Table of Contents

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** For the fiscal quarter ended September 30, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** For the transition period from to

Commission File Number: 001-39724

**LIQUIDIA CORPORATION**
(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **85-1710962** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **419 Davis Drive, Suite 100**<br>**Morrisville, North Carolina** | **27560** |
| (Address of Principal Executive Offices) | (Zip Code) |

Registrant's telephone number, including area code: **(919) 328-4400**

**N/A**
(Former name, former address and former fiscal year, if changed since last report)

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, $0.001 par value per share | LQDA | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer ☒ Smaller Reporting Company ☒
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 ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of October 28, 2021, there were 51,977,995 shares of the registrant's common stock outstanding.

**LIQUIDIA CORPORATION**



This quarterly report on Form 10-Q includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo and PRINT, or Particle Replication In Non-wetting Templates, which are protected under applicable intellectual property laws and are the property of Liquidia Technologies, Inc. This quarterly report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this quarterly report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

**Cautionary Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report may be forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations", but are also contained elsewhere in this Quarterly Report. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "should," "expects," "plans," "anticipates," "could," "would," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- those identified and disclosed in our public filings with the U.S. Securities and Exchange Commission ("SEC") including, but not limited to (i) the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including the NDA for LIQ861 that was resubmitted to the U.S. Food and Drug Administration ("FDA") in May 2021 following our receipt of a Complete Response Letter in November 2020 from the FDA and the potential for, and timing regarding, eventual FDA approval of and our ability to commercially launch, LIQ861, including the potential impact of regulatory review, approval, and exclusivity developments which may occur for competitors; (ii) the timeline or outcome related to our current patent litigation with United Therapeutics pending in the U.S. District Court for the District of Delaware, the *inter partes* review with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office or any appeals of any decisions issued by the U.S. District Court for the District of Delaware or the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office; (iii) our ability to predict, foresee, and effectively address or mitigate future developments resulting from the COVID-19 pandemic or other global shutdowns, which could include a negative impact on the availability of key personnel, the temporary closure of our facility or the facilities of our business partners, suppliers, third-party service providers or other vendors, or delays in payments or purchasing decisions, or the interruption of domestic and global supply chains, liquidity and capital or financial markets; and (iv) our ability to continue operations as a going concern without obtaining additional funding;
- our expectations regarding the size of the patient populations for, market acceptance and opportunity for those drug products and medical devices that we commercialize in collaboration with third parties, including Sandoz Inc.'s first-to-file fully substitutable generic treprostinil injection and the RG 3ml Medication Cartridge that we developed in collaboration with Chengdu Shifeng Medical Technologies LTD.;
- successfully integrating our and Liquidia PAH, LLC's (formerly known as RareGen, LLC) businesses, and avoiding problems which may result in our company not operating as effectively and efficiently as expected;
- the possibility that the expected benefits of the completed merger transaction with RareGen, LLC (the "Merger Transaction"), will not be realized within the expected timeframe or at all, including without limitation, anticipated revenue, expenses, earnings and other financial results, and growth and expansion of our operations, and the anticipated tax treatment;
- our ability to retain, attract and hire key personnel;
- prevailing economic, market and business conditions;
- the cost and availability of capital and any restrictions imposed by lenders or creditors;
- changes in the industry in which we operate;
- the failure to renew, or the revocation of, any license or other required permits;
- unexpected charges or unexpected liabilities arising from a change in accounting policies, including any such changes by third parties with whom we collaborate and from whom we receive a portion of their net profits, or the effects of acquisition accounting varying from our expectations;
- the risk that the credit ratings of our company or our subsidiaries may be different from what the companies expect, which may increase borrowing costs and/or make it more difficult for us to pay or refinance our debts and require us to borrow or divert cash flow from operations in order to service debt payments;
- fluctuations in interest rates;

- adverse outcomes of pending or threatened litigation or governmental investigations, if any, unrelated to the Merger Transaction;
- the effects on the companies of future regulatory or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject;
- conduct of and changing circumstances related to third-party relationships on which we rely, including the level of credit worthiness of counterparties;
- the volatility and unpredictability of the stock market and credit market conditions;
- conditions beyond our control, such as natural disasters, global pandemics (including COVID-19), or acts of war or terrorism;
- variations between the stated assumptions on which forward-looking statements are based and our actual experience;
- other legislative, regulatory, economic, business, and/or competitive factors;
- our plans to develop and commercialize our product candidates;
- our planned clinical trials for our product candidates;
- the timing of the availability of data from our clinical trials;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates and the sufficiency of our current manufacturing facilities to produce development and commercial quantities of our product candidates;
- our ability to establish and maintain collaborations;
- our estimates regarding the market opportunities for our product candidates;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- our expected use of proceeds from prior public offerings and the period over which such proceeds, together with cash, will be sufficient to meet our operating needs.

You should refer to the “Risk Factors” section of this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements, including, but not limited to, the impact of the COVID-19 pandemic on our company and our financial condition and results of operations. The forward-looking statements in this Quarterly Report are only predictions, and we may not actually achieve the plans, intentions or expectations included in our 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 business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

These forward-looking statements speak only as of the date of this Quarterly Report. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

*Unless the context otherwise requires, references in this Quarterly Report on Form 10-Q to "we," "us", "our", "Liquidia" and the "Company" refer to Liquidia Corporation, a Delaware corporation, and unless specified otherwise, include our wholly owned subsidiaries, Liquidia Technologies, Inc., a Delaware corporation, or Liquidia Technologies, and Liquidia PAH, LLC (formerly known as RareGen, LLC, or RareGen), a Delaware limited liability company, or Liquidia PAH.*

**PART I. FINANCIAL INFORMATION**

**Item 1. Condensed Financial Statements**

**Liquidia Corporation**
**Condensed Consolidated Balance Sheets (unaudited)**

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 64,053,795 | $ 65,316,481 |
| Accounts receivable, net | 3,050,384 | — |
| Prepaid expenses and other current assets | 375,695 | 752,447 |
| Total current assets | 67,479,874 | 66,068,928 |
| Property, plant and equipment, net | 5,452,269 | 6,805,570 |
| Operating lease right-of-use assets, net | 2,477,786 | 2,649,328 |
| Indemnification asset, related party | 5,713,551 | 1,387,275 |
| Contract acquisition costs, net | 10,439,634 | 12,792,491 |
| Intangible asset, net | 4,520,088 | 5,534,843 |
| Goodwill | 3,903,282 | 3,903,282 |
| Other assets | 312,925 | 390,043 |
| Total assets | $ 100,299,409 | $ 99,531,760 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,609,162 | $ 3,734,227 |
| Accrued compensation | 2,060,773 | 3,259,515 |
| Other accrued expenses | 2,323,130 | 1,386,880 |
| Refund liability, net | — | 1,768,864 |
| Current portion of operating lease liabilities | 745,891 | 664,670 |
| Current portion of finance lease liabilities | 325,436 | 923,218 |
| Total current liabilities | 7,064,392 | 11,737,374 |
| Litigation finance payable | 5,074,507 | 1,154,360 |
| Long-term operating lease liabilities | 4,437,490 | 5,006,301 |
| Long-term finance lease liabilities | 427,363 | 255,402 |
| Long-term debt | 10,331,648 | 10,292,485 |
| Total liabilities | 27,335,400 | 28,445,922 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock — 10,000,000 shares authorized as of September 30, 2021 and December 31, 2020, 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020 | — | — |
| Common stock — $0.001 par value, 80,000,000 shares authorized as of September 30, 2021 and December 31, 2020, 51,976,804 and 43,336,277 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively | 51,977 | 43,336 |
| Additional paid-in capital | 370,929,782 | 346,044,721 |
| Accumulated deficit | (298,017,750) | (275,002,219) |
| Total stockholders' equity | 72,964,009 | 71,085,838 |
| Total liabilities and stockholders' equity | $ 100,299,409 | $ 99,531,760 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**
**Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue | $ 3,178,621 | $ — | $ 9,638,338 | $ — |
| Costs and expenses: | | | | |
| Cost of revenue | 889,511 | — | 2,296,983 | — |
| Research and development | 4,487,098 | 7,660,979 | 15,136,201 | 26,974,320 |
| General and administrative | 4,881,669 | 7,151,788 | 14,639,752 | 16,201,249 |
| Total costs and expenses | 10,258,278 | 14,812,767 | 32,072,936 | 43,175,569 |
| Loss from operations | (7,079,657) | (14,812,767) | (22,434,598) | (43,175,569) |
| Other income (expense): | | | | |
| Interest income | 3,875 | 34,633 | 29,521 | 155,852 |
| Interest expense | (205,110) | (190,546) | (610,454) | (656,543) |
| Total other income (expense), net | (201,235) | (155,913) | (580,933) | (500,691) |
| Net loss and comprehensive loss | $ (7,280,892) | $ (14,968,680) | $ (23,015,531) | $ (43,676,260) |
| Net loss per common share, basic and diluted | $ (0.14) | $ (0.40) | $ (0.47) | $ (1.38) |
| Weighted average common shares outstanding, basic and diluted | 52,081,497 | 37,755,472 | 48,822,303 | 31,576,992 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**
**Condensed Consolidated Statements of Stockholders' Equity (unaudited)**

| | Common Stock Shares | Common Stock Amount | Additional Paid in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| **Balance as of December 31, 2020** | 43,336,277 | $ 43,336 | $ 346,044,721 | $ (275,002,219) | $ 71,085,838 |
| Issuance of common stock upon exercise of stock options | 281 | — | 494 | — | 494 |
| Issuance of common stock upon vesting of restricted stock units | 10,366 | 11 | (11) | — | — |
| Issuance of warrant | — | — | 261,000 | — | 261,000 |
| Stock-based compensation | — | — | 745,000 | — | 745,000 |
| Net loss | — | — | — | (9,183,153) | (9,183,153) |
| **Balance as of March 31, 2021** | 43,346,924 | $ 43,347 | $ 347,051,204 | $ (284,185,372) | $ 62,909,179 |
| Issuance of common stock upon vesting of restricted stock units | 2,088 | 2 | (2) | — | — |
| Sale of common stock, net | 8,626,037 | 8,626 | 21,701,323 | — | 21,709,949 |
| Stock-based compensation | — | — | 953,215 | — | 953,215 |
| Net loss | — | — | — | (6,551,486) | (6,551,486) |
| **Balance as of June 30, 2021** | 51,975,049 | $ 51,975 | $ 369,705,740 | $ (290,736,858) | $ 79,020,857 |
| Issuance of common stock upon vesting of restricted stock units | 1,755 | 2 | (2) | — | — |
| Stock-based compensation | — | — | 1,224,044 | — | 1,224,044 |
| Net loss | — | — | — | (7,280,892) | (7,280,892) |
| **Balance as of September 30, 2021** | 51,976,804 | $ 51,977 | $ 370,929,782 | $ (298,017,750) | $ 72,964,009 |

| | Common Stock Shares | Common Stock Amount | Additional Paid in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| **Balance as of December 31, 2019** | 28,231,267 | $ 28,231 | $ 250,158,766 | $ (215,239,450) | $ 34,947,547 |
| Issuance of common stock upon exercise of stock options | 2,035 | 2 | (2) | — | — |
| Issuance of common stock upon vesting of restricted stock units | 702 | 1 | (1) | — | — |
| Issuance of common stock under employee stock purchase plan | 3,269 | 3 | 11,488 | — | 11,491 |
| Sale of common stock, net | 131,425 | 131 | 725,267 | — | 725,398 |
| Stock-based compensation | — | — | 878,963 | — | 878,963 |
| Net loss | — | — | — | (14,791,479) | (14,791,479) |
| **Balance as of March 31, 2020** | 28,368,698 | $ 28,368 | $ 251,774,481 | $ (230,030,929) | $ 21,771,920 |
| Issuance of common stock upon exercise of stock options | 5,184 | 5 | 25,646 | — | 25,651 |
| Issuance of common stock upon vesting of restricted stock units | 703 | 1 | (1) | — | — |
| Stock-based compensation | — | — | 988,119 | — | 988,119 |
| Net loss | — | — | — | (13,916,101) | (13,916,101) |
| **Balance as of June 30, 2020** | 28,374,585 | $ 28,374 | $ 252,788,245 | $ (243,947,030) | $ 8,869,589 |
| Issuance of common stock upon exercise of stock options | 153 | — | 273 | — | 273 |
| Issuance of common stock upon vesting of restricted stock units | 702 | 1 | (1) | — | — |
| Issuance of common stock under employee stock purchase plan | 1,821 | 2 | 7,923 | — | 7,925 |
| Sale of common stock, net | 9,375,000 | 9,375 | 70,281,625 | — | 70,291,000 |
| Stock-based compensation | — | — | 1,081,000 | — | 1,081,000 |
| Net loss | — | — | — | (14,968,680) | (14,968,680) |
| **Balance as of September 30, 2020** | 37,752,261 | $ 37,752 | $ 324,159,065 | $ (258,915,710) | $ 65,281,107 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**
**Condensed Consolidated Statements of Cash Flows (unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| **Operating activities** | | |
| Net loss | $ (23,015,531) | $ (43,676,260) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 2,922,259 | 2,948,082 |
| Depreciation and amortization | 4,740,244 | 2,178,402 |
| Non-cash lease expense | 171,542 | 125,086 |
| Loss on disposal of property and equipment | 29,122 | — |
| Non-cash interest expense | 207,834 | 47,183 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (3,050,384) | — |
| Prepaid expenses and other current assets | 376,752 | (505,080) |
| Other non-current assets | 77,118 | — |
| Accounts payable | (6,451,341) | 133,521 |
| Accrued compensation | (1,198,742) | (1,096,207) |
| Other accrued expenses | 971,250 | 203,833 |
| Refund liability | (1,768,864) | — |
| Operating lease liabilities | (487,590) | (414,960) |
| Net cash used in operating activities | (26,476,331) | (40,056,400) |
| **Investing activities** | | |
| Purchases of property, plant and equipment | (87,240) | (713,121) |
| Net cash used in investing activities | (87,240) | (713,121) |
| **Financing activities** | | |
| Principal payments on finance leases | (387,034) | (876,793) |
| Principal payments on long-term debt | (10,352,940) | (4,235,294) |
| Proceeds from issuance of long-term debt with warrants, net | 10,410,269 | — |
| Receipts from litigation financing | 3,920,147 | — |
| Proceeds from sale of common stock, net of underwriting fees and commissions | 21,709,949 | 71,225,398 |
| Payments for offering costs | — | (1,634,467) |
| Proceeds from issuance of common stock under stock incentive plans | 494 | 45,340 |
| Net cash provided by financing activities | 25,300,885 | 64,524,184 |
| Net (decrease) increase in cash and cash equivalents | (1,262,686) | 23,754,663 |
| Cash and cash equivalents, beginning of period | 65,316,481 | 55,796,378 |
| Cash and cash equivalents, end of period | $ 64,053,795 | $ 79,551,041 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 309,302 | $ 601,838 |
| Cash paid for operating lease liabilities | $ 901,271 | $ 875,229 |
| Reduction of lease liability and right-of-use asset from lease modification | $ 38,787 | $ — |
| Non-cash increase in indemnification asset through accounts payable | $ 4,326,276 | $ — |
| Changes in purchases of property, plant and equipment in accounts payable and accrued expenses | $ — | $ 400,308 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**

**Notes to Condensed Consolidated Financial Statements (unaudited)**

**1. Business**

Liquidia Corporation ("Liquidia" or the "Company") is a biopharmaceutical company focused on the development, manufacturing, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension ("PH"). Liquidia Corporation operates through its wholly owned operating subsidiaries, Liquidia Technologies, Inc. ("Liquidia Technologies") and Liquidia PAH, LLC ("Liquidia PAH"), formerly known as RareGen, LLC ("RareGen").

