

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): **November 9, 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 | The Nasdaq Stock Market LLC |

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 November 9, 2020, Liquidia Technologies, Inc., a Delaware corporation, issued a press release announcing its financial results for the three months ended September 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 November 9, 2020. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

* 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.

November 9, 2020

Liquidia Technologies, Inc.

By: /s/ Steven Bariahtaris

Name: Steven Bariahtaris

Title: Interim Chief Financial Officer



Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
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Liquidia Reports Third Quarter 2020 Financial Results and Provides Corporate Update

- *Raised \$75 Million through Underwritten Public Offering*
 - *Bolstered and Defended LIQ861 Patent Position*
- *Advanced Efforts in Support of the RareGen, LLC Merger and Integration*
- *Company to Host Webcast and Conference Call Today at 8:00 a.m. ET*

RESEARCH TRIANGLE PARK, N.C., November 9, 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 third quarter ended September 30, 2020 and provided a corporate update.

“Despite the ongoing COVID-19 pandemic, we continue to make progress in defending our right to bring LIQ861 forward for patients, while also making significant strides to advance our mission through an improved balance sheet, cash runway, and intellectual property position with respect to dry powder inhaled treprostinil. These are all important achievements as we move closer to the potential approval and long-term commercialization of LIQ861.” said Neal Fowler, Chief Executive Officer of Liquidia. “Recent events, including the unsolicited proposal to license LIQ861, have reinforced our resolve to bring LIQ861 to the PAH community and renewed our belief that this innovative treatment and the proposed RareGen merger will benefit patients and bring value to our company and its stockholders.”

Corporate Update:

- **Raised \$75 Million in Gross Proceeds from Public Offering to Strengthen Balance Sheet**

Closed underwritten public offering of 9,375,000 shares of common stock at a public offering price of \$8.00 on July 2, 2020, generating net proceeds of approximately \$70.3 million, which further augments the Company’s balance sheet in advance of potential U.S. Food and Drug Administration (FDA) approval of LIQ861.

- **Completed Chief Financial Officer Transition and Initiated Optimization of Financial Operations**

Completed a transition of Chief Financial Officer responsibilities to Steven Bariahtaris as interim Chief Financial Officer in August 2020. Following his appointment, Mr. Bariahtaris and the finance team enhanced the Company’s financial planning and budget controls and initiated a process of implementing a more cost-efficient operating plan to further improve the Company’s cashflow into 2022.

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- **Bolstered LIQ861 Intellectual Property Position**

Received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for patent application No. 16/099,135 ('135) in August 2020 related to LIQ861 covering methods of treating pulmonary hypertension (PH) with doses between about 100 micrograms to about 300 micrograms of dry powder treprostinil. The patent will substantially strengthen Liquidia's intellectual property position with respect to dry powder inhaled treprostinil and represents an important milestone for LIQ861 on its path to potential commercialization. Of note, greater than 70 percent of patients who have been enrolled in the INSPIRE and extension studies titrated to LIQ861 doses of 100 micrograms or more. For context, pharmacokinetic studies demonstrated that the 79.5 mcg dose of LIQ861 correlates with nine breaths of Tyvaso (54 mcg), the maximum recommended label dose of Tyvaso. The patent, which is expected to be issued in the fourth quarter of 2020, should have a term that expires no earlier than 2037.

- **Defended Right to Advance LIQ861 as an Innovation for Patients**

Continued vigorously defend patent positions in order to bring the innovation of dry powder treprostinil to patients.

Defended against assertion of infringement. In July 2020, Liquidia filed its answer to the complaint filed by United Therapeutics Corporation (UTC) in June 2020 against Liquidia under the Hatch-Waxman Act in the U.S. District Court for the District of Delaware (the "Delaware District Court"). The Company's answer included counterclaims of invalidity, non-infringement, and Orange Book de-listing of two UTC patents related to the manufacturing of treprostinil. As background, the complaint asserts infringement of U.S. Patent(s) 9,593,066 (the "'066 patent") and 9,604,901 (the "'901 patent") allegedly relating to UTC's Tyvaso®, which triggered a statutory 30-month stay on the regulatory approval of the LIQ861 new drug application (NDA) currently under review by the FDA.

