

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 11, 2020**

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))

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 2.02 Results of Operations and Financial Condition.

On March 11, 2020, Liquidia Technologies, Inc., a Delaware corporation, issued a press release announcing its financial results for the three months and year ended December 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)

**Exhibit
No.**

Exhibit

[99.1 Press Release of Liquidia Technologies, Inc., dated March 11, 2020.](#)

* 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.

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 11, 2020

Liquidia Technologies, Inc.

By: /s/ Richard D. Katz, M.D.

Name: Richard D. Katz, M.D.

Title: Chief Financial Officer



**Liquidia Reports Fourth Quarter and Full-Year 2019
Financial Results and Provides Corporate Update**

*Submitted New Drug Application (NDA) for LIQ861 in January 2020
Management to Host Webcast and Conference Call Today at 8:00 a.m. ET*

RESEARCH TRIANGLE PARK, NC, March 11, 2020 – Liquidia Technologies, Inc. (Nasdaq: LQDA) (“Liquidia” or the “Company”), a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing its proprietary PRINT® technology, today reported financial results for the fourth quarter and full-year ended December 31, 2019, and provided a corporate update.

“We are pleased to have submitted our NDA for LIQ861, an important milestone in our continued evolution towards becoming a fully-integrated, commercial biopharmaceutical company. We were also pleased to raise additional equity capital through a private placement and ATM sales during the fourth quarter. We look forward to continuing to advance our pipeline based upon our PRINT technology to bring meaningful benefits to patients,” stated Neal Fowler, Liquidia’s Chief Executive Officer.

Corporate Update

· **Completed INSPIRE clinical trial and submitted NDA for LIQ861**

Based upon the favorable results of the pivotal Phase 3 INSPIRE trial and pharmacokinetic studies in healthy volunteers, the Company submitted an NDA for LIQ861 to the U.S. Food and Drug Administration (FDA) on January 24, 2020 under the 505(b)(2) regulatory pathway. As previously reported, the safety and tolerability profile of LIQ861, the primary endpoint of the INSPIRE trial, was observed to be favorable. Also, as previously reported, a high rate of sustained treatment benefit across certain exploratory endpoints was observed, including the maintenance or improvement of New York Heart Association (NYHA) functional class in more than 90% of all patients enrolled in the trial who completed two months of treatment. As recently reported at the 14th Annual Pulmonary Vascular Research Institute (PVRI) Conference, results of a pharmacokinetic study in healthy volunteers have also demonstrated that treprostinil exposure from a 79.5 mcg dose of LIQ861 is comparable to that of nine breaths of Tyvaso, the reference listed drug.

· **Continuing clinical studies to evaluate long-term safety, tolerability and hemodynamic effects of LIQ861**

Most patients from INSPIRE continue to receive LIQ861 in the extension study, including several patients with at least 18 months of treatment. The safety and tolerability profile of LIQ861 in this extension study remains consistent with the results seen in the INSPIRE trial. In addition, a clinical study has been initiated in patients with pulmonary arterial hypertension at certain investigational sites in Europe to characterize the hemodynamic dose-response relationship to LIQ861.



· **Advancing the Company's pipeline to leverage the demonstrated advantages of PRINT technology**

The Company continues to conduct Phase 2-enabling toxicology studies for LIQ865, a proprietary formulation of bupivacaine, a non-opioid anesthetic, targeting local post-operative pain relief for three to five days following a single administration. Results of the ongoing toxicology work are expected during the second half of 2020, and, subject to the availability of capital, the Company intends to determine next steps with regard to the clinical development program for LIQ865 following a review of all toxicology results. Additionally, the Company has recently initiated a pre-clinical program to develop an inhaled product leveraging the benefits of PRINT technology to engineer particles with precise, uniform, aerodynamic size and shape for deep lung delivery.

· **Completion of private placement and ATM sales**

In December 2019, the Company completed a private placement of common stock, resulting in gross proceeds of \$22.4 million. Additionally, the Company raised gross proceeds of \$8.4 million through the sale of common stock pursuant to the Company's "at-the-market" (ATM) equity issuance facility during the fourth quarter.

