

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 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 May 11, 2020, Liquidia Technologies, Inc., a Delaware corporation, issued a press release announcing its financial results for the three months ended March 31, 2020 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 May 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.

May 11, 2020

Liquidia Technologies, Inc.

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

Name: Richard D. Katz, M.D.

Title: Chief Financial Officer



Liquidia Reports First Quarter 2020 Financial Results and Provides Corporate Update

*Received FDA Acceptance of LIQ861 NDA for Review
Reported Final Safety and Tolerability Results for LIQ861 Inspire Trial
Management to Host Webcast and Conference Call Today at 4:30p.m. ET*

RESEARCH TRIANGLE PARK, NC – May 11, 2020 – Liquidia Technologies, Inc. (Nasdaq:LQDA), a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products using its proprietary PRINT® technology, today reported financial results for the first quarter ended March 31, 2020 and provided a corporate update.

“FDA acceptance of the LIQ861 NDA for review is a significant milestone and a testament to the progress we have made as a company, including our ability to harness the power of our PRINT technology to advance our product candidates through clinical development,” said Neal Fowler, Chief Executive Officer of Liquidia. “If approved, LIQ861 represents an important step forward for patients in need of additional treatment options and will serve as the gateway for Liquidia to achieve its goal of becoming a fully integrated, commercial organization. I am proud of the progress we have made as a company on all fronts, even in the face of a global crisis, and remain confident in our approach toward our 2020 objectives.”

Corporate Update

- **Received FDA acceptance of LIQ861 NDA for regulatory review**
In January 2020, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for LIQ861, the Company’s lead product candidate, as a potential treatment for patients with pulmonary arterial hypertension (PAH). In April 2020, the FDA accepted the NDA for review and provided a Prescription Drug User Fee Act (PDUFA) goal date of November 24, 2020. Liquidia is developing LIQ861 under the 505(b)(2) regulatory pathway with Tyvaso® as the reference listed drug, which allows Liquidia to rely in part on the FDA’s previous findings of efficacy and safety of Tyvaso and the active ingredient tadalafil, which has been approved in four different products administered through the oral, inhaled and continuous infusion (parenteral) routes.
 - **Reported final LIQ861 safety and tolerability results from pivotal INSPIRE trial**
In April 2020, the Company reported final safety and tolerability results from the two-month endpoint of the open-label phase 3 trial, INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Tadalafil, for LIQ861. Of the 121 PAH patients, 113, or 93 percent, completed their two-month visit. The most common reported treatment-emergent adverse events (TEAEs) (reported in ≥ four percent) were cough (42 percent), headache (26 percent), throat irritation (16 percent), dizziness (11 percent), diarrhea (9 percent), chest discomfort (8 percent), nausea (7 percent), dyspnea (5 percent), flushing (5 percent) and oropharyngeal pain (4 percent). These final primary endpoint findings are consistent with the safety and tolerability results previously reported.
 - **Initiated *inter partes* review of two patents with Patent Trial and Appeal Board**
In late March 2020, Liquidia filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office (USPTO). One petition is for *inter partes* review of U.S. Patent No. 9,604,901, and a second petition is for *inter partes* review of U.S. Patent No. 9,593,066, both of which are owned by United Therapeutics Corporation, or United Therapeutics, are entitled “Process to Prepare Tadalafil, the Active Ingredient in Remodulin®” and are related to the LIQ861 505(b)(2) NDA submission. A determination by the PTAB to institute the petitions is expected before the end of the third quarter of 2020, and a final written decision determining the validity of the challenged claims of the ‘066 patent and the ‘901 patent, if the petitions are instituted by the PTAB, is expected within 12 months from institution.
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First Quarter 2020 Financial Results

Research and development expenses were \$10.8 million for the three months ended March 31, 2020, which approximated the amount recognized of \$10.7 million for the three months ended March 31, 2019. Research and development expenses for consulting costs increased by \$1.2 million during the first quarter of 2020 compared with the first quarter of 2019. This increase was primarily offset by a decrease of \$0.8 million from the reclassification of costs for efforts to prepare for potential commercialization and certain insurance costs to general and administrative expenses during the first quarter of 2020 compared with the first quarter of 2019.