Also in July 2020, the Company responded to the filing of an amended complaint by UTC asserting infringement of an additional recently issued U.S. Patent No. 10,716,793 (the "'793 patent"). The allegations of infringement of the '793 patent should have no effect on the FDA's review of the LIQ861 NDA and is not associated with the 30-month regulatory stay. Importantly, Judge Andrews, presiding over the Hatch-Waxman litigation, recently denied UTC's motion to dismiss Liquidia's invalidity defenses and counterclaims concerning the '793 patent.

In July 2020, Judge Andrews set a claim construction hearing in May 2021 and set the trial to begin in March 2022. Liquidia remains confident that its arguments and defenses to be made in Delaware District Court will result in a favorable outcome and pave the way to bring LIQ861 forward for patients in need. The 30-month stay expires on the earlier of October 24, 2022 or resolution of the litigation in Liquidia's favor, whichever occurs first.

Petition for *Inter Partes* Review. At the end of March 2020, Liquidia filed two petitions with the Patent Trial and Appeal Board (PTAB), of the USPTO for *inter partes* review (IPR) of the '901 patent and '066 patent seeking a determination that the claims in both patents are invalid. In October 2020, the PTAB instituted an IPR against the '901 patent and concurrently denied institution on the '066 patent. The Company expects a final decision by the PTAB on the '901 patent by October 2021. A favorable decision invalidating the '901 patent may be considered by the court in concurrent patent litigation under the 30 month stay.

· **Advanced Efforts in Support of the Proposed RareGen, LLC Merger and Integration**

The proposed acquisition of RareGen, LLC ("RareGen") reinforces Liquidia's commitment to the PAH community and Liquidia's continued pursuit to address the unmet needs of patients and the healthcare professionals who treat them. The potential introduction of LIQ861 as a more convenient inhaled treprostinil over the currently available inhaled option, combined with RareGen's parenteral treprostinil option, emphasize Liquidia's commitment to addressing the patient continuum of treatment. In addition, these combined entities further enhance the organization's knowledge base, customer reach and commercial planning in preparation for the potential launch of LIQ861, if approved. The special meeting of Liquidia stockholders to consider the RareGen merger and related matters is scheduled for November 13, 2020.

Third Quarter 2020 Financial Results

As of September 30, 2020, cash totaled \$79.6 million. 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 \$70.3 million. The company has begun to implement a more cost-efficient operating plan and estimates that its cash will be sufficient to fund its operating plan into 2022. In addition, a successful close of the RareGen acquisition has the potential to improve the Company's cash runway going forward.

- **Research and Development (R&D):** R&D expenses were \$7.7 million for the third quarter of 2020 compared with \$10.9 million for the same period of 2019. The decrease of \$3.3 million was primarily driven by a decrease in clinical trial related expenses.
 - **General and Administrative (G&A):** G&A expenses were \$7.2 million for the third quarter of 2020, compared with \$2.4 million for the same period of 2019. The increase of \$4.8 million was primarily due to an increase of \$2.8 million expenses related to the RareGen acquisition and other legal expenses, \$1.1 million in compensation and consulting expenses, and \$0.9 million of reclassified spending from R&D to G&A.
 - **Interest Income:** Interest income was \$35,000 for the third quarter of 2020, compared with \$162,000 for the same period of 2019.
 - **Interest Expense:** Interest expense was \$191,000 for the third quarter of 2020, compared with \$265,000 for the same period of 2019.
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Net Loss: Net loss was \$15.0 million for the third quarter of 2020, compared with \$13.4 million for the third quarter of 2019. The increase of \$1.5 million was primarily due to an increase in G&A expenses, partially offset by a decrease in R&D expenses.

Webcast and Conference Call

The Company will host a webcast and conference call Monday, November 9, 2020 at 8:00 a.m. ET 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: 7617005. 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.