Fourth Quarter 2019 Financial Results

Revenues for the three months ended December 31, 2019 were \$0, compared to \$0.6 million for the three months ended December 31, 2018. The decrease in revenues was due to the full recognition during the second quarter of 2019 of \$8.1 million of deferred revenue from the Company's collaboration with GlaxoSmithKline plc (GSK) following the Company's determination that the earnings process related to the collaboration had been completed.

Research and development expenses for the fourth quarter of 2019 increased to \$8.2 million from \$8.0 million for the fourth quarter of 2018, primarily due to an increase in non-clinical expenses related to the LIQ865 program.

General and administrative expenses for the fourth quarter of 2019 increased to \$5.8 million from \$2.3 million for the fourth quarter of 2018, primarily due to increased commercial spending related to the LIQ861 program.



Loss from operations for the fourth quarter of 2019 increased to \$14.0 million from \$9.8 million for the fourth quarter of 2018, primarily due to an increase in commercial expenses related to the LIQ861 program as well as an increase in non-clinical expenses related to the LIQ865 program.

Interest income was \$0.1 million for the fourth quarter of 2019, compared with \$0.2 million for the fourth quarter of 2018, reflecting a lower average cash balance during the fourth quarter of 2019.

Interest expense was \$0.6 million for the fourth quarter of 2019, compared with \$0.2 million for the fourth quarter of 2018, reflecting a higher level of debt outstanding during the fourth quarter of 2019.

Net loss for the fourth quarter of 2019 increased to \$14.5 million from \$9.7 million for the fourth quarter of 2018, primarily due to an increase in commercial expenses related to the LIQ861 program as well as an increase in non-clinical expenses related to the LIQ865 program.

Cash and cash equivalents totaled \$55.8 million at December 31, 2019 and reflect the completion of the Company's private placement and ATM sales that resulted in gross proceeds of \$22.4 million and \$8.4 million (net proceeds of \$21.1 million and \$8.2 million), respectively, during the fourth quarter of 2019. There were 28.2 million shares outstanding as of December 31, 2019.

Full Year 2019 Financial Results

Revenues for the year ended December 31, 2019 were \$8.1 million, compared to \$2.7 million for the year ended December 31, 2018. The increase in revenues was due to the full recognition in the second quarter of 2019 of \$8.1 million of deferred revenue from the Company's collaboration with GSK following the Company's determination that the earnings process related to the collaboration had been completed.

Cost of sales for 2019 increased to \$0.8 million from \$0.1 million for 2018 due to the amortization of the deferred sublicense payments that were previously paid to the University of North Carolina at Chapel Hill related to the Company's collaboration with GSK following the Company's determination that the earnings process related to the collaboration has been completed.

Research and development (R&D) expenses for 2019 increased to \$40.5 million from \$28.7 million for 2018, primarily due to an increase in expenses related to the LIQ861 clinical program as well as an increase in non-clinical expenses related to the LIQ865 program.

General and administrative expenses for 2019 increased to \$13.6 million from \$8.8 million for 2018, primarily due to increased commercial spending related to the LIQ861 program.



Loss from operations for 2019 increased to \$46.8 million from \$34.9 million for 2018, primarily due to an increase in expenses related to the LIQ861 program, including both R&D and commercial expenses, and an increase in non-clinical expenses related to the LIQ865 program, partially offset by the increase in revenues noted above.

Interest income was \$0.6 million for 2019, compared with \$0.3 million for 2018, reflecting a higher average cash balance in 2019.

Interest expense was \$1.4 million for 2019, compared with \$19.0 million for 2018, reflecting a lower level of debt during the year 2019 and the conversion of \$27.4 million of convertible notes into shares of Series D preferred stock in February 2018.

Net loss for 2019 decreased to \$47.6 million from \$53.1 million for 2018, primarily due to a decrease in interest expense and an increase in revenues, which were partially offset by an increase in expenses related to the LIQ861 program, including both R&D and commercial expenses, as well as an increase in non-clinical expenses related to the LIQ865 program.

