

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): August 10, 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 August 10, 2020, Liquidia Technologies, Inc., a Delaware corporation, issued a press release announcing its financial results for the three months ended June 30, 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 August 10, 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.

August 10, 2020

Liquidia Technologies, Inc.

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

Name: Richard D. Katz, M.D.

Title: Chief Financial Officer



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MEDIA RELEASE

Liquidia Reports Second 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
Appointed Tushar Shah, M.D. as Chief Medical Officer
Announced Definitive Agreement to Acquire RareGen, LLC
Completed Public Offering of Common Stock
Company to Host Webcast and Conference Call Today at 4:30p.m. ET*

RESEARCH TRIANGLE PARK, N.C., August 10, 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 second quarter ended June 30, 2020 and provided a corporate update.

“The second quarter of 2020 was marked by progress as we continued to execute effectively against key milestones that strengthen our position for the launch of LIQ861 and the future value of our company,” said Neal Fowler, Chief Executive Officer of Liquidia. “The proposed acquisition of RareGen would be significant as it would provide Liquidia with a relevant sales force and, importantly, would bolster Liquidia’s ability to advance much needed treatment options for the PAH community. Combined with the closing of a \$75 million public offering and the appointment of Tushar Shah, M.D. as Chief Medical Officer, I am confident that we have the resources and talent required to advance our mission as a company.”

Corporate Update

- **Received FDA acceptance of LIQ861 NDA for regulatory review**

In April 2020, the U.S. Food and Drug Administration (FDA) accepted Liquidia’s New Drug Application (NDA) for LIQ861, the Company’s lead product candidate as a potential treatment for patients with pulmonary arterial hypertension (PAH), for review and provided a Prescription Drug User Fee Act (PDUFA) goal date of November 24, 2020. LIQ861 is an investigational, inhaled dry powder formulation of treprostinil designed and engineered using Liquidia’s novel PRINT technology with the goal of enhancing deep-lung delivery of treprostinil in PAH patients by means of a convenient, palm-sized dry powder inhaler.

- **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 Treprostinil, 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 \geq 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.

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- **Appointed Tushar Shah, M.D. as Chief Medical Officer**

In May 2020, the Company announced the appointment of Tushar Shah, M.D. to the newly created position of Chief Medical Officer. In this role, Dr. Shah will oversee all aspects of research, clinical development, medical affairs and regulatory affairs. Dr. Shah has 27 years of pharmaceutical research and development experience, successfully advancing more than 20 products from early development to commercialization.

- **Announced definitive agreement to acquire RareGen, LLC**

In June 2020, the Company announced it had entered into a definitive agreement to acquire RareGen, LLC, a portfolio company of PBM Capital, through an all-stock merger. Liquidia and RareGen will consolidate under a new holding company, named Liquidia Corporation, which is expected to trade on the Nasdaq Capital Market under the ticker symbol "LQDA," as the successor to Liquidia Technologies following completion of the proposed merger.

- **Completed \$75 million public offering of common stock**

In July 2020, the Company announced the closing of an underwritten public offering of 9,375,000 shares of its common stock at a price of \$8.00 per share, for total gross proceeds of \$75 million, before deducting underwriting discounts and commissions and other offering expenses.

- **Received complaint from United Therapeutics Corporation under Hatch-Waxman Act**

In June 2020, United Therapeutics Corporation (UTC) filed a complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware asserting infringement of U.S. Patent Nos. 9,604,901 (the '901 Patent) and 9,593,066 (the '066 Patent) relating to United Therapeutics' Tyvaso®, a nebulized treprostinil solution for the treatment of PAH. The complaint is in response to the LIQ861 NDA filed with the FDA. The LIQ861 NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso® as the reference listed drug. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving the LIQ861 NDA for up to 30 months, absent an earlier judgment unfavorable to UTC by the court with respect to the '901 Patent and '066 Patent. In July 2020, UTC filed an amended complaint in the lawsuit asserting infringement of U.S. Patent No. 10,716,793 (the '793 Patent). The infringement allegations of the '793 Patent is separate from the 30-month regulatory stay on final approval of the NDA for LIQ861, which is only associated with the infringement allegations of the '901 Patent and the '066 Patent. On July 30, 2020, Judge Andrews, presiding over the Hatch-Waxman Litigation, conducted a scheduling conference and set a claim construction hearing in May 2021 and set the trial to begin in March 2022.