The Company generates revenue pursuant to a promotion agreement between Liquidia PAH and Sandoz Inc. ("Sandoz"), dated as of August 1, 2018, as amended (the "Promotion Agreement"), sharing profit derived from the sale of the first-to-file fully substitutable generic treprostinil injection ("Treprostinil Injection") in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. The Company employs a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of pulmonary arterial hypertension ("PAH") in the United States, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, the Company believes that its commercial presence in the field will enable an efficient base to expand from for the launch of LIQ861 upon approval, leveraging existing relationships and further validating its reputation as a company committed to supporting PAH patients.

The Company conducts research, development and manufacturing of novel products by applying its proprietary PRINT® technology, a particle engineering platform, to enable precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. The Company's lead product candidate, for which it holds worldwide commercial rights, is LIQ861 for the treatment of PAH.

LIQ861 is an inhaled dry powder formulation of treprostinil designed to improve the therapeutic profile of treprostinil by enhancing deep lung delivery and achieving higher dose levels than current inhaled therapies. The Company submitted the New Drug Application ("NDA") for LIQ861 in January 2020. In November 2020, the Company received a Complete Response Letter ("CRL") issued by the Food and Drug Administration ("FDA") with respect to the NDA for LIQ861. In May 2021, the Company resubmitted the NDA for LIQ861 in response to the CRL. In June 2021, the FDA accepted the Company's resubmitted NDA for LIQ861 for review and established a PDUFA goal date of November 7, 2021.

The Company is subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the impact of the COVID-19 coronavirus, and the ability to secure additional capital to fund operations. The Company expects to incur significant expenses and operating losses for the foreseeable future as it seeks regulatory approval and pursues commercialization of any approved product candidates. In addition, if the Company obtains marketing approval for any of its current or future product candidates, it would incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales. The Company may need to seek additional funding through public or private financings, debt financing or collaboration. If the Company determines it requires but is unable to obtain funding, the Company could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect its business prospects.

In accordance with Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. The Company has financed its growth and operations through a combination of funds generated from revenues, the issuance of convertible preferred stock and common stock, finance leases, bank borrowings, bank borrowings with warrants and the issuance of convertible notes and warrants. Since inception, the Company has incurred recurring losses, including net loss of $23.0 million for the the nine months ended September 30, 2021 and the Company had an accumulated deficit of $298.0 million as of September 30, 2021. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of the September 30, 2021 condensed consolidated financial statements, the Company expects that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these unaudited interim condensed consolidated financial statements. The accompanying unaudited interim condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business.

**2. Basis of Presentation, Significant Accounting Policies and Fair Value Measurements**

**Basis of Presentation**

The unaudited interim condensed consolidated financial statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting. These condensed consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments and accruals) necessary for a fair statement of the results for the periods presented in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The year-end condensed consolidated balance sheet data was derived from the Company's audited consolidated financial statements but does not include all disclosures required by GAAP. Operating results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2021. Certain information and footnote disclosures normally included in the annual consolidated financial statements prepared in accordance with GAAP have been omitted in accordance with the SEC's rules and regulations for interim reporting. The Company's financial position, results of operations and cash flows are presented in U.S. Dollars.

The accompanying unaudited condensed consolidated financial statements and related notes should be read in conjunction with the Company's audited consolidated financial statements for the year ended December 31, 2020, which are included in the Company's 2020 Annual Report on Form 10-K.

There have been no material changes to the Company's significant accounting policies during the the nine months ended September 30, 2021 compared with the significant accounting policies disclosed in Note 2 of the consolidated financial statements for the years ended December 31, 2020 and 2019, which are included in the Company's 2020 Annual Report on Form 10-K.

***Consolidation***

The accompanying condensed consolidated financial statements include the Company's wholly owned subsidiaries, Liquidia Technologies and Liquidia PAH. All intercompany accounts and transactions have been eliminated.

***Use of Estimates***

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, at the date of the financial statements, as well as the reported amounts of revenues and expenses during the period. These estimates are based on historical experience and various other assumptions believed reasonable under the circumstances. The Company evaluates its estimates on an ongoing basis and makes changes to the estimates and

related disclosures as experience develops or new information becomes known. Actual results will most likely differ from those estimates.

**Summary of Significant Accounting Policies**

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents as of September 30, 2021 were $64.1 million and included cash investments in money market funds of $63.1 million. Cash as of December 31, 2020 was $65.3 million and included no cash equivalents.

***Accounts Receivable***

Accounts receivable are stated at net realizable value including an allowance for doubtful accounts as of each balance sheet date, if applicable. As of September 30, 2021 and December 31, 2020, the Company has not recorded an allowance for doubtful accounts.

***Business Combination***

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition.

***Long-Lived Assets***

The Company reviews long-lived assets, including definite-life intangible assets, for realizability on an ongoing basis. Changes in depreciation and amortization, generally accelerated depreciation and variable amortization, are determined and recorded when estimates of the remaining useful lives or residual values of long-term assets change. The Company also reviews for impairment when conditions exist that indicate the carrying amount of the assets may not be fully recoverable. In those circumstances, the Company performs undiscounted operating cash flow analyses to determine if an impairment exists. When testing for asset impairment, the Company groups assets and liabilities at the lowest level for which cash flows are separately identifiable. Any impairment loss is calculated as the excess of the asset's carrying value over its estimated fair value. Fair value is estimated based on the discounted cash flows for the asset group over the remaining useful life or based on the expected cash proceeds for the asset less costs of disposal. Any impairment losses would be recorded in the consolidated statements of operations. To date, no such impairments have occurred.

***Goodwill***

The Company acquired goodwill on its condensed consolidated balance sheet during the fourth quarter of 2020 from the Merger Transaction. The Company assesses goodwill for impairment at least annually as of July 1 or whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. For example, significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for LIQ861, could trigger testing of our goodwill for impairment at an interim date. The Company has one reporting unit. The Company has the option to first assess qualitative factors to determine whether events or circumstances indicate it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, in which case a quantitative impairment test is not required.

Per ASU 2017-04 the quantitative goodwill impairment test is performed by comparing the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount,

goodwill is not impaired. An impairment loss is recognized for any excess of the carrying amount of the reporting unit's goodwill over the fair value up to the amount of goodwill allocated to the reporting unit. Income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit are considered when measuring the goodwill impairment loss, if applicable. The Company completed its annual impairment test as of July 1, 2021 and concluded that no impairments have occurred.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents. The Company is exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding its cash and cash equivalents to the extent of amounts recorded on the condensed consolidated balance sheet. 100% of the Company's cash and cash equivalents are held with Silicon Valley Bank ("SVB").

For the three and nine months ended September 30, 2021, one customer accounted for 99% of revenue. As of September 30, 2021 one customer accounted for 99% of the Company's accounts receivable.

***Revenue Recognition***

The Company recognizes revenue in accordance with Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (Topic 606). The core principle of Topic 606 is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, the Company assesses the promised goods or services in the contract and identifies each promised good or service that is distinct.

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company evaluates any non-cash consideration, consideration payable to the customer, potential returns and refunds, and whether consideration contains a significant financing element in determining the transaction price.

Revenue is measured based on consideration specified in a contract with a customer. The Company recognizes revenue when it satisfies a performance obligation by transferring control over a service to a customer. The amount of revenue

recognized reflects estimates for refunds and returns, which are presented as a reduction of Accounts receivable where the right of setoff exists.

***Stock-Based Compensation***

The Company estimates the grant date fair value of its stock-based awards and amortizes this fair value to compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award (see Note 7). The grant date fair value of stock options is determined using the Black-Scholes option-pricing model.

***Net Loss Per Share***

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration of common stock equivalents.

Diluted net loss per share is calculated by adjusting the weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options, restricted stock units and the SVB Warrant (see Note 13) are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive as the Company is in a net loss position for all periods presented. Due to their anti-dilutive effect, the calculation of diluted net loss per share for the three and nine months ended September 30, 2021 and 2020 does not include the following common stock equivalent shares:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Stock Options | 5,451,114 | 2,747,538 | 5,101,347 | 2,516,604 |
| Restricted Stock Units | 283,691 | 123,369 | 304,230 | 98,355 |
| SVB Warrant | 200,000 | — | 158,242 | — |
| Total | 5,934,805 | 2,870,907 | 5,563,819 | 2,614,959 |

For the three and nine months ended September 30, 2021 and 2020, certain common stock warrants are included in the calculation of basic and diluted net loss per share since their exercise price is de minimis.

***Recent Accounting Pronouncements***

In March 2020, the Financial Accounting Standards Board ("FASB") issued guidance that provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by the discontinuation of the London Interbank Offered Rate (“LIBOR”) or by another reference rate expected to be discontinued. The Company adopted this guidance during the first quarter of 2021 and it did not have a material impact on its consolidated financial position, results of operations or cash flows.

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*. This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity’s own equity. Key provisions of the guidance include reducing the number of accounting models, simplifying the earnings per share calculations and expanding the disclosures related to convertible instruments. The guidance is effective for fiscal years, and interim periods within these fiscal years, beginning after December 15, 2021. The Company is in the process of evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

In May 2021, the FASB issues ASU 2021-04, *Issuer’s Accounting for certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. This guidance clarifies and reduces diversity in the accounting for modifications or exchanges of freestanding equity-classified written call options (for example warrants) that remain equity classified after modification or exchange. The guidance is effective for fiscal years, and interim periods within

those fiscal years, beginning after December 15, 2021. The Company is in the process of evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

**Fair Value of Measurements**

The Company's valuation of financial instruments is based on a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities;

Level 2 — Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly; and

Level 3 — Unobservable inputs for the asset and liability used to measure fair value, to the extent that observable inputs are not available.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The following tables present the placement in the fair value hierarchy of financial liabilities measured at fair value as of September 30, 2021 and December 31, 2020:

| September 30, 2021 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Carrying Value |
|---|---|---|---|---|
| **Assets** | | | | |
| Money market mutual funds | $ 63,053,795 | $ — | $ — | $ 63,053,795 |
| **Liabilities** | | | | |
| Silicon Valley Bank term loan | $ — | $ 10,274,486 | $ — | $ 10,331,648 |

| December 31, 2020 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Carrying Value |
|---|---|---|---|---|
| **Liabilities** | | | | |
| Pacific Western Bank term loan | $ — | $ 9,842,069 | $ — | $ 10,292,485 |

Money market mutual funds are included in cash and cash equivalents on the Company's condensed consolidated balance sheets. They are valued using quoted market prices and therefore are classified within Level 1 of the fair value hierarchy.

The carrying amounts reflected in the Company's condensed consolidated balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses and other liabilities approximate their fair values due to their short-term nature.

The fair value of debt is measured in accordance with ASU 2016-01, *Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. The fair value is determined based on the exit price notion using credit spreads and an illiquidity premium for each loan. The credit spread is determined by the credit risk rating, loan rate index, and maturity date. The illiquidity premium is based on the loan's credit risk rating.

**3. Acquisition of RareGen, LLC (now Liquidia PAH, LLC)**

On November 18, 2020 (the "Closing Date"), the Company completed the previously announced acquisition contemplated by the Agreement and Plan of Merger, dated as of June 29, 2020, as amended by a Limited Waiver and Modification to the Merger Agreement, dated as of August 3, 2020 (the "Merger Agreement"), by and among Liquidia Technologies, the Company, RareGen, Gemini Merger Sub I, Inc., a Delaware corporation ("Liquidia Merger Sub"), Gemini Merger Sub II, LLC, a Delaware limited liability company ("RareGen Merger Sub"), and PBM RG Holdings, LLC, a Delaware limited liability company ("PBM"). Upon consummation of the Merger Transaction, the separate corporate existences of Liquidia Merger Sub and RareGen Merger Sub ceased and Liquidia Technologies and RareGen (now Liquidia PAH) continue as wholly owned subsidiaries of Liquidia Corporation.