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Important Information About the Transaction and Where to Find It

In connection with the proposed RareGen merger transaction, the Company and Liquidia Corporation have filed documents with the SEC, including the filing by Liquidia Corporation of a registration statement on Form S-4, which was declared effective on September 16, 2020, and a final proxy statement/prospectus (including any supplements thereto), and the Company mailed a proxy statement regarding the proposed merger transaction to its stockholders that also constitutes a prospectus of the Company. This document is not a substitute for the proxy statement/prospectus or registration statement or any other document which the Company or Liquidia Corporation have filed 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 because they will contain important information.** Investors and security holders may obtain free copies of the registration statement and the proxy statement/prospectus 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:

Liquidia Technologies, Inc.
Jason Adair
Investor Relations
(919) 328-4350
Jason.adair@liquidia.com

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 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 FDA approval of the 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 its *inter partes* review with the PTAB, the issuance of patents by the USPTO 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 SEC, including the risk that our proposed acquisition of RareGen 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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-Financial Tables Follow-

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| Liquidia Technologies, Inc. Balance Sheets | September 30, 2020 (Unaudited) | December 31, 2019 |
|---|---|------------------------------|
| Assets | | |
| Current assets: | | |
| Cash | \$ 79,551,041 | \$ 55,796,378 |
| Prepaid expenses and other current assets | 1,095,331 | 590,251 |
| Total current assets | <u>80,646,372</u> | <u>56,386,629</u> |
| Property, plant and equipment, net | 7,388,376 | 9,253,965 |
| Operating lease right-of-use assets, net | 2,698,344 | 2,823,430 |
| Other assets | 378,043 | 378,043 |
| Total assets | <u>\$ 91,111,135</u> | <u>\$ 68,842,067</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,414,978 | \$ 3,498,043 |
| Accrued compensation | 2,068,480 | 3,164,687 |
| Accrued stock offering expenses | 0 | 1,289,413 |
| Other accrued expenses | 1,409,976 | 1,525,919 |
| Current portion of operating lease liabilities | 638,862 | 566,390 |
| Current portion of finance lease liabilities | 1,113,670 | 1,244,229 |
| Current portion of long-term debt | 5,585,636 | 5,585,637 |
| Total current liabilities | <u>14,231,602</u> | <u>16,874,318</u> |
| Long-term operating lease liabilities | 5,183,539 | 5,670,971 |
| Long-term finance lease liabilities | 310,513 | 1,056,747 |
| Long-term debt | 6,104,374 | 10,292,484 |
| Total liabilities | <u>25,830,028</u> | <u>33,894,520</u> |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock — 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019, 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019 | — | — |
| Common stock — \$0.001 par value, 60,000,000 shares authorized as of September 30, 2020 and December 31, 2019, 37,752,261 and 28,231,267 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively | 37,752 | 28,231 |
| Additional paid-in capital | 324,159,065 | 250,158,766 |
| Accumulated deficit | (258,915,710) | (215,239,450) |
| Total stockholders' equity | <u>65,281,107</u> | <u>34,947,547</u> |
| Total liabilities and stockholders' equity | <u>\$ 91,111,135</u> | <u>\$ 68,842,067</u> |

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| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|-----------------|--|-----------------|
| | 2020 | 2019 | 2020 | 2019 |
| Revenue | \$ — | \$ — | \$ — | \$ 8,072,120 |
| Costs and expenses: | | | | |
| Cost of revenue | — | — | — | 807,192 |
| Research and development | 7,660,979 | 10,942,561 | 26,974,320 | 32,330,454 |
| General and administrative | 7,151,788 | 2,377,687 | 16,201,249 | 7,807,920 |
| Total costs and expenses | 14,812,767 | 13,320,248 | 43,175,569 | 40,945,566 |
| Loss from operations | (14,812,767) | (13,320,248) | (43,175,569) | (32,873,446) |
| Other income (expense): | | | | |
| Interest income | 34,633 | 162,207 | 155,852 | 519,861 |
| Interest expense | (190,546) | (265,018) | (656,543) | (737,429) |
| Total other income (expense), net | (155,913) | (102,811) | (500,691) | (217,568) |
| Net loss and comprehensive loss | \$ (14,968,680) | \$ (13,423,059) | \$ (43,676,260) | \$ (33,091,014) |
| Net loss attributable to common stockholders, basic and diluted | \$ (0.40) | \$ (0.72) | \$ (1.38) | \$ (1.85) |
| Weighted average common shares outstanding, basic and diluted | 37,755,472 | 18,757,166 | 31,576,992 | 17,856,826 |