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Second Quarter 2020 Financial Results

- **Revenues:** No revenue was recorded for the second quarter of 2020, compared with \$8.1 million for the second quarter of 2019. Revenue during the second quarter of 2019 was due to the recognition of \$8.1 million of deferred revenue from our Inhaled Collaboration and Option Agreement with a subsidiary of GlaxoSmithKline plc, resulting from the third amendment to such agreement that was entered into in June 2019.
 - **Cost of Revenue:** Cost of revenue was \$0 for the second quarter of 2020, compared to \$0.8 million for the second quarter of 2019. The decrease of \$0.8 million was due to the decrease in revenue. Cost of revenue represents sub-licensing fees paid to The University of North Carolina at Chapel Hill, or UNC, when licensing revenue is recognized from the use of the intellectual property in-licensed from UNC.
 - **Research and Development (R&D):** R&D expenses were \$8.5 million for the second quarter of 2020 compared with \$10.7 million for the second quarter of 2019. The decrease of \$2.2 million was primarily driven by a decrease in clinical trial related expenses of \$2.8 million, partially offset by a \$0.5 million increase in consulting fees.
 - **General and Administrative (G&A):** G&A expenses were \$5.2 million for the second quarter of 2020, compared with \$2.4 million for the second quarter of 2019. The increase of \$2.8 million was primarily due to a \$1.5 million increase in legal expenses due to the proposed RareGen acquisition, intellectual property, and litigation related expenses, and other general increases in salaries, consulting fees, audit and tax services and recruiting expenses.
 - **Interest Income:** Interest income was \$12,000 for the second quarter of 2020, compared with \$220,000 for the second quarter of 2019, primarily due to lower interest rates in 2020 compared with 2019 and to a lesser extent, a decrease in cash balances held in interest bearing accounts during 2020 compared with 2019.
 - **Interest Expense:** Interest expense was \$211,000 for the second quarter of 2020, compared with \$254,000 for the second quarter of 2019, primarily due to lower levels of debt during the second quarter of 2020 compared with the second quarter of 2019.
 - **Net Loss:** Net loss was \$13.9 million for the second quarter of 2020, compared with \$5.9 million for the second quarter of 2019. The increase of \$8.0 million was primarily due to zero revenue and cost of revenue recognized during the second quarter of 2020 compared with \$8.1 million of revenue and \$0.8 million cost of revenue during the second quarter of 2019. Additionally, an increase in general and administrative expenses was partially offset by a decrease in research and development expenses during the second quarter of 2020 compared with the second quarter of 2019.
 - **Cash Position and Shares Outstanding:** As of June 30, 2020, cash and cash equivalents totaled \$23.6 million and there were 28.4 million shares outstanding. On July 2, 2020, the Company completed an underwritten public offering of 9.375 million shares at a price of \$8.00 per share, resulting in gross proceeds of \$75.0 million and net proceeds of approximately \$69.8 million after deducting underwriting discounts and commissions and other offering expenses.
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Webcast and Conference Call

The Company will host a webcast and conference call at 4:30 p.m. ET today to discuss financial results and provide a corporate update. The live call may be accessed by dialing 1-877-707-8711 (domestic) or 1-857-270-6219 (international) and entering the conference code: 7295403. A live and archived webcast of the call will also be available on the [Events & Presentations](#) page of the Liquidia 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.

About RareGen

RareGen is a portfolio company of PBM Capital Group, a healthcare investment firm. RareGen provides strategy, investment, and commercialization for rare disease pharmaceutical products. RareGen has a national sales force focused on cardiology and pulmonology specialties.

Important Information About the Transaction and Where to Find It

In connection with the proposed merger transaction, the Company and Liquidia Corporation will be filing documents with the Securities and Exchange Commission, or the SEC, including the filing by Liquidia Corporation of a registration statement on Form S-4 on August 5, 2020, and the Company intends to mail a proxy statement regarding the proposed merger transaction to its stockholders that will also constitute a prospectus of the Company. After the registration statement is declared effective, the Company plans to mail to its stockholders the notice of internet availability of the definitive proxy statement/prospectus and may also file other documents with the SEC regarding the proposed merger transaction. This document is not a substitute for the proxy statement/prospectus or registration statement or any other document which the Company or Liquidia Corporation may file with the SEC. **Investors and security holders of the Company and RareGen are urged to read the registration statement, the proxy statement/prospectus and any other relevant documents, as well as any amendments or supplements to these documents, carefully and in their entirety when they become available because they will contain important information.** Investors and security holders may obtain free copies of the registration statement and the proxy statement/prospectus (when available) and other documents filed with the SEC by the Company through the website maintained by the SEC at www.sec.gov or by contacting the investor relations department of the Company at the following:

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Participants in the Solicitation

The Company, RareGen and certain of their respective directors, executive officers and employees may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction and related matters. Information regarding the Company's directors and executive officers, including a description of their direct interests, by security holdings or otherwise, is contained in the Company's Form 10-K for the year ended December 31, 2019 and its proxy statement filed on April 28, 2020, which are filed with the SEC. Additional information is and will be available in the registration statement on Form S-4 and the proxy statement/prospectus.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote of approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Cautionary Statements Regarding 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 or outcome related to our patent litigation pending in the U.S. District Court for the District of Delaware or 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 and Liquidia Corporation's filings with the Securities and Exchange Commission, including the risk that our proposed acquisition of RareGen, LLC is not consummated or that the expected benefits and synergies from the proposed acquisition are not realized, 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.

Contact Information

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Liquidia Technologies, Inc.

Balance Sheets

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash	\$ 23,586,442	\$ 55,796,378
Prepaid expenses and other current assets	750,023	590,251
Total current assets	24,336,465	56,386,629
Property, plant and equipment, net	7,976,411	9,253,965
Operating lease right-of-use assets, net	2,743,600	2,823,430
Prepaid expenses and other assets	378,043	378,043
Total assets	<u>\$ 35,434,519</u>	<u>\$ 68,842,067</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,520,467	\$ 3,498,043
Accrued compensation	2,141,133	3,164,687
Accrued stock offering expenses	65,000	1,289,413
Other accrued expenses	1,068,276	1,525,919
Current portion of operating lease liabilities	614,083	566,390
Current portion of finance lease liabilities	1,336,833	1,244,229
Current portion of long-term debt	5,585,636	5,585,637
Total current liabilities	13,331,428	16,874,318
Long-term operating lease liabilities	5,350,198	5,670,971
Long-term finance lease liabilities	378,547	1,056,747
Long-term debt	7,504,757	10,292,484
Total liabilities	26,564,930	33,894,520
Commitments and contingencies		
Stockholders' equity:		
Common stock — \$0.001 par value, 60,000,000 shares authorized as of June 30, 2020 and December 31, 2019, 28,374,585 and 28,231,267 issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	28,374	28,231
Additional paid-in capital	252,788,245	250,158,766
Accumulated deficit	(243,947,030)	(215,239,450)
Total stockholders' equity	8,869,589	34,947,547
Total liabilities and stockholders' equity	<u>\$ 35,434,519</u>	<u>\$ 68,842,067</u>

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	\$ —	\$ 8,072,120	\$ —	\$ 8,072,120
Costs and expenses:				
Cost of revenue	—	807,192	—	807,192
Research and development	8,490,418	10,723,591	19,313,342	21,387,894
General and administrative	5,226,264	2,408,651	9,049,460	5,430,233
Total costs and expenses	13,716,682	13,939,434	28,362,802	27,625,319
Loss from operations	(13,716,682)	(5,867,314)	(28,362,802)	(19,553,199)
Other income (expense):				
Interest income	11,631	219,869	121,220	357,654
Interest expense	(211,050)	(253,720)	(465,998)	(472,410)
Total other expense, net	(199,419)	(33,851)	(344,778)	(114,756)
Net loss	(13,916,101)	(5,901,165)	(28,707,580)	(19,667,955)
Other comprehensive income (loss)	—	—	—	—
Comprehensive loss	\$ (13,916,101)	\$ (5,901,165)	\$ (28,707,580)	\$ (19,667,955)
Net loss per common share:				
Basic	\$ (0.49)	\$ (0.31)	\$ (1.01)	\$ (1.13)
Diluted	\$ (0.49)	\$ (0.31)	\$ (1.01)	\$ (1.13)
Weighted average common shares outstanding:				
Basic	28,479,016	18,749,239	28,453,812	17,408,667
Diluted	28,479,016	18,749,239	28,453,812	17,408,667