On the Closing Date, an aggregate of 5,550,000 shares of common stock, $0.001 par value per share ("Liquidia Corporation Common Stock"), were issued to RareGen members in exchange for 10,000 RareGen common units, representing all of the issued and outstanding RareGen equity. Additionally, on the Closing Date, an aggregate of 616,666 shares of Liquidia Corporation Common Stock were withheld from RareGen members to secure the indemnification obligations of RareGen members. Additionally, RareGen members received a pro rata portion of the RareGen cash at closing in excess of $1 million. RareGen members are also entitled to receive a pro rata portion of up to an additional 2,708,333 shares of Liquidia Corporation Common Stock in the aggregate in 2022, based on the amount of 2021 net sales of the generic treprostinil product ("Net Sales Earnout Shares") owned by Sandoz, which RareGen markets pursuant to the Promotion Agreement. The fair value of the purchase consideration or the purchase price was approximately $20.8 million.

**Reasons for the Acquisition and Merger**

The Company acquired Liquidia PAH to improve financial strength and operational efficiencies including the generation of cash flow through sales of a generic version of Remodulin, which is a parenteral formulation of treprostinil, for the treatment of PAH. Strategically, the Company believes that its commercial presence in the field will enable an efficient launch of LIQ861 upon approval, leveraging existing relationships and further validating its reputation as a company committed to supporting PAH patients.

**Merger Consideration**

The fair value of the purchase consideration or the purchase price, was approximately $20.8 million. The purchase consideration consisted of the 6,166,666 shares of Liquidia Corporation Common Stock at a per share price of $3.38, which represented the closing price of Liquidia Technologies Common Stock on the Closing Date. 5,550,000 of the shares were issued as of December 31, 2020 and the remaining 616,666 shares were withheld from RareGen members to secure their indemnification obligations pursuant to the Merger Agreement.

**Accounting for the Acquisition**

The acquisition of Liquidia PAH was accounted for as a business combination and reflects the application of acquisition accounting in accordance with Accounting Standards Codification (ASC) 805, Business Combinations. The acquired Liquidia PAH assets, including identifiable intangible assets and liabilities assumed, have been recorded at their estimated fair values with the excess purchase price assigned to goodwill. A preliminary purchase price allocation has been performed and the recorded amounts for intangible assets, other assets, indemnification asset, goodwill, litigation finance payable, deferred tax liability and other liabilities are subject to change pending finalization of valuation efforts and review of tax matters. The amounts recognized will be finalized as the information necessary to complete the analysis is obtained, but no later than one year after the Closing Date.

***Purchase Price Allocation***

The preliminary purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed as of the Closing Date of November 18, 2020 based on their respective preliminary fair values summarized below:

| | |
|---|---|
| Cash | $ 1,000,000 |
| Property and equipment | 79,330 |
| Prepaid and other current assets | 30,190 |
| Intangible asset | 5,620,000 |
| Contract acquisition costs | 12,980,000 |
| Indemnification asset, related party | 1,065,538 |
| Goodwill | 3,903,282 |
| Less other current liabilities | (492,499) |
| Less refund liability | (2,696,000) |
| Less litigation finance payable, long-term | (646,510) |
| Total estimated purchase price | $ 20,843,331 |

4. **Contract Acquisition Costs, Intangible Asset, and Goodwill**

Contract acquisition costs and the Intangible asset consist of the total value assigned to the Promotion Agreement (see Note 3 for Purchase Price Allocation). The Company is amortizing the value of the contract acquisition costs and intangible asset on a pro-rata basis based on the estimated total revenue or net profits to be recognized over the period from the date of the Merger Transaction through May 2027 (see Note 2 for Revenue Recognition accounting policy). Amortization of contract acquisition costs is recorded as a reduction of revenue and amortization of the intangible asset is recorded as cost of revenue. During the three and nine months ended September 30, 2021, the Company recorded total amortization of $779,873 and $2,350,086 from the contract acquisition costs as a reduction in revenue, respectively. Net contract acquisition costs totaled $10,439,634 and $12,792,491 as of September 30, 2021 and December 31, 2020. During the three and nine months ended September 30, 2021, the Company recorded total amortization of $337,665 and $1,017,526 from the intangible asset as cost of revenue, respectively.

The Company acquired goodwill in the Merger Transaction of $3,903,282 which primarily represents the Liquidia PAH assembled workforce and the residual value of the purchase consideration and assumed liabilities that exceeded the assets acquired (see Note 2 for Goodwill accounting policy). None of the goodwill recognized is expected to be deductible for income tax purposes.

**5. Indemnification Asset with Related Party and Litigation Finance Payable**

On June 3, 2020, Liquidia PAH entered into a litigation financing arrangement (the “Financing Agreement”) with Henderson SPV, LLC (“Henderson”). Liquidia PAH, along with Sandoz (collectively the “Plaintiffs”), are pursuing litigation against United Therapeutics Corporation (“United Therapeutics”) and, prior to entering into a binding settlement term sheet with Smiths Medical ASC in November 2020, were pursuing litigation against Smiths Medical. Under the Financing Agreement, Henderson will fund Liquidia PAH’s legal and litigation expenses (referred to as “Deployments”) in exchange for a share of certain litigation or settlement proceeds. Deployments received from Henderson are recorded as a Litigation finance payable.

Litigation proceeds will be split equally between Liquidia PAH and Sandoz. Unless there is an event of default by Henderson, litigation proceeds received by Liquidia PAH must be applied first to repayment of total Deployments received. Litigation proceeds in excess of Deployments received are split between Liquidia PAH and Henderson according to a formula. Unless there is an event of default by PBM, proceeds received by Liquidia PAH are due to PBM as described further below.

On November 17, 2020, Liquidia PAH entered into a Litigation Funding and Indemnification Agreement ("Indemnification Agreement") with PBM. PBM is considered to be a related party as it is controlled by a major stockholder (which beneficially owns approximately 9.9% of Liquidia Corporation Common Stock as of October 15, 2021) who is also a member of the Company's Board of Directors.

Under the terms of the Indemnification Agreement, PBM now controls the litigation, with Liquidia PAH's primarily responsibility being to cooperate to support the litigation proceedings as needed. The Indemnification Agreement provides that Liquidia PAH and its affiliates will not be entitled to any proceeds resulting from, or bear any financial or other liability for, the United Therapeutics and Smiths Medical ASC litigation unless there is an event of default by PBM. Any Liquidia PAH litigation expenses not reimbursed by Henderson under the Financing Agreement will be reimbursed by PBM. Any proceeds received which Henderson is not entitled to under the Financing Agreement will be due to PBM.

The Indemnification Asset is increased as the Company records third party legal and litigation expenses related to the United Therapeutics and Smiths Medical ASC litigation.

As of September 30, 2021 and December 31, 2020, the Indemnification Asset and Litigation Finance Payable were classified as long-term assets and liabilities, respectively as it is considered unlikely that the litigation would conclude prior to September 30, 2022.

**6. Stockholders' Equity Authorized Capital**

As of September 30, 2021, the authorized capital of the Company consists of 90,000,000 shares of capital stock, $0.001 par value per share, of which 80,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock.

**Common Stock**

Upon any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company, the holders of the common stock shall be entitled to receive that portion of the remaining funds to be distributed to the stockholders, subject to the liquidation preferences of any outstanding preferred stock, if any. Such funds shall be paid to the holders of common stock on the basis of the number of shares so held by each of them.

***Issuance of Common Stock on April 13, 2021 from a Private Placement***

On April 12, 2021, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with a fund and account managed by Caligan Partners LP and certain other accredited investors for the sale by the Company in a private placement (the "Private Placement") of an aggregate of 8,626,037 shares of the Company's Common Stock at a purchase price of $2.52 per share.

The Private Placement closed on April 13, 2021 and the Company received gross proceeds of approximately $21.7 million. The Company intends to use the proceeds from the Private Placement to strengthen its commercial capability for the introduction of LIQ861 and the subcutaneous administration of Treprostinil Injection, for growth initiatives, and for general corporate purposes.

***Issuance of Common Stock on July 2, 2020 from an Underwritten Public Offering***

On June 29, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Jefferies LLC, as representative of the several underwriters named therein (collectively, the "Underwriters"), pursuant to which 9,375,000 shares of the Company's Common Stock were sold in an underwritten registered public offering at an offering price of $8.00 per Share (the "Offering").

The Offering closed on July 2, 2020, and the Company received net proceeds of approximately $70.3 million from the sale of the Shares, after deducting the underwriting discounts and commissions and other offering expenses. The

Company intends to use the net proceeds from this Offering for ongoing commercial development of LIQ861 and for general corporate purposes. The Company's management will retain broad discretion over the allocation of the net proceeds.

***Issuance of Common Stock from the ATM Agreement Commencing in August 2019***

In August 2019, the Company entered into a sales agreement (the "ATM Agreement") with Jefferies LLC ("Jefferies") to issue and sell shares of the Company's common stock, having an aggregate offering price of up to $40.0 million, from time to time during the term of the ATM Agreement, through an "at-the-market" equity offering program at the Company's sole discretion, under which Jefferies acted as the Company's agent and/or principal. The Company paid Jefferies a commission equal to 3.0% of the gross proceeds of any common stock sold through Jefferies under the ATM Agreement. During the nine months ended September 30, 2021, the Company sold 131,425 shares of common stock for net proceeds of $0.7 million after deducting the underwriting discounts and other offering expenses under the ATM Agreement. The ATM Agreement terminated upon the closing of the Merger Transaction.

**Warrants**

During the nine months ended September 30, 2021 and 2020, no warrants to purchase shares of common stock were exercised.

As of September 30, 2021 outstanding warrants consisted of the following:

| | Number of warrants | Exercise Price | Expiration Date |
|---|---|---|---|
| SVB Warrant - Initial Tranche (see Note 13) | 100,000 | $ 3.05 | February 26, 2031 |
| SVB Warrant - Term B and Term C Tranches (see Note 13) | 100,000 | $ n/a | February 26, 2031 |
| Other warrants | 106,274 | $ 0.02 | December 31, 2026 |

As of December 31, 2020 outstanding warrants consisted of the following:

| | Number of warrants | Exercise Price | Expiration Date |
|---|---|---|---|
| Other warrants | 106,274 | $ 0.02 | December 31, 2026 |

**7. Stock-Based Compensation**

The Company's 2020 Long-Term Incentive Plan (the "2020 Plan") was approved by stockholders in November 2020. In addition to stock options, the 2020 Plan provides for the granting of stock appreciation rights, stock awards, stock units, and other stock-based awards. The 2020 Plan provides for accelerated vesting under certain change of control transactions. A total of 1,700,000 shares of the Company's common stock was initially authorized and reserved for issuance under the 2020 Plan. This reserve will automatically increase each subsequent anniversary of January 1 through 2030, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Board of Directors (the "Evergreen Provision"). On January 1, 2021, the number of shares of common stock available for issuance under the 2020 Plan automatically increased by 1,733,432 shares to 2,955,432 shares from 1,222,000 pursuant to the Evergreen Provision. As of September 30, 2021, the Company had 939,709 shares available to issue under the 2020 Plan.

The 2020 Plan replaced the Company's 2018 Long-Term Incentive Plan (the "2018 Plan") and as a result the 2018 Plan was discontinued. The 2018 Plan had replaced the 2016 Equity Incentive Plan (the "2016 Plan") and 2004 Stock Option Plan (the "2004 Plan") as the Company's primary long-term incentive program. The 2018, 2016 and 2004 Plans have been discontinued but the outstanding awards under the 2018, 2016 and 2004 Plans will continue to remain in effect in accordance with their terms. Shares that are returned under the 2018, 2016 and 2004 Plans upon cancellation, termination or otherwise of awards outstanding under the 2018, 2016 and 2004 Plans will not be available for grant under the 2020 Plan. As of September 30, 2021, the Company had reserved for issuance 894,072 shares of common

stock under the 2018 Plan, 313,652 shares of common stock under the 2016 Plan and 200,392 shares of common stock under the 2004 Plan, representing the remaining outstanding options granted under the 2018, 2016 and 2004 Plans.

During December 2020, the Company issued a stock option grant to its new chief executive officer (the "CEO") to purchase up to 2,000,000 shares of the Company's common stock (the "CEO Option") at the exercise price on the grant date of $3.00 per share. The CEO Option was issued outside of the 2020 Plan and is subject to the following vesting schedule: 25% of the CEO Option will become vested and exercisable on the first anniversary of December 14, 2020 and the balance will become vested and exercisable in equal monthly installments over the following thirty-six months, subject to the CEO's continuous employment with the Company. However, the CEO Option is subject to the following accelerated vesting events:

(i) If the Company receives tentative approval by the FDA of the Company's New Drug Application for LIQ861 prior to June 30, 2022, and the CEO is actively employed by the Company on such date, then 25% of the then-unvested portion of the CEO Option shall become vested and exercisable as of the date of the FDA's tentative approval. As of September 30, 2021 this event had not occurred.

(ii) If the Company achieves commercial availability of the subcutaneous Treprostinil product with cartridge supplies sufficient to support the market for one year by December 31, 2021, and the CEO is actively employed by the Company on such date, then 25% of the then-unvested portion of the CEO Option shall become vested and exercisable as of the date the Company can document by competent proof to the Board of the achievement of such milestone. In addition, the CEO Option will become 100% vested upon certain change of control transactions. As of September 30, 2021 this event was deemed probable to occur and an additional $236,176 charge to stock-based compensation expense was recorded during the quarter ended September 30, 2021 associated with the acceleration.

***Stock-Based Compensation Valuation and Expense***

The Company accounts for its employee stock-based compensation plans using the fair value method. The fair value method requires the Company to estimate the grant-date fair value of its stock-based awards and amortize this fair value to compensation expense over the requisite service period or vesting term. The fair value of each option grant is estimated using a Black-Scholes option-pricing model.

For restricted stock units ("RSUs"), the grant-date fair value is based upon the market price of the Company's common stock on the date of the grant. This fair value is then amortized to compensation expense over the requisite service period or vesting term.