General and administrative expenses were \$3.8 million for the first quarter of 2020, compared with \$3.0 million for the first quarter of 2019. The increase of \$0.8 million, or 26.5 percent, was primarily due to a reclassification of costs for efforts to prepare for potential commercialization and certain insurance costs to general and administrative expenses from research and development expenses during the first quarter of 2020 compared with the first quarter of 2019.

Interest income was \$0.1 million for the first quarter of 2020, which approximated interest income of \$0.1 million during the first quarter of 2019.

Interest expense was \$0.3 million for the first quarter of 2020, compared with \$0.2 million for the first quarter of 2019, primarily due to higher levels of debt during the first quarter of 2020 as compared with the first quarter of 2019.

Net loss was \$14.8 million for the first quarter of 2020, compared with \$13.8 million for the first quarter of 2019. The increase of \$1.0 million, or 7.4 percent, was primarily due to an increase in research and development consulting costs during the first quarter of 2020 compared with the first quarter of 2019.

Cash and cash equivalents totaled \$40.1 million as of March 31, 2020. There were 28.4 million shares outstanding as of March 31, 2020.

Webcast and Conference Call

The Liquidia Management Team will host a webcast and conference call at 4:30 p.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: **1438598**. 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 using its proprietary PRINT® technology to transform the lives of patients. PRINT is a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. Currently, Liquidia is focused on the development of two product candidates for which it holds worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension (PAH) and LIQ865 for the treatment of local post-operative pain. Liquidia is headquartered in Research Triangle Park, NC. For more information, please visit 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 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 potential U.S. Food and Drug Administration (FDA) approval of the New Drug Application (NDA) for LIQ861, the timeline related to our two petitions for *inter partes* review with the Patent Trial and Appeal Board, 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, including 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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-Financial Tables Follow-



Liquidia Technologies, Inc.
Balance Sheets

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash	\$ 40,127,919	\$ 55,796,378
Prepaid expenses and other current assets	884,923	590,251
Total current assets	41,012,842	56,386,629
Property, plant and equipment, net	8,599,985	9,253,965
Operating lease right-of-use assets, net	2,785,238	2,823,430
Prepaid expenses and other assets	381,043	378,043
Total assets	<u>\$ 52,779,108</u>	<u>\$ 68,842,067</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,530,526	\$ 3,498,043
Accrued compensation	1,428,270	3,164,687
Accrued stock offering expenses	—	1,289,413
Other accrued expenses	1,463,772	1,525,919
Current portion of operating lease liabilities	589,931	566,390
Current portion of finance lease liabilities	1,484,882	1,244,229
Current portion of long-term debt	5,585,636	5,585,637
Total current liabilities	16,083,017	16,874,318
Long-term operating lease liabilities	5,512,485	5,670,971
Long-term finance lease liabilities	511,809	1,056,747
Long-term debt	8,899,877	10,292,484
Total liabilities	31,007,188	33,894,520
Commitments and contingencies		
Stockholders' equity:		
Common stock — \$0.001 par value, 40,000,000 shares authorized as of March 31, 2020 and December 31, 2019, 28,368,698 and 28,231,267 issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	28,368	28,231
Additional paid-in capital	251,774,481	250,158,766
Accumulated deficit	(230,030,929)	(215,239,450)
Total stockholders' equity	21,771,920	34,947,547
Total liabilities and stockholders' equity	<u>\$ 52,779,108</u>	<u>\$ 68,842,067</u>



Liquidia Technologies, Inc.
Statements of Operations and Comprehensive Loss

	Three Months Ended	
	March 31,	
	2020	2019
Revenues	\$ —	\$ —
Costs and expenses:		
Research and development	10,822,924	10,664,302
General and administrative	3,823,197	3,021,581
Total costs and expenses	<u>14,646,121</u>	<u>13,685,883</u>
Loss from operations	(14,646,121)	(13,685,883)
Other income (expense):		
Interest income	109,590	137,785
Interest expense	(254,948)	(218,691)
Total other income (expense), net	<u>(145,358)</u>	<u>(80,906)</u>
Net loss	(14,791,479)	(13,766,789)
Other comprehensive income (loss)	\$ —	\$ —
Comprehensive loss	<u>(14,791,479)</u>	<u>(13,766,789)</u>
Net loss per common share:		
Basic	\$ (0.52)	\$ (0.86)
Diluted	(0.52)	(0.87)
Weighted average common shares outstanding:		
Basic	28,428,616	16,037,767
Diluted	28,322,342	15,892,619