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: 6994366. A live and archived webcast of the call will be available on the Events & Presentations page of Liquidia's website.

About Liquidia

Liquidia is a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing 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. 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. In January 2020, Liquidia submitted a New Drug Application (NDA) for LIQ861 to the U.S. Food and Drug Administration (FDA). 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.

** Tyvaso® is a registered trademark of United Therapeutics Corporation.*



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 U.S. Food and Drug Administration (FDA) acceptance of the New Drug Application (NDA) submission for LIQ861 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. 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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash	\$ 55,796,378	\$ 39,534,985
Accounts receivable, net	—	272,557
Prepaid expenses and other current assets	590,251	219,057
Total current assets	56,386,629	40,026,599
Property, plant and equipment, net	9,253,965	8,130,708
Operating lease right-of-use assets, net	2,823,430	—
Prepaid expenses and other assets	378,043	1,260,951
Total assets	\$ 68,842,067	\$ 49,418,258
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,498,043	\$ 3,235,949
Accrued compensation	3,164,687	2,515,519
Accrued stock offering expenses	1,289,413	—
Other accrued expenses	1,525,919	1,459,182
Deferred rent	—	268,599
Current portion of operating lease liabilities	566,390	—
Current portion of finance lease liabilities	1,244,229	452,703
Current portion of long-term debt	5,585,637	316,906
Total current liabilities	16,874,318	8,248,858
Long-term operating lease liabilities	5,670,971	—
Long-term finance lease liabilities	1,056,747	376,082
Long-term deferred rent	—	2,406,084
Long-term deferred revenue	—	8,071,920
Long-term debt	10,292,484	11,627,643
Total liabilities	33,894,520	30,730,587
Commitments and contingencies		
Stockholders' equity:		
Common stock — \$0.001 par value, 40,000,000 shares authorized as of December 31, 2019 and December 31, 2018, 28,231,267 and 15,519,469 issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	28,231	15,520
Additional paid-in capital	250,158,766	185,726,048
Accumulated deficit	(215,239,450)	(167,053,897)
Total stockholders' equity	34,947,547	18,687,671
Total liabilities and stockholders' equity	\$ 68,842,067	\$ 49,418,258



Liquidia Technologies, Inc.
Statements of Operations and Comprehensive Loss

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Revenues	\$ —	\$ 568,402	\$ 8,072,120	\$ 2,706,981
Costs and expenses:				
Cost of sales	—	—	807,192	121,391
Research and development	8,160,904	7,998,554	40,491,358	28,699,576
General and administrative	5,789,199	2,329,196	13,597,119	8,754,088
Total costs and expenses	13,950,103	10,327,750	54,895,669	37,575,055
Loss from operations	(13,950,103)	(9,759,348)	(46,823,549)	(34,868,074)
Other income (expense):				
Interest income	93,855	165,016	613,716	304,981
Interest expense	(636,193)	(229,098)	(1,373,622)	(18,988,176)
Gain on early extinguishment of long-term debt	—	137,695	—	137,695
Derivative and warrant fair value adjustments	—	—	—	277,715
Total other income (expense), net	(542,338)	73,613	(759,906)	(18,267,785)
Net income (loss)	(14,492,441)	(9,685,735)	(47,583,455)	(53,135,859)
Other comprehensive income (loss)	\$ —	\$ —	\$ —	\$ —
Comprehensive income (loss)	(14,492,441)	(9,685,735)	(47,583,455)	(53,135,859)
Net income (loss) per common share:				
Basic	\$ (0.71)	\$ (0.62)	\$ (2.57)	\$ (7.42)
Diluted	(0.72)	(0.62)	(2.59)	(7.51)
Weighted average common shares outstanding:				
Basic	20,357,315	15,692,205	18,482,455	7,163,304
Diluted	20,251,041	15,498,802	18,371,083	7,078,757