The Company recorded the following stock-based compensation expense:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **By Expense Category:** | **2021** | **2020** | **2021** | **2020** |
| Research and development | $ 288,116 | $ 292,386 | $ 816,966 | $ 853,704 |
| General and administrative | 935,928 | 788,614 | 2,105,293 | 2,094,378 |
| Total stock-based compensation expense | $ 1,224,044 | $ 1,081,000 | $ 2,922,259 | $ 2,948,082 |

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **By Type of Award:** | **2021** | **2020** | **2021** | **2020** |
| Stock options | $ 1,218,694 | $ 1,044,991 | $ 2,927,149 | $ 2,843,409 |
| Restricted stock units | 5,350 | 36,009 | (4,890) | 104,673 |
| Total stock-based compensation expense | $ 1,224,044 | $ 1,081,000 | $ 2,922,259 | $ 2,948,082 |

The following table summarizes the unamortized compensation expense and the remaining years over which such expense would be expected to be recognized, on a weighted average basis, by type of award:

| | As of September 30, 2021 | |
|---|---|---|
| | Unamortized Expense | Weighted Average Remaining Recognition Period (Years) |
| Stock options | $ 9,139,975 | 3.1 |
| Restricted stock units | $ 812,560 | 1.3 |

***Stock Options***

The following table summarizes the assumptions used for estimating the fair value of stock options granted under the Black-Scholes option-pricing model during:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Expected dividend yield | — | — |
| Risk-free interest rate | 0.62% - 1.67% | 0.40% - 1.60% |
| Expected volatility | 91% - 96% | 87% - 90% |
| Expected life (years) | 5.2 - 6.1 | 6.3 |

As a result of using these assumptions in the Black-Scholes option-pricing model, the weighted average fair value for options granted during the nine months ended September 30, 2021 and 2020 was $2.02 and $4.16 per share, respectively.

The following describes each of these assumptions and the Company's methodology for determining each assumption:

Expected Dividend Yield

The dividend yield percentage is zero because the Company neither currently pays dividends nor intends to do so during the expected option term.

Risk-Free Interest Rate

The risk-free interest rate is based on the U.S. Treasury yield curve approximating the term of the expected life of the award in effect on the date of grant.

Expected Volatility

Expected stock price volatility is based on a weighted average of several peer public companies and the historical volatility of the Company's common stock during the period for which it has traded since the initial public offering. For purposes of identifying peer companies, the Company considered characteristics such as industry, length of trading history and similar vesting terms.

Expected Life

The expected life represents the period the awards are expected to be outstanding. The Company's historical share option exercise experience does not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data. Therefore, the Company estimates the expected term by using the simplified method.

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2021:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Contractual Term (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| **Outstanding as of December 31, 2020** | 4,692,071 | $ 5.51 | | |
| Granted | 2,000,750 | 2.70 | | |
| Exercised | (623) | 2.33 | | |
| Cancelled | (1,062,059) | 7.11 | | |
| **Outstanding as of September 30, 2021** | 5,630,139 | $ 4.21 | 8.3 | $ 291,098 |
| Exercisable as of September 30, 2021 | 1,308,478 | $ 7.22 | 5.0 | $ 49,750 |
| Vested and expected to vest as of September 30, 2021 | 5,605,939 | $ 4.20 | 8.3 | $ 291,098 |

The aggregate intrinsic value of stock options in the table above represents the difference between the $2.76 closing price of the Company's common stock as of September 30, 2021 and the exercise price of outstanding, exercisable, and vested and expected to vest in-the-money stock options.

***Restricted Stock Units***

Restricted Stock Units ("RSUs") represent the right to receive shares of common stock of the Company at the end of a specified time period or upon the achievement of a specific milestone. RSUs can only be settled in shares of the Company's common stock. During the nine months ended September 30, 2021, the Board of Directors approved grants of an aggregate of 334,015 performance-based RSUs to employees. These performance RSUs vest upon the tentative approval by the FDA of the Company's New Drug Application for LIQ861. The achievement of this performance milestone was not deemed probable as of September 30, 2021. During March 2020, the Board of Directors approved grants of an aggregate of 138,464 non-performance-based RSUs to employees. RSUs represent the right to receive shares of common stock of the Company at the end of a specified time period. The RSUs vest over a four-year period similar to stock options granted to employees.

A summary of nonvested RSU awards outstanding as of September 30, 2021 and changes during the nine months then ended is as follows:

| | Number of RSUs | Weighted Average Grant-Date Fair Value (per RSU) |
|---|---|---|
| Nonvested as of December 31, 2020 | 88,131 | $ 4.68 |
| Granted | 334,015 | 2.97 |
| Vested | (14,209) | 3.33 |
| Forfeited | (136,237) | 3.99 |
| Nonvested as of September 30, 2021 | 271,700 | $ 2.99 |

***Employee Stock Purchase Plan***

In November 2020, stockholders approved the Liquidia Corporation 2020 Employee Stock Purchase Plan (the "2020 ESPP"). As of September 30, 2021, a total of 300,000 shares of the Company's common stock are reserved for issuance under the 2020 ESPP. The initial six-month offering period commenced on September 1, 2021 and will be followed by successive six-month offering periods. The 2020 ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions, subject to plan limitations. Unless otherwise determined by the administrator, the Company's common stock will be purchased for the accounts of employees participating in the 2020 ESPP at a price per share that is 85% of the fair market value of the Company's common stock on the last trading day of the offering period.

**8. License Agreements**

The Company performs research under a license agreement with The University of North Carolina at Chapel Hill ("UNC") as amended to date (the "UNC License Agreement"). As part of the UNC License Agreement, the Company holds an exclusive license to certain research and development technologies and processes in various stages of patent pursuit, for use in its research and development and commercial activities, with a term until the expiration date of the last to expire patent subject to the UNC License Agreement, subject to industry standard contractual compliance. Under the UNC License Agreement, the Company is obligated to pay UNC royalties equal to a low single digit percentage of all net sales of drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC License Agreement, including LIQ861. The Company may grant sublicenses of UNC licensed intellectual property in return for specified payments based on a percentage of any fee, royalty or other consideration received.

**9. Revenue From Contracts With Customers**

On August 1, 2018, the Company partnered with Sandoz in the Promotion Agreement to launch the first-to-file generic of Treprostinil Injection for the treatment of patients with PAH. Under the Promotion Agreement, the Company provides certain promotional and nonpromotional activities on an exclusive basis for the product in the United States of America for the treatment of PAH. In addition, the Company paid Sandoz $20 million at the inception of the Promotion Agreement, in consideration for the right to conduct the promotional and nonpromotional activities for the product. In exchange for its services, the Company is entitled to receive a portion of net profits, as defined within the Promotion Agreement, based on specified profit levels associated with the product.

The Company determined that certain activities within the contract are within the scope of ASC 808, Collaborative Arrangements. The commercialization of the product is a joint operating activity where the Company will provide promotional and nonpromotional activities for Sandoz's product and Sandoz will be responsible for items such as supply of the product, distribution to customers, managing sales, processing returns, and regulatory matters. Both parties will be active participants, each carrying out its assigned responsibilities, and participating in the joint operating activity and will share in the risks and rewards of the commercialization through the profit-sharing arrangement.

In addition, the Company determined that the services provided under the Promotion Agreement fall within the scope of Topic 606. The promotional and nonpromotional activities the Company performs are one of the services the Company expects to provide as part of its ordinary activities, and it is receiving consideration for this service from Sandoz in the form of a share of "Net Profits" (as defined in the Promotion Agreement). The Company has one combined performance obligation under the Promotion Agreement, which is to perform promotional and nonpromotional activities to encourage the appropriate use of the product in accordance with the product labeling and applicable law. As such, and in accordance with ASU 2018-18: Clarifying the Interaction between Topic 808 and Topic 606, the Company will account for the entire Promotion Agreement under Topic 606.

The Company derived approximately 99% of its revenue from the Promotion Agreement during the three and nine months ended September 30, 2021

***Refund Liability***

In accordance with the Promotion Agreement, Liquidia PAH receives consideration from Sandoz in the form of a share of Net Profits for the promotional activities it performs. The share of Net Profits received is subject to adjustments from Sandoz for items such as distributor chargebacks, rebates, inventory returns, inventory write-offs and other adjustments (the "Net Profits Adjustment"). The Company expects to refund certain amounts to Sandoz through a reduction of the cash received from future Net Profits generated under the Promotion Agreement. As of September 30, 2021, a $526,491 refund liability is offset against accounts receivable from Sandoz related to net service revenues recognized during the nine months ended September 30, 2021. As of December 31, 2020 $927,136 of accounts receivable from Sandoz related to net service revenues was offset against the refund liability.

**10. Property, Plant and Equipment**

Property, plant and equipment consisted of the following:

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Lab and build-to-suit equipment | $ 7,544,098 | $ 7,499,645 |
| Office equipment | 28,410 | 31,205 |
| Furniture and fixtures | 257,774 | 257,774 |
| Computer equipment | 463,789 | 404,558 |
| Leasehold improvements | 11,506,332 | 11,524,738 |
| Construction-in-progress | — | 65,820 |
| Total property, plant and equipment | 19,800,403 | 19,783,740 |
| Accumulated depreciation and amortization | (14,348,134) | (12,978,170) |
| Property, plant and equipment, net | $ 5,452,269 | $ 6,805,570 |

The Company recorded depreciation and amortization expense of $428,010 and $722,325 for the three months ended September 30, 2021 and 2020, respectively, and $1,372,632 and $2,178,402 for the nine months ended September 30, 2021 and 2020, respectively.

**11. Income Taxes**

The Company did not record a federal or state income tax expense or benefit during the three and nine months ended September 30, 2021 as a result of the establishment of a full valuation allowance being required against the Company's net deferred tax assets.

**12. Leases, Commitments and Contingencies**

**Leases**

The Company leases certain laboratory space, office space, and equipment. Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term. For lease agreements entered into or reassessed after the adoption of Topic 842, the Company combines lease and non-lease components, if any. Most leases include one or more options to renew. The exercise of lease renewal options is at the Company's sole discretion. Certain leases also include options to purchase the leased property. Consistent with past practice and current intent, the Company has recognized all such purchase options as part of its right-of-use assets and lease liabilities. The depreciable life of assets and leasehold improvements are limited by the expected lease term unless there is a transfer of title or purchase option reasonably certain of exercise. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company conducts its operations from leased facilities of approximately 45,000 square feet in Morrisville, North Carolina with a lease expiration date of October 31, 2026. In addition, the Company leases specialized laboratory equipment under finance leases. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset.

The Company does not have access to certain inputs used by its lessors to calculate the rate implicit in its finance leases. As such, the Company utilized its estimated incremental borrowing rate for the discount rate applied to its finance leases. The original incremental borrowing rate used on finance leases was 7.5%. During February 2021, the Company exercised the lease purchase option for certain finance leases that had expired and entered into a lease modification agreement with its existing lessor for certain other finance leases. The modification resulted in an increase in the remaining lease term of between 24 and 48 months as well as a decrease in the monthly payments associated with the respective modified leases. The incremental borrowing rate used on the modified leases was 6.5%. The lease modification had an immaterial impact on the Company's condensed consolidated financial statements.

The Company's lease cost is reflected in the accompanying condensed statements of operations and comprehensive loss as follows:

| | Classification | Three Months Ended September 30, 2021 | Three Months Ended September 30, 2020 | Nine Months Ended September 30, 2021 | Nine Months Ended September 30, 2020 |
|---|---|---|---|---|---|
| Operating lease cost | General and administrative | $ 195,118 | $ 195,118 | $ 585,353 | $ 585,353 |
| Finance lease cost: | | | | | |
| Amortization of lease assets | General and administrative | 41,800 | 328,946 | 227,187 | 1,027,123 |
| Interest on lease liabilities | Interest expense | 12,632 | 27,431 | 31,651 | 100,911 |
| Total Lease Cost | | $ 249,550 | $ 551,495 | $ 844,191 | $ 1,713,387 |

The weighted average remaining lease term and discount rates as of September 30, 2021 were as follows:

| | |
|---|---|
| Weighted average remaining lease term (years): | |
| Operating leases | 5.1 |
| Finance leases | 2.6 |
| Weighted average discount rate: | |
| Operating leases | 10.3 % |
| Finance leases | 6.5 % |

The discount rate for operating leases was estimated based upon market rates of collateralized loan obligations of comparable companies on comparable terms.

The future minimum lease payment as of September 30, 2021 were as follows:

| Year ending December 31: | Operating Leases | Finance Leases | Total |
|---|---|---|---|
| 2021 - three months remaining | $ 306,436 | $ 101,326 | $ 407,762 |
| 2022 | 1,243,934 | 342,762 | 1,586,696 |
| 2023 | 1,283,253 | 195,350 | 1,478,603 |
| 2024 | 1,316,540 | 114,727 | 1,431,267 |
| 2025 | 1,355,923 | 64,161 | 1,420,084 |
| Thereafter | 1,157,807 | — | 1,157,807 |
| Total minimum lease payments | 6,663,893 | 818,326 | 7,482,219 |
| Less: Interest | (1,480,512) | (65,527) | (1,546,039) |
| Present value of lease liabilities | $ 5,183,381 | $ 752,799 | $ 5,936,180 |

**Commitments**

In connection with the Merger Transaction, we agreed to issue additional consideration of up to 2,708,333 additional shares of common stock to the former equity holders of RareGen (now Liquidia PAH) contingent on achievement of certain Liquidia PAH revenue targets during the year ending December 31, 2021. As of September 30, 2021 and December 31, 2020, the fair value of this contingent consideration was deemed to be immaterial.

In March 2012, the Company entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to the Company's manufacturing capabilities during the term of the agreement. The Company agreed to pay future contingent royalties, totaling no more than $1,500,000, on net sales of certain products. As of September 30, 2021, none of the contingent royalties had been earned.

We enter into contracts in the normal course of business with contract service providers to assist in the performance of our research and development and manufacturing activities. Subject to required notice periods and our obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. In addition, we have entered into a multi-year agreement with LGM Pharma, LLC (LGM) to produce active pharmaceutical ingredients

for LIQ861. Under our manufacturing agreement with LGM, we are required to provide rolling forecasts, a portion of which will be considered a binding, firm order, subject to an annual minimum purchase commitment of $3,050,000 for the term of the agreement. The agreement expires five years from the first marketing authorization approval of LIQ861. This minimum commitment was waived for the year ending December 31, 2021.

