaborating and licensing our proprietary PRINT[®] technology to pharmaceutical companies. The decrease primarily reflects lower research and development services performed as we prioritize developing our own pharmaceutical products.
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- **Research and Development (R&D):** R&D expenses for the third quarter of 2018 were \$7.2 million, compared to \$6.5 million for the third quarter of 2017. The increase in R&D expenses was primarily due to our ongoing Phase 3 clinical trial of LIQ861 (INSPIRE), which commenced in late December 2017.
- **General and Administrative (G&A):** G&A expenses for the third quarter of 2018 were \$2.3 million, compared to \$3.0 million for the third quarter of 2017. The decrease in G&A expenses was primarily due to costs of an abandoned equity offering being expensed during the third quarter of 2017.
- **Net Loss:** A net loss of \$9.7 million for the third quarter of 2018 was reported, compared to \$19.2 million for the third quarter of 2017. The decrease was due to several factors including the decrease in G&A expenses, the decrease in interest expense of \$3.5 million, and the decrease in derivative and warrant fair value adjustments (expense) of \$7.4 million, partially offset by the decrease in revenues and the increase in R&D expenses.
- **Cash Position:** As of September 30, 2018, we had \$47.5 million in cash.

Webcast and Conference Call

Liquidia's management team will host a webcast and conference call at 8 a.m. ET today to provide a corporate update for the third quarter of 2018. The live call may be accessed by dialing 1-877-707-8711 (domestic) and 1-857-270-6219 (international), and entering the conference code: 1695584. A live and archived webcast of the call will be available on the Events & Presentations page of our website.

About Liquidia Technologies

Liquidia Technologies is a late-stage clinical biopharmaceutical company focused on the development and commercialization of human 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, disposable dry powder inhaler. LIQ865, for which Liquidia has completed a U.S. Phase 1b clinical trial, 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. In addition to developing its own product candidates, Liquidia collaborates with leading pharmaceutical companies to develop their own product candidates across a wide range of therapeutic areas, molecule types and routes of administration, leveraging Liquidia's PRINT[®] technology. For more information visit our 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 (including the funding therefor, anticipated patient enrollment, safety 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:

Jennifer Almond

Director, Investor Relations & Corporate Communications

919.328.4389

IR@liquidia.com

Financial Statements:

Liquidia Technologies, Inc.
Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	\$ 169,730	\$ 1,820,848	\$ 2,138,579	\$ 5,442,020
Costs and expenses:				
Cost of sales	—	79,940	121,391	239,819
Research and development	7,156,618	6,532,940	20,701,022	17,966,244
General and administrative	2,283,936	3,004,612	6,424,892	8,079,304
Total costs and expenses	9,440,554	9,617,492	27,247,305	26,285,367
Loss from operations	(9,270,824)	(7,796,644)	(25,108,726)	(20,843,347)
Other income (expense):				
Interest income	128,120	—	139,965	268
Interest expense	(636,573)	(4,155,714)	(18,759,078)	(8,323,924)
Derivative and warrant fair value adjustments	106,265	(7,284,256)	277,715	(8,197,356)
Total other income (expense), net	(402,188)	(11,439,970)	(18,341,398)	(16,521,012)
Net loss	(9,673,012)	(19,236,614)	(43,450,124)	(37,364,359)
Other comprehensive loss	—	—	—	—
Comprehensive loss	\$ (9,673,012)	\$ (19,236,614)	\$ (43,450,124)	\$ (37,364,359)
Net loss per common share:				
Basic	\$ (0.83)	\$ (34.91)	\$ (10.16)	\$ (68.54)
Diluted	(0.84)	(34.91)	(10.27)	(68.54)
Weighted average common shares outstanding:				
Basic	11,606,489	551,097	4,277,554	545,132
Diluted	11,464,459	551,097	4,229,691	545,132

Liquidia Technologies, Inc.
Balance Sheet Data
(unaudited)

	September 30, 2018	December 31, 2017
Cash	\$ 47,515,790	\$ 3,418,979
Working capital	\$ 40,204,309	\$ (25,039,296)
Total assets	\$ 57,230,383	\$ 14,843,602
Long-term debt and capital leases	\$ 11,975,705	\$ 22,145,554
Total stockholders' equity (deficit)	\$ 27,855,536	\$ (33,692,236)