We also have employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control or termination without cause, occur.

**Contingencies**

The Company from time-to-time is subject to claims and litigation in the normal course of business, none of which the Company believes represent a risk of material loss or exposure.

**13. Long-Term Debt**

Long-term debt consisted of the following as of September 30, 2021 and December 31, 2020:

| | Maturity Date | September 30, 2021 | December 31, 2020 |
|---|---|---|---|
| Pacific Western Bank term loan | October 25, 2022 | $ — | $ 10,292,485 |
| Silicon Valley Bank term loan | September 1, 2024 | 10,331,648 | — |
| Less current portion | | — | — |
| Long-term debt | | $ 10,331,648 | $ 10,292,485 |

During 2020, the Company, Liquidia Merger Sub and RareGen Merger Sub entered into a Joinder and Second Amendment to Amended and Restated Loan and Security Agreement, dated as of October 26, 2018 (the "A&R LSA"), with Pacific Western Bank ("PWB"). The A&R LSA included interest only payments through December 2019 with principal and interest payments beginning in January 2020 and was scheduled to mature in October 2022.

The Company and its two wholly owned subsidiaries, Liquidia Technologies and Liquidia PAH, entered into a Loan and Security Agreement with SVB on February 26, 2021 (the "Effective Date") and a First Loan Modification Agreement with SVB on August 26, 2021. The Loan and Security Agreement, as amended by the First Loan Modification Agreement, is referred to as the "Loan Agreement." The Loan Agreement established a term loan facility in the aggregate principal amount of up to $20.5 million (the "Term Loan Facility"). An initial $10.5 million (the "Term A Loan") was funded on March 1, 2021 and was used to satisfy the Company's existing obligations under the A&R LSA, consisting of approximately $9.4 million in outstanding principal and interest, and such obligations are considered fully repaid and terminated as of that date, with the excess proceeds funded to the Company. The Company accounted for the repayment of the A&R LSA in accordance with ASC 405, *Extinguishments of Liabilities*, which resulted in a loss on extinguishment during the nine months ended September 30, 2021 of approximately $53,150, which is included in interest expense in the consolidated statement of operations and comprehensive loss.

Availability of $5.0 million under a second tranche of the Term Loan Facility (the "Term B Loan") is conditioned upon Liquidia having received tentative FDA approval for LIQ861 by June 30, 2022, and availability of $5.0 million under a third tranche of the Term Loan Facility (the "Term C Loan" and, collectively with the Term A Loan and Term B Loan, the "Term Loans") is conditioned upon Liquidia having received final and unconditional FDA approval for LIQ861 by December 31, 2022.

As security for its obligations under the Loan Agreement, Liquidia granted SVB a continuing security interest in substantially all of the assets of Liquidia, other than intellectual property.

The Term Loans made under the Term Loan Facility mature on September 1, 2024 (the "Maturity Date") and have an interest-only monthly payment period through March 31, 2023 (the "Interest-Only Period"). Following the Interest-Only Period, the Company will begin making monthly payments of principal and interest until the Maturity Date. Interest will accrue on the unpaid principal balance of the outstanding Term Loans at a floating per annum rate equal to the greater of

(i) the Wall Street Journal prime rate plus 0.75% and (ii) four percent (4.0%). Furthermore, on the earliest to occur of (x) the Maturity Date, (y) the date the Term Loans are repaid in full or (z) the date of termination of the Loan Agreement, the Company shall pay to SVB five percent (5.0%) of the aggregate original principal amount of all Term Loans made by SVB (the "Final Payment").

In the event that Liquidia elects to terminate the Term Loan Facility in its entirety, it may do so at any time by paying the outstanding principal balance, unpaid accrued interest, the Final Payment and a prepayment fee equal to (i) five percent (5.0%) of the outstanding principal balance, if such prepayment is made during the Interest-Only Period or (ii) zero, if such prepayment is made after the Interest-Only Period and before the Maturity Date.

Subject to certain exceptions, the Loan Agreement contains covenants prohibiting the Company from, among other things, and subject to certain limited exceptions: (a) conveying, selling, leasing, transferring or otherwise disposing of its properties or assets; (b) liquidating or dissolving; (c) engaging in any business other than the business currently engaged in or reasonably related thereto by it or any of its subsidiaries; (d) engaging in mergers or acquisitions; (e) incurrence of additional indebtedness; (f) allowing any lien or encumbrance on any of its property; (g) paying any dividends; (h) repurchasing its equity; and (i) making payment on subordinated debt. In addition, the Loan Agreement requires Liquidia to maintain an unrestricted and unencumbered "Minimum Cash Balance" (as defined therein) equal to at least (i) $30.0 million during the period commencing on the Effective Date and including the date immediately prior to the funding date of the Term B Loan (the "Term B Loan Funding Date") and (ii) during the period commencing on the Term B Loan Funding Date through and including the date immediately prior to the funding date of the Term C Loan (the "Term C Loan Funding Date"), $35.0 million. Moreover, in the event the Minimum Cash Balance is not achieved during any calendar quarter during the term of the Loan Agreement, the Loan Agreement requires Liquidia to maintain cumulative "Cash Burn" (as defined in the Loan Agreement) for the periods ending March 31, 2021, June 30, 2021, September 30, 2021, December 31, 2021 and March 31, 2022 and for each calendar quarter thereafter less than or equal to $10.5 million, $17.0 million, $56.1 million, $61.1 million and $65.6 million, respectively; *provided*, *however*, that the above amounts shall be increased by an amount equal to 75% of the aggregate net cash proceeds received by the Company from the sale of the Company's equity securities on or after June 30, 2021 but on or prior to the last day of such calendar quarter; *provided*, *further*, that upon the Term C Loan Funding Date, the Cash Burn covenant shall no longer apply. The Company was in compliance with the loan covenants as of September 30, 2021.

The Loan Agreement also contains customary events of default, including among other things, the Company's failure to make any principal or interest payments when due, the occurrence of certain bankruptcy or insolvency events or the Company's breach of the covenants under the Loan Agreement, or other material adverse changes relating to Liquidia. Furthermore, per the Loan Agreement, an event of default shall occur upon any formal court ruling against Liquidia that the SVB determines in its good faith business judgment is reasonably likely to prohibit its ability to obtain final approval from the FDA with respect to its New Drug Application for LIQ861 or impair or delay Liquidia's ability to commercialize LIQ861 as currently contemplated. Upon the occurrence of an event of default, SVB may, among other things, accelerate Liquidia's obligations under the Loan Agreement.

In connection with the Loan Agreement, the Company issued to SVB a warrant, dated as of the Effective Date (the "SVB Warrant") to purchase up to 200,000 shares of the Company's common stock, $0.001 par value per share (the "Common Stock"), of which (x) 100,000 shares vested on the Effective Date, with an exercise price per share equal to $3.05 (the "Initial Tranche"), and (y) 50,000 shares shall become exercisable on each of the Term B Loan Funding Date and Term C Loan Funding Date (if these events occur), with an exercise price per share equal to the lower of (i) the trailing 10-day average price of the Common Stock on the applicable funding date and (ii) the closing price per share of Common Stock on the trading day prior to applicable funding date (the "Term B and C Tranches"). The SVB Warrant is exercisable for ten (10) years from the date of issuance, and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of Common Stock is greater than the exercise price then in effect.

The Company evaluated the features of the Loan Agreement and SVB Warrant in accordance with ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. The Company determined that the Loan Agreement and Warrant did not contain any features that would qualify as a derivative or embedded derivative. In addition, the Company determined that the SVB Warrant should be classified as equity. The value of the SVB Warrant

is included in Additional Paid-in-Capital in the Company's condensed consolidated balance sheet as of September 30, 2021. The estimated fair value of the SVB Warrant of was calculated using the Black-Scholes Option Pricing Model based on the following inputs:

| | |
|---|---|
| Expected dividend yield | — |
| Risk-free interest rate | 1.43% |
| Expected volatility | 90.8% |
| Expected life (years) | 10.0 |

In accordance with ASC 470, *Debt*, the value of the Warrant and the Term A Loan were allocated using a relative fair value allocation with $261,000 allocated to the Warrant as a debt discount and additional paid-in-capital and $10,239,000 allocated to the Term A Loan. In addition, the Company incurred fees of approximately $88,000, which were recorded as a reduction in the face value of the Term A Loan. The debt discount and debt issuance costs are being amortized to interest expense and the Final Payment is being accreted using the effective interest method over the term of the Term A Loan.

Scheduled annual maturities of long-term debt as of September 30, 2021 are as follows:

| **Year ending December 31:** | |
|---|---|
| 2021 – three months remaining | $ — |
| 2022 | — |
| 2023 | 5,250,000 |
| 2024 | 5,250,000 |
| Thereafter | — |
| Total | 10,500,000 |
| Less: Unamortized discount, debt issuance costs and accretion | (168,352) |
| Less: Current portion of long-term debt | — |
| Long-term debt, noncurrent | $ 10,331,648 |

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.*

**Overview**

We are a biopharmaceutical company focused on the development, manufacturing and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension (PH). We operate as a single entity through our two wholly owned operating subsidiaries, Liquidia Technologies and Liquidia PAH (formerly known as RareGen).

We generate revenue pursuant to a Promotion Agreement between Liquidia PAH and Sandoz Inc. ("Sandoz") sharing profit derived from the sale of the first-to-file fully substitutable generic treprostinil injection ("Treprostinil Injection") in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies in the treatment of pulmonary arterial hypertension ("PAH"), as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of LIQ861 upon approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

We conduct research, development and manufacturing of novel products by applying our proprietary PRINT® technology, a particle engineering platform, to enable precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. We have development experience in inhaled therapies, vaccines, biologics, and implants, among others.

Since our inception, we have incurred significant operating losses. Our net loss was $23.0 million for the nine months ended September 30, 2021 and $59.8 million and $47.6 million for the years ended December 31, 2020 and 2019, respectively. As of September 30, 2021, we had an accumulated deficit of $298.0 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates.

**Product Pipeline**

Our lead product candidate is LIQ861 for the treatment of PAH. LIQ861, is an inhaled dry powder formulation of treprostinil designed to improve the therapeutic profile of treprostinil by enhancing deep lung delivery and achieving higher dose levels than current inhaled therapies while using a convenient, east-to-use dry-powder inhaler ("DPI"). We submitted the New Drug Application ("NDA") for LIQ861 in January 2020. In November 2020, the Company received a Complete Response Letter ("CRL") issued by the Food and Drug Administration ("FDA") with respect to the NDA for LIQ861. In May 2021, the Company resubmitted the NDA for LIQ861 in response to the CRL. In June of 2021, the FDA accepted the Company's resubmitted NDA for LIQ861 for review and established a PDUFA goal date of November 7, 2021. Subsequent to the resubmission of the NDA for LIQ861, the FDA confirmed the need to conduct on-site pre-approval inspections of two U.S. manufacturing facilities before the NDA for LIQ861 can be approved: the Company's Morrisville, NC facility and the facility of the third-party provider of encapsulation and packaging services for LIQ861. These pre-approval inspections were completed in August of 2021 and October of 2021, respectively.

**Components of Consolidated Statements of Operations**

***Revenue***

We primarily generate revenue pursuant to the Promotion Agreement, under which we share in the profit derived from the sale of Treprostinil Injection in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. On May 21, 2021 Liquidia PAH's manufacturing partner, Chengdu Shifeng Medical Technologies LTD ("Chengdu") began selling the RG 3ml Medication Cartridge, which may be used to supply medications to PAH patients. Following this clearance, we expect unit sales of Treprostinl Injection to increase, however, due to a reduction in the contractual profit split percentage from 80% to 50% as a result of achievement of predetermined cumulative sales thresholds revenues are expected to grow at a slower pace than unit sales. Previously, we also derived revenue from licensing our proprietary PRINT® technology and from conducting research, development and manufacturing of novel products by applying our proprietary PRINT® technology.

***Cost of Revenue***

Cost of revenue consists of (i) the cost of employing a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of PAH, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection and (ii) a portion of the amortization of the intangible asset associated with the Promotion Agreement. Previously, cost of revenue also included amortization of license fees owed to UNC upon our receipt of licensing revenues. We amortize the Promotion Agreement in a manner consistent with our recognition of the related revenue.

***Research and Development Expenses***

Research and development expenses consist of expenses incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing process development and scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation for personnel in research and development functions;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. In the near term we expect our research and development expenses to remain consistent with the three months ended September 30, 2021, however, levels of research and development spending are highly dependent upon the selection and progression of product candidates. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of

our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, or our ability to manufacture and supply product, we could be required to expend significant additional financial resources and time on the completion of clinical development. Drug commercialization will take several years and millions of dollars in development costs.

***General and Administrative Expenses***

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for marketing, legal, auditing and tax services and insurance costs. When we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to sales and marketing.

***Other Income (Expense)***

Other income (expense) is comprised primarily of interest income and expense. Interest income consists of interest earned on our cash deposits. Interest expense consists of interest charges on leases and debt. These charges include monthly recurring interest on such obligations in addition to non-cash charges. Non-cash charges include loss on extinguishment, interest accretion, expensing of debt issuance costs and amortization of discounts on long-term debt to interest expense.

**Critical Accounting Estimates**

We discussed our accounting policies and significant assumptions used in our estimates in Note 2 of our audited financial statements included in our 2020 Annual Report on Form 10-K. There have been no material changes during the nine months ended September 30, 2021 to our critical accounting policies, significant judgments and estimates disclosed in our 2020 Annual Report on Form 10-K.

**Results of Operations**

***Three and Nine Months Ended September 30, 2021 compared with the Three and Nine Months Ended September 30, 2020***

The following table summarizes the results of our operations for the three and nine months ended September 30, 2021 and 2020, together with the changes in those items in dollars and as a percentage (in thousands, except for percentages):

| | Three Months Ended September 30, | | $ | % | Nine Months Ended September 30, | | $ | % |
|---|---|---|---|---|---|---|---|---|
| | 2021 | 2020 | Change | Change | 2021 | 2020 | Change | Change |
| | | | | (in thousands) | | | | |
| Revenue | $ 3,179 | $ — | $ 3,179 | * | $ 9,638 | $ — | $ 9,638 | * |
| Costs and expenses: | | | | | | | | |
| Cost of revenue | 890 | — | 890 | * | 2,297 | — | 2,297 | * |
| Research and development | 4,487 | 7,661 | (3,174) | (41.4)% | 15,136 | 26,975 | (11,839) | (43.9)% |
| General and administrative | 4,882 | 7,152 | (2,270) | (31.7)% | 14,640 | 16,201 | (1,561) | (9.6)% |
| Total costs and expenses | 10,259 | 14,813 | (4,554) | (30.7)% | 32,073 | 43,176 | (11,103) | (25.7)% |
| Loss from operations | (7,080) | (14,813) | 7,733 | (52.2)% | (22,435) | (43,176) | 20,741 | (48.0)% |
| Other income (expense): | | | | | | | | |
| Interest income | 4 | 35 | (31) | (88.6)% | 30 | 156 | (126) | (80.8)% |
| Interest expense | (205) | (191) | (14) | 7.3 % | (610) | (656) | 46 | (7.0)% |
| Total other expense, net | (201) | (156) | (45) | 28.8 % | (580) | (500) | (80) | 16.0 % |
| Net loss and comprehensive loss | $ (7,281) | $ (14,969) | $ 7,688 | (51.4)% | $ (23,015) | $ (43,676) | $ 20,661 | (47.3)% |

* Not meaningful

**Revenue**

We recognized no revenue for the three months ended September 30, 2020, compared to $3.2 million for the three months ended September 30, 2021. Revenue recognized during 2021 related primarily to the Promotion Agreement after the acquisition of Liquidia PAH in November 2020.

We recognized no revenue for the nine months ended September 30, 2020, compared to $9.6 million for the the nine months ended September 30, 2021. Revenue recognized during 2021 related primarily to the Promotion Agreement after the acquisition of Liquidia PAH in November 2020.

**Cost of Revenue**

We recognized no cost of revenue for the three months ended September 30, 2020, compared to $0.9 million for the three months ended September 30, 2021. Cost of revenue recognized during 2021 related to the Promotion Agreement as noted above.

We recognized no cost of revenue for the nine months ended September 30, 2020, compared to $2.3 million for the nine months ended September 30, 2021. Cost of revenue recognized during 2021 related to the Promotion Agreement as noted above.

**Research and Development Expenses**

Research and development expenses were $4.5 million for the three months ended September 30, 2021 compared with $7.7 million for the three months ended September 30, 2020, a decrease of $3.2 million or 41.4%. The decrease

primarily related to lower expenses from our LIQ861 clinical program as well as lower employee and consulting expenses. During the three months ended September 30, 2021, we incurred $1.3 million related to LIQ861 compared to $4.2 million during the three months ended September 30, 2020. Research and development expenses for the three months ended September 30, 2021 and 2020 also included $2.0 million and $2.9 million in consulting and personnel costs, including stock-based compensation, respectively. This decrease was primarily driven by lower headcount year-over-year.

Research and development expenses were $15.1 million for the nine months ended September 30, 2021 compared with $27.0 million for the nine months ended September 30, 2020, a decrease of $11.9 million or 43.9%. The decrease primarily related to lower expenses from our LIQ861 clinical program, which was substantially completed prior to filing the NDA in April 2020 and lower employee and consulting expenses. During the nine months ended September 30, 2021, we incurred $5.6 million related to LIQ861 compared to $14.6 million during the the nine months ended September 30, 2020. Research and development expenses for the the nine months ended September 30, 2021 and 2020 also included $6.2 million and $9.9 million in consulting and personnel costs, including stock-based compensation, respectively. This decrease was primarily driven by lower headcount year-over-year.

**General and Administrative Expenses**

General and administrative expenses were $4.9 million for the three months ended September 30, 2021, compared with $7.2 million for the three months ended September 30, 2020. The decrease of $2.3 million or 31.7% was primarily due to $2.9 million lower consulting expenses and professional fees associated with corporate activities offset by a $0.6 million increase in legal fees related to our ongoing LIQ861-related litigation.

General and administrative expenses were $14.6 million for the nine months ended September 30, 2021 compared with $16.2 million for the nine months ended September 30, 2020. The decrease of $1.6 million or 9.6% was primarily due to $5.1 million lower consulting expenses and professional fees associated with corporate activities offset by a $3.8 million increase in legal fees related to our ongoing LIQ861-related litigation.

**Liquidity and Capital Resources**

As of September 30, 2021 and December 31, 2020, we had cash and cash equivalents of $64.1 million and $65.3 million, respectively.

We have financed our growth and operations through a combination of funds generated from revenues, the issuance of convertible preferred stock and common stock, finance leases, bank borrowings and the issuance of convertible notes. Our principal uses of cash and cash equivalents have been for working capital requirements and capital expenditures. As of September 30, 2021, we had a cash and cash equivalents of $64.1 million, stockholders’ equity of $73.0 million and an accumulated deficit of $298.0 million.

In April 2021, we entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with certain institutional, accredited investors (the “Purchasers”) for the sale by us in a private placement (the “Private Placement”) of an aggregate of 8,626,037 shares (the “Private Placement Shares”) of our common stock, at a purchase price of $2.52 per Private Placement Share. The gross proceeds from the sale of the Private Placement Shares were $21.7 million.

In July 2020, we closed an underwritten public offering of 9,375,000 shares of our common stock at a price of $8.00 per share. The gross proceeds from the offering were $75.0 million and net proceeds were approximately $70.3 million, after deducting underwriting discounts and commissions and other offering expenses.

In August 2019, we entered into a sales agreement (the “ATM Agreement”) with Jefferies to issue and sell shares of our common stock, having an aggregate offering price of up to $40.0 million, from time to time during the term of the ATM Agreement, through an “at-the-market” equity offering program at our sole discretion, under which Jefferies acted as our agent and/or principal. We paid Jefferies a commission equal to 3.0% of the gross proceeds of any common stock sold through Jefferies under the ATM Agreement. During the year ended December 31, 2020, we sold 131,425 shares of our

common stock for net proceeds of $0.7 million, after deducting underwriting discounts and other offering expenses under the ATM Agreement.

We entered into a Loan and Security Agreement with SVB in February 2021 and a First Loan Modification Agreement with SVB in August 2021. The Loan and Security Agreement, as amended by the First Loan Modification Agreement, is referred to as the "Loan Agreement." The proceeds of the Loan Agreement were used to pay off the approximately $9.4 million in outstanding principal and interest under the A&R LSA. We received a 24-month interest-only period and also have access to additional tranches of capital, pending achievement of certain milestones.

The Loan Agreement established a term loan facility in the aggregate principal amount of up to $20.5 million (the "Term Loan Facility"). An initial $10.5 million (the "Term A Loan") was funded on March 1, 2021. Availability of $5.0 million under the second tranche of the Term Loan Facility (the "Term B Loan") is conditioned upon us having received tentative U.S. Food and Drug Administration (FDA) approval for LIQ861 by June 30, 2022, and availability of $5.0 million under the third tranche of the Term Loan Facility (the "Term C Loan" and, collectively with the Term A Loan and Term B Loan, the "Term Loans") is conditioned upon us having received final and unconditional FDA approval for LIQ861 by December 31, 2022. The entire Term A Loan was used to satisfy our existing obligations under our previously disclosed Amended and Restated Loan and Security Agreement, dated as of October 26, 2018, as amended, by and between us and PWB, consisting of approximately $9.4 million in outstanding principal and interest, and such obligations are considered fully repaid and terminated.

As security for its obligations under the Loan Agreement, we granted SVB a continuing security interest in substantially all of our assets, other than intellectual property.

The Term Loans made under the Term Loan Facility mature on September 1, 2024 (the "Maturity Date") and have an interest-only monthly payment period through March 31, 2023 (the "Interest-Only Period"). Following the Interest-Only Period, we will begin making monthly payments of principal and interest until the Maturity Date. Interest will accrue on the unpaid principal balance of the outstanding Term Loans at a floating per annum rate equal to the greater of (i) the Wall Street Journal prime rate plus 0.75% and (ii) four percent (4.0%). Furthermore, on the earliest to occur of (x) the Maturity Date, (y) the date the Term Loans are repaid in full or (z) the date of termination of the Loan Agreement, we shall pay to SVB five percent (5.0%) of the aggregate original principal amount of all Term Loans made by SVB (the "Final Payment").

In the event that we elect to terminate the Term Loan Facility in its entirety, we may do so at any time by paying the outstanding principal balance, unpaid accrued interest, the Final Payment and a prepayment fee equal to (i) five percent (5.0%) of the outstanding principal balance, if such prepayment is made during the Interest-Only Period or (ii) zero, if such prepayment is made after the Interest-Only Period and before the Maturity Date.

Subject to certain exceptions, the Loan Agreement contains covenants prohibiting us from, among other things, and subject to certain limited exceptions: (a) conveying, selling, leasing, transferring or otherwise disposing of our properties or assets; (b) liquidating or dissolving; (c) engaging in any business other than the business currently engaged in or reasonably related thereto by us or any of our subsidiaries; (d) engaging in mergers or acquisitions; (e) incurrence of additional indebtedness; (f) allowing any lien or encumbrance on any of our property; (g) paying any dividends; (h) repurchasing our equity; and (i) making payment on subordinated debt. In addition, the Loan Agreement requires us to maintain an unrestricted and unencumbered "Minimum Cash Balance" (as defined therein) equal to at least (i) $30.0 million during the period commencing on the Effective Date and including the date immediately prior to the funding date of the Term B Loan (the "Term B Loan Funding Date") and (ii) during the period commencing on the Term B Loan Funding Date through and including the date immediately prior to the funding date of the Term C Loan (the "Term C Loan Funding Date"), $35.0 million. Moreover, in the event the Minimum Cash Balance is not achieved during any calendar quarter during the term of the Loan Agreement, the Loan Agreement requires us to maintain cumulative "Cash Burn" (as defined in the Loan Agreement) for the periods ending March 31, 2021, June 30, 2021, September 30, 2021, December 31, 2021 and March 31, 2022 and for each calendar quarter thereafter equal to $10.5 million, $17.0 million, $56.1 million, $61.1 million and $65.6 million, respectively; *provided*, *however*, that the above amounts shall be increased by an amount equal to 75% of the aggregate net cash proceeds received by us from the sale of our equity

securities on or after June 30, 2021 but on or prior to the last day of such calendar quarter; *provided*, *further*, that upon the Term C Loan Funding Date, the Cash Burn covenant shall no longer apply.

The Loan Agreement also contains customary events of default, including among other things, our failure to make any principal or interest payments when due, the occurrence of certain bankruptcy or insolvency events or our breach of the covenants under the Loan Agreement, or other material adverse changes relating to our company. Furthermore, per the Loan Agreement, an event of default shall occur upon any formal court ruling against us that SVB determines in its good faith business judgment is reasonably likely to prohibit our ability to obtain final approval from the FDA with respect to our NDA for LIQ861 or impair or delay our ability to commercialize LIQ861 as currently contemplated. Upon the occurrence of an event of default, SVB may, among other things, accelerate our obligations under the Loan Agreement.

In connection with the Loan Agreement, we issued to SVB a warrant, dated as of the Effective Date (the "SVB Warrant"), to purchase up to 200,000 shares of our common stock, of which (x) 100,000 shares vested on the Effective Date, with an exercise price per share equal to $3.05, and (y) 50,000 shares shall vest on each of the Term B Loan Funding Date and Term C Loan Funding Date, with an exercise price per share equal to the lower of (i) the trailing 10-day average price of the common stock on the applicable funding date and (ii) the closing price per share of common stock on the trading day prior to applicable funding date. The SVB Warrant is exercisable for ten (10) years from the date of issuance, and will be exercised automatically on a net issuance basis if not exercised prior to the expiration date and if the then-current fair market value of one share of common stock is greater than the exercise price then in effect.

**Funding Requirements**

We plan to focus in the near-term on the regulatory approval and potential commercialization of LIQ861. In addition, we plan to continue promotion of Treprostinil Injection through our Liquidia PAH acquisition, expand our corporate infrastructure and continue to invest in research and development efforts to explore additional product candidates. We expect to incur significant expenses and operating losses for the foreseeable future as we advance potential product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. We may not be able to complete the plans listed above if, among other reasons, the FDA does not approve LIQ861 when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related personnel expenses, clinical costs, manufacturing process development, external research and development services, laboratory and related supplies, legal and other regulatory expenses, sales, marketing, and commercialization expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support development of potential product candidates. Additionally, as a publicly traded company we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules adopted by the SEC and Nasdaq Stock Market LLC ("Nasdaq") require public companies to implement specified corporate governance practices.

We believe that our current cash balance will enable us to fund our current operating expenses and planned capital expenditures beyond the projected expiration of the regulatory stay related to LIQ861 in October 2022. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect or accelerate our commercialization activities in preparation for a potential launch of LIQ861. We have implemented a more cost-efficient operating plan to further improve our cash flow. In addition, sales of Treprostinil Injection are expected to continue to contribute positive cashflow. If we receive regulatory approval for LIQ861, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Some of these expenses may be accelerated prior to the expiration of the regulatory stay related to LIQ861 in October 2022. We may require additional capital to commercialize LIQ861, if we receive regulatory approval, and to pursue in-licenses or acquisitions of other product candidates. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to raise sufficient additional capital, we may need to substantially curtail our planned operations and the pursuit of our growth strategy.

We may raise additional capital through non-dilutive licensing activities, other business arrangements or the sale of equity or convertible debt securities. In such an event, the ownership of our existing shareholders may be diluted, and the

terms of these securities may include liquidation or other preferences that adversely affect the rights associated with holdings of our common stock.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceuticals, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of manufacturing our product candidates and any product we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

See “Risk Factors” for additional risks associated with our substantial capital requirements.

***Cash Flows***

The following table summarizes our sources and uses of cash and cash equivalents:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ (26,476) | $ (40,056) |
| Investing activities | (87) | (713) |
| Financing activities | 25,301 | 64,524 |
| Net increase (decrease) in cash and cash equivalents | $ (1,262) | $ 23,755 |

***Operating Activities***

Net cash used in operating activities decreased $13.6 million to $26.5 million for the the nine months ended September 30, 2021 from $40.1 million for the nine months ended September 30, 2020. The increase was mainly due to an increase in revenue and a decrease in our research and development and general and administrative expenses during the nine months ended September 30, 2021 ended compared with the nine months ended September 30, 2020.

***Investing Activities***

Net cash used in investing activities consisting of property, plant and equipment was $0.1 million the nine months ended September 30, 2021 compared with $0.7 million during the nine months ended September 30, 2020

***Financing activities***

Net cash provided by financing activities was $25.3 million during the nine months ended September 30, 2021 compared with $64.5 million during the nine months ended September 30, 2020. During the nine months ended September 30, 2021, we received $21.7 million net proceeds from the Private Placement which closed on April 13, 2021, as well as $3.9 million in litigation financing Deployments, which will be paid directly to attorneys involved in the UTC/Smiths Medical Litigation in the following quarter. The ongoing costs of the UTC/Smiths Medical Litigation are included as operating outflows. During the nine months ended September 30, 2020, we received $70.3 million in net proceeds from the public offering of our common stock in July 2020 and $0.7 million from the sale of our common stock under the ATM Agreement, which was offset by $4.2 million in principal payments under the the A&R LSA, $1.4 million paid for expenses related to our sale of Private Placement Shares that closed in December 2019 and $0.9 million in principal payments on finance leases.

***Contractual Obligations and Commitments***

In connection with the Merger Transaction, we agreed to issue additional consideration of up to 2,708,333 additional shares of common stock to the former equity holders of RareGen (now Liquidia PAH) contingent on achievement of certain revenue targets during the year ended December 31, 2021. As of September 30, 2021, the fair value of this contingent consideration was deemed to be immaterial.

In March 2012, the Company entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to the Company's manufacturing capabilities during the term of the agreement. The Company agreed to pay future contingent royalties, totaling no more than $1,500,000, on net sales of certain products. As of September 30, 2021, none of the contingent royalties had been earned.

We enter into contracts in the normal course of business with contract service providers to assist in the performance of our research and development and manufacturing activities. Subject to required notice periods and our obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. In addition, we have entered into a multi-year agreement with LGM Pharma, LLC ("LGM") to produce active pharmaceutical ingredients for LIQ861. Under our manufacturing agreement with LGM, we are required to provide rolling forecasts, a portion of which will be considered a binding, firm order, subject to an annual minimum purchase commitment of $3.1 million for the term of the agreement. The agreement expires five years from the first marketing authorization approval of LIQ861. This minimum commitment was waived for the year ended December 31, 2021.

We have operating lease obligations including rental amounts due on leases of certain laboratory, manufacturing and office space and equipment under the terms of non-cancelable operating leases. These leases expire at various times through October 2026. We also lease specialized laboratory equipment under finance leases expiring in 2025.

We from time-to-time are subject to claims and litigation in the normal course of business, none of which we believe represent a risk of material loss or exposure.

We also have employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control or termination without cause, occur.

**Internal Controls and Procedures**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed by, or under the supervision of, the issuer's Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, and effected by the issuer's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the issuer; (ii) provide reasonable assurance that transactions are recorded

as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, management has assessed the effectiveness of our internal control over financial reporting based on the criteria set forth in the *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Management concluded that our internal control over financial reporting was not effective as of September 30, 2021 as a result of material weaknesses in our internal control over financial reporting.

*Previously Identified Material Weaknesses in Internal Control Over Financial Reporting*

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the assessment of the effectiveness of our internal control over financial reporting, our management identified the following material weaknesses that existed as of September 30, 2021:

During 2019 and 2020, we experienced significant turnover in finance personnel that reduced the complement and skill of the resources within the Company. As a result, we did not maintain an effective control environment as we lacked a sufficient complement of resources with an appropriate level of knowledge, experience and training to design, maintain and monitor our internal control over financial reporting commensurate with our financial reporting requirements. As a result, this material weakness contributed to the following material weaknesses:

- We did not design and maintain controls to ensure adequate segregation of duties within our financial reporting function, including the preparation and review of journal entries. Specifically, some key accounting personnel had the ability to both prepare and post journal entries without an independent review by someone without the ability to prepare and post journal entries.

- We did not design and maintain effective controls over certain information technology general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain effective user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications and data to appropriate Company personnel.

These material weaknesses did not result in a material misstatement of the annual or interim financial statements. However, these material weaknesses could result in a misstatement of the relevant account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

*Remedial Actions to Address Material Weaknesses*

We continue to evaluate the effectiveness of our remediation efforts, including demonstrating that the new or improved controls are designed appropriately and operate effectively for a reasonable period of time. We expect to make further changes to our internal controls. The following actions have been, or are expected to be, taken, to strengthen our controls and organizational structure:

- To address issues with recent employee turnover, we have hired a new Chief Financial Officer and controller. We regularly assess the need for additional accounting personnel to assist with maintaining and improving our internal control environment. We have leveraged the services of consulting firms to assist us with strengthening and monitoring of our internal controls processes and documentation. In addition, we have provided training to individuals that provide key information and perform key roles within our financial accounting and reporting group in order to enhance the level of understanding and the level of documentation of the performance of internal controls processed.

- We have completed installation of a new accounting system and have designed and implemented controls to ensure adequate segregation of duties within our financial reporting function, including the preparation and review of journal entries. Specifically, all journal entries now follow an automated workflow that requires an independent review by someone without the ability to post the journal entry.

- We have implemented a formal policy to restrict and monitor user and privileged access to financial applications and data to appropriate Company personnel.

We are committed to continuing to improve our internal control processes and will continue to review, optimize and enhance our financial reporting controls and procedures. We believe the measures described above have strengthened our internal control over financial reporting, however, the material weaknesses will not be considered remediated until a sustained period of time has passed to allow for continued operation of the new controls and for management to test the operational effectiveness of the new controls. Testing is expected to continue during the year ending December 31, 2021 and will continue to provide an update on the status of our remediation activities on a quarterly basis.

**JOBS Act**

As an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Subject to certain conditions, as an emerging growth company, we rely on certain of these exemptions, including without limitation:

- reduced disclosure about our executive compensation arrangements;

- no advisory votes on executive compensation or golden parachute arrangements; and

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (ii) the last day of 2023; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

**Smaller Reporting Company**

As a "smaller reporting company," as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in addition to providing reduced disclosure about our executive compensation arrangements and business developments, among other reduced disclosure requirements available to smaller reporting companies, we present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

Under the supervision of and with the participation of our management, including our Chief Executive Officer, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2021, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting discussed under "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Internal Controls and Procedures."

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Internal Controls and Procedures – Remedial Actions to Address Material Weaknesses" for additional information regarding the status of our remediation activities.

**PART II. OTHER INFORMATION.**

**Item 1. Legal Proceedings.**

**LIQ861-Related Litigation**

On June 4, 2020, United Therapeutics Corporation, a Delaware corporation ("United Therapeutics"), filed a complaint for patent infringement against us in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-UNA) (the "Hatch-Waxman Litigation") asserting infringement by us of U.S. Patent Nos. 9,604,901, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'901 Patent") and 9,593,066, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®" (the "'066 Patent") relating to United Therapeutics' Tyvaso, a nebulized treprostinil solution for the treatment of pulmonary arterial hypertension (PAH). On July 16, 2020, we filed an answer to United Therapeutics' complaint and also included defenses and counterclaims of invalidity, non-infringement, and Orange Book de-listing of the '901 Patent and '066 Patent. United Therapeutics seeks a judgment that the asserted patents are infringed and an injunction of FDA final approval and subsequent commercial launch of LIQ861 product until after the latest to expire asserted patent. United Therapeutics' complaint is in response to our New Drug Application (the "LIQ861 NDA"), filed with the U.S. Food and Drug Administration (FDA) requesting approval to market LIQ861, a dry powder inhalation of treprostinil for the treatment of PAH. 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 United Therapeutics by the court. Although we believe our LIQ861 dry powder inhaler for the treatment of PAH is highly differentiated from Tyvaso, since we are seeking approval of the LIQ861 NDA under the 505(b)(2) regulatory pathway, the LIQ861 NDA is subject to the provisions of the Hatch-Waxman Act.

On July 21, 2020, the U.S. Patent and Trademark Office (the "USPTO"), issued U.S. Patent No. 10,716,793 (the "'793 Patent") entitled "Treprostinil Administration by Inhalation", to United Therapeutics. On July 22, 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of LIQ861. The infringement allegation 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. United Therapeutics' motion to dismiss the Company's invalidity defenses and counterclaims concerning the '793 Patent was denied by the U.S. District Court for the District of Delaware on November 3, 2020.

On July 30, 2020, Judge Andrews, presiding over the Hatch-Waxman Litigation, conducted a scheduling conference and set a claim construction hearing, which was held in June 2021, and a date for trial, which is to begin in March 2022. Following the claim construction hearing, the Court issued an order that two of the terms under consideration would be given their plain and ordinary meaning and ruling in our favor regarding a third term. Two of the terms that were under consideration at the claim construction hearing remain under consideration by the Court.

On June 4, 2021, United Therapeutics filed a motion seeking leave to amend its complaint in the Hatch-Waxman Litigation. United Therapeutics alleges that we and a former United Therapeutics employee who later joined us as an employee conspired to misappropriate certain trade secrets of United Therapeutics. We disagree with United Therapeutics' allegations, deny any liability for misappropriation of any trade secrets and intend to vigorously defend against these new allegations. The motion for leave to amend remains under consideration by the Court.

On March 30, 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (the PTAB) of USPTO. One petition was for *inter partes* review of the '901 Patent, and sought a determination that the claims in the '901 Patent are invalid, and a second petition was for *inter partes* review of the '066 Patent, and sought a determination that the claims in the '066 Patent are invalid. Both the '901 Patent and '066 Patent are owned by United Therapeutics and both patents are related to U.S. Patent No. 8,497,393 which was granted to United Therapeutics and subsequently invalidated by the USPTO in an *inter partes* review instituted in 2016 by SteadyMed Ltd. On October 13, 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. On March 1, 2021, PTAB denied a request from United Therapeutics for a rehearing regarding PTAB's decision to institute an *inter partes* review of the '901 patent. On

October 8, 2021, the PTAB issued a final written decision concluding that seven of the claims in the ‘901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium.

On January 7, 2021, we filed a petition for *inter partes* review with the PTAB, relating to the ‘793 patent, which is also owned by United Therapeutics, seeking a determination that the claims in the ‘793 patent are invalid. On August 11, 2021, the PTAB instituted an inter partes review of the ‘793 Patent. A final written decision determining the validity of the challenged claims of the ‘793 patent is expected within 12 months from institution.

**Liquidia PAH-Related Litigation**

On April 16, 2019, Sandoz and Liquidia PAH (then known as RareGen) filed a complaint against United Therapeutics and Smiths Medical in the District Court of New Jersey (Case No. No. 3:19-cv-10170) (the “UTC/Smiths Medical Litigation”), alleging that United Therapeutics and Smiths Medical violated the Sherman Antitrust Act of 1890, state law antitrust statutes and unfair competition statutes by engaging in anticompetitive acts regarding the drug treprostinil for the treatment of PAH. On March 20, 2020, Sandoz and Liquidia PAH filed a first amended complaint adding a claim that United Therapeutics breached a settlement agreement that was entered into in 2015, in which United Therapeutics agreed to not interfere with Sandoz’s efforts to launch its generic treprostinil, by taking calculated steps to restrict and interfere with the launch of Sandoz’s competing generic product. United Therapeutics developed treprostinil under the brand name Remodulin and Smiths Medical manufactured a pump and cartridges that are used to inject treprostinil into patients continuously throughout the day. Sandoz and Liquidia PAH allege that United Therapeutics and Smiths Medical entered into anticompetitive agreements whereby United Therapeutics and Smiths Medical placed restrictions on the cartridges such that they can only be used with United Therapeutics’ branded Remodulin product and requiring Smiths Medical to enter into agreements with specialty pharmacies to sell the cartridges only for use with Remodulin.

On January 29, 2020, the court denied Liquidia PAH’s and Sandoz’s motion for a preliminary injunction and United Therapeutics’ and Smiths Medicals’ motion to dismiss. On November 6, 2020, Sandoz and Liquidia PAH entered into a binding term sheet (the “Term Sheet”) with Smiths Medical in order to resolve the outstanding UTC/Smiths Medical Litigation solely with respect to disputes between Smiths Medical, Liquidia PAH and Sandoz. On April 12, 2021, Liquidia PAH and Sandoz entered into a Long Form Settlement Agreement (the “Settlement Agreement”) with Smiths Medical to further detail the terms of the settlement among such parties as reflected in the Term Sheet. Pursuant to the Term Sheet and the Settlement Agreement, the former RareGen members and Sandoz received a payment of $4.25 million that was evenly split between the parties. In addition, pursuant to the Term Sheet and Settlement Agreement, Smiths Medical disclosed and made available to Sandoz and Liquidia PAH certain specifications and other information related to the cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 Infusion pump (the “CADD-MS 3 Cartridge”). Pursuant to the Settlement Agreement, Smiths Medical also granted Liquidia PAH and Sandoz a non-exclusive, royalty-free license in the United States to Smiths Medical’s patents and copyrights associated with the CADD-MS 3 Cartridge and certain other information for use of the CADD-MS 3 pump and the CADD-MS 3 Cartridges. Smiths also agreed in the Settlement Agreement to provide information and assistance in support of Liquidia PAH’s efforts to receive FDA clearance for the RG Cartridge and to continue to service certain CADD-MS 3 pumps that are available for use with the Treprostinil Injection through January 1, 2025. Liquidia PAH and Sandoz agreed, among other things, to indemnify Smiths from certain liabilities related to the RG Cartridge. As of the date of this Quarterly Report on Form 10-Q, the UTC/Smiths Medical Litigation is ongoing. On September 10, 2021, United Therapeutics filed a motion for summary judgment with respect to all of the claims brought by Sandoz and Liquidia PAH against United Therapeutics. Briefing with respect to the motion for summary judgment is in process.

We may become subject to additional legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, except as disclosed herein, there are currently no claims that would have a material adverse effect on our financial position, results of operations or cash flows.

**Item 1A. Risk Factors.**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the information contained under the heading "Cautionary Note Regarding Forward-Looking Statements" before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. We may update these risk factors in our periodic and other filings with the SEC.*

The following is a summary of the principal risk factors described in this section:

- We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company is dependent on our ability to raise additional capital to finance our future operations.
- We have a history of losses and our future profitability remains uncertain.
- We are primarily dependent on the success of our product candidate, LIQ861, for which we recently resubmitted an NDA with the FDA in response to a CRL received from the FDA in November 2020, and this product candidate may fail to receive marketing approval (in a timely manner or at all) or may not be commercialized successfully.
- United Therapeutics has initiated a lawsuit against us in which it claims that LIQ861 is infringing three of its patents, which may result in our company being delayed in its efforts to commercialize LIQ861.
- Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection or the RG Cartridge and is dependent on Sandoz and Chengdu to manufacture and supply Treprostinil Injection and the RG Cartridge, respectively, in compliance with FDA requirements, and is more broadly dependent on Sandoz's and Chengdu's FDA and healthcare compliance relative to Treprostinil Injection and the RG Cartridge, respectively.
- Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration and the medical devices used for administration of Treprostinil Injection, including the RG Cartridge, by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.
- We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than LIQ861 or for which there may be a greater likelihood of success.
- We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.
- Our credit facility with SVB contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in SVB taking possession and disposing of any collateral.
- Our products may not achieve market acceptance.

- Our product candidates are based on our proprietary, novel technology, PRINT, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.
- Our business and operations are likely to be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or enter into agreements with third parties to market and sell our drug products.
- We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of LIQ861.
- We rely on third parties to conduct our preclinical studies and clinical trials.
- We may become involved in litigation to protect our intellectual property, to enforce our intellectual property rights or to defend against claims of intellectual property infringement by third parties, which could be expensive, time-consuming and may not be successful.
- We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel.
- We expect that the market price of our common stock may be volatile, and you may lose all or part of your investment.
- As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares. The results of our assessment of the effectiveness of internal control over financial reporting ("ICFR") indicate that we had multiple material weaknesses which have not been fully remedied as of September 30, 2021.

**Risks Related to our Financial Position and Need for Additional Capital**

***We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company is dependent on our ability to raise additional capital to finance our future operations.***

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the impact of the COVID-19 coronavirus, and the ability to secure additional capital to fund operations. We expect to incur significant expenses and operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. In addition, if we obtain marketing approval for any of our product candidates, we would incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. The future viability of our company is dependent on its ability to raise additional capital to finance our future operations. We will seek additional funding through public or private financings, debt financing or collaboration. The inability to obtain funding, as and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

***We have a history of losses and our future profitability remains uncertain.***

We have incurred net losses of $23.0 million during the nine months ended September 30, 2021 and $59.8 million and $47.6 million during the years ended December 31, 2020 and 2019, respectively. We also had negative operating cash flows for each of these periods. As of September 30, 2021, we had an accumulated deficit of $298.0 million.

Since our incorporation, we have invested heavily in the development of our product candidates and technologies, as well as in recruiting management and scientific personnel. To date, we have not commenced the commercialization of our product candidates and all of our revenue has been derived from up-front fees and milestone payments made to us in connection with licensing and collaboration arrangements we have entered into and the Promotion Agreement, under which we share in the profit derived from the sale of Treprostinil Injection in the United States. These up-front fees and milestone payments have been, and combined with revenue generated from Treprostinil Injection may continue to be, insufficient to match our operating expenses. We expect to continue to devote substantial financial and other resources to the clinical development of our product candidates and, as a result, must generate significant revenue to achieve and maintain profitability or raise additional capital to fund clinical development. We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow.

***We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than LIQ861 or for which there may be a greater likelihood of success.***

We anticipate that we will need to raise additional funds to meet our future funding requirements for the continued research, development and commercialization of our product candidates and technology. In the event that funds generated from our operations are insufficient to fund our future growth, we may raise additional funds through the issuance of equity or debt securities or by borrowing from banks or other financial institutions. We cannot assure you that we will be able to obtain such additional financing on terms that are acceptable to us, or at all. Global and local economic conditions could negatively affect our ability to raise funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing, even if obtained, may be accompanied by restrictive covenants that may, among others, limit our ability to pay dividends or require us to seek consent for payment of dividends, or restrict our freedom to operate our business by requiring consent for certain actions.

If we fail to obtain additional financing on terms that are acceptable to us, we will not be able to implement our growth plans, and we may be required to significantly curtail, delay or discontinue one or more of our research, development or manufacturing programs or the commercialization of any approved product. Furthermore, if we fail to obtain additional financing on terms that are acceptable to us, we may forgo or delay the pursuit of opportunities presented by other potential product candidates or indications that may later prove to have greater commercial potential than the product candidates and indications that we have chosen to pursue.

***Our credit facility with SVB contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in SVB taking possession and disposing of any collateral.***

Our credit facility contains restrictions that limit our flexibility in operating our business. Under the terms of the loan and security agreement dated as of February 26, 2021, as amended on August 26, 2021, with SVB (the “LSA”), pursuant to which SVB extended a $20.5 million term loan facility to us, of which $10.5 million was received on March 1, 2021 in an initial tranche and up to an aggregate of $10.0 million may be received in two equal tranches subject to our satisfaction of certain conditions thereunder, we may not, among other actions, without the prior written consent of SVB, (a) pay any dividends or make any other distribution or payment or redeem, retire or purchase any capital stock, except in certain prescribed circumstances, (b) create, incur, assume, or be or be liable with respect to any indebtedness except certain permitted indebtedness, or make or permit any payment on any subordinated debt, except under certain limited circumstances, or (c) merge or consolidate with any other person, other than certain limited exceptions. Additionally, in the event that we do not maintain the applicable Minimum Cash Balance, which is currently $30.0 million, under our facility with SVB for any calendar quarter, we are required, during the term of the LSA to maintain to have at all times cumulative “Cash Burn” (as defined in the LSA) for the periods ending March 31, 2021, June 30, 2021, September 30, 2021, December 31, 2021 and March 31, 2022

and for each calendar quarter thereafter less than or equal to $10.5 million, $17.0 million, $56.1 million, $61.1 million and $65.6 million, respectively; *provided*, *however*, that the above amounts shall be increased by an amount equal to 75% of the aggregate net cash proceeds received by us from the sale of our equity securities on or after June 30, 2021 but on or prior to the last day of such calendar quarter; *provided*, *further*, that upon the Funding Date of the Term C Loan Advance (as such terms are defined in the LSA), the Cash Burn covenant shall no longer apply. Our facility with SVB is collateralized by all of our assets excluding our intellectual property, on which we have granted a negative pledge.

If we breach certain of our debt covenants and are unable to cure such breach within the prescribed period or are not granted waivers in relation to such breach, it may constitute an event of default under the LSA, giving SVB the right to require us to repay the then outstanding debt immediately, and SVB could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness, which excludes our intellectual property, if we are unable to pay the outstanding debt immediately.

***Our management has broad discretion in using the net proceeds from prior equity offerings and may not use them effectively.***

We are using the net proceeds of our April 2021 private offering and prior public and private equity offerings for ongoing commercial development of LIQ861 and for general corporate purposes. Our management has broad discretion in the application of such proceeds and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish cash flows available to service our debt, cause the value of our equity to decline and delay the development of our product candidates. Pending their use, we may invest such proceeds in short-term, investment-grade, interest-bearing securities, which may not yield favorable returns.

***Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.***

Under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change", generally defined as a greater than 50.0% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With our April 2021 private placement, the closing of the RareGen acquisition in November 2020, our July 2020 equity offering, our December 2019 private placement, issuances under our prior at-the-market facility, our March 2019 follow-on equity offering and our July 2018 initial public offering, as well as other past transactions, we may have already triggered an "ownership change" limitation. We have not completed a formal study to determine if any "ownership changes" within the meaning of IRC Section 382 have occurred. If "ownership changes" within the meaning of Section 382 of the Code have occurred, and if we earn net taxable income, our ability to use our net operating loss carryforwards and research and development tax credits generated since inception to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

***We are a late-stage clinical biopharmaceutical company with no approved products and no historical revenue from the sale of our own products, which may make it difficult for you to evaluate our business, financial condition and prospects.***

We are a late-stage clinical biopharmaceutical company with no history of commercial operations upon which you can evaluate our prospects other than the activities we have undertaken with respect to the Promotion Agreement with Sandoz. Drug product development involves a substantial degree of uncertainty. Our operations to date have been limited to engaging in promotional and nonpromotional activities under the Promotion Agreement with Sandoz, developing our PRINT technology, undertaking preclinical studies and clinical trials for our product candidates and collaborating with pharmaceutical companies, including GSK, to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. We have not obtained marketing approval for

any of our product candidates and, accordingly, have not demonstrated an ability to generate revenue from our own pharmaceutical products or successfully overcome the risks and uncertainties frequently encountered by companies undertaking drug product development. Consequently, your ability to assess our business, financial condition and prospects may be significantly limited. Further, the net losses that we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise.

***Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection and is dependent on Sandoz to manufacture and supply Treprostinil Injection in compliance with FDA requirements, and is more broadly dependent on Sandoz's FDA and healthcare compliance relative to Treprostinil Injection.***

Sandoz holds the FDA approval (the ANDA) for and controls Treprostinil Injection and is responsible among other things for the compliant manufacture, distribution, labeling, and advertising of Treprostinil Injection. Our role is one of a specialized service provider to Sandoz. As a result, we are dependent on Sandoz to manufacture and supply Treprostinil Injection, and dependent on Sandoz for the continued FDA compliance of Treprostinil Injection. We do not have control over Sandoz's compliance with laws and regulations applicable to drug manufacturers and ANDA holders (for example, applicable current good manufacturing practices (GMPs); FDA labeling, promotional labeling, and advertising requirements; pharmacovigilance and adverse event reporting; and other ongoing FDA reporting and submission requirements), nor over its compliance with healthcare compliance and fraud, waste, and abuse laws, or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. In addition, we have no control over the ability of Sandoz to maintain adequate quality control, quality assurance and qualified personnel, or other personnel with roles related to the regulatory compliance of Treprostinil Injection and its labeling, promotion, and advertising or of Sandoz's activities in relation to government healthcare programs. If the FDA or a comparable foreign regulatory authority finds deficiencies with the manufacture or quality assurance of Treprostinil Injection or identifies safety or efficacy concerns related to Treprostinil Injection, or if Sandoz otherwise is unable to comply with applicable laws, regulations and standards, Sandoz's ability to manufacture, sell and supply Treprostinil Injection could be limited.

Sandoz's ability to consistently manufacture and supply Treprostinil Injection in a timely manner may also be interrupted by production shortages or other supply interruptions, including as a result of the ongoing COVID-19 pandemic. Our share of net profits under the Promotion Agreement is reduced by certain manufacturing costs and other write-offs related to Sandoz's inability to sell Treprostinil Injection, including in the event that Treprostinil Injection expires prior to sale. Currently, Treprostinil Injection expires 24 months after the date of manufacture.

***Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.***

Our ability to sell Treprostinil Injection is dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors. If Treprostinil Injection does not achieve an adequate level of acceptance, we may not generate sufficient revenue to offset our cost of revenue.

At the same time, arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain its business or financial arrangements and relationships.

The degree of market acceptance of Treprostinil Injection will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer Treprostinil Injection for sale at competitive prices (generic drug prices, after initial generic entry, have been observed to decline with the entrance of additional generic competition);
- the convenience and ease of administration compared to alternative treatments;

- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;
- the willingness of the target patient population to try new treatments, including the generic version of a brand, and of physicians to prescribe such treatments;
- our ability to hire and retain sales and marketing personnel and their ability to support Sandoz under the Promotion Agreement;
- the strength of Sandoz's manufacturing and distribution support;
- the requirement by third-party payors to use generic treprostinil for parenteral administration in place of Remodulin;
- the availability of third-party coverage and adequate reimbursement for Treprostinil Injection;
- the prevalence and severity of any side effects;
- any restrictions on the use of Treprostinil Injection together with other medications;
- our and Sandoz's ability to maintain relationships with the specialty pharmacies; and
- the services provided by specialty pharmacies related to use of Treprostinil Injection.

Our business may also be impacted by the need to maintain compliant operations (including oversight and monitoring of personnel and our activities) in relation to interactions with the persons and parties noted above, relative to FDA and healthcare law requirements, and with consideration of government and industry compliance best practices.

***Medical devices, which we do not control, are necessary for the administration of Treprostinil Injection.***

In order for Treprostinil Injection to be administered to patients, patients must use certain other medical equipment, including pumps, cartridges and infusion sets. We do not manufacture or control such medical equipment, which is manufactured by third parties and owned and dispensed by specialty pharmacies, hospitals or other third parties. Our ability to serve patients is dependent upon the ability of specialty pharmacies to maintain sufficient inventory of such medical equipment to provide to patients. If manufacturers cease to manufacture or support medical equipment or if specialty pharmacies are unable to obtain or maintain sufficient inventories of such medical equipment, our sales may be adversely impacted.

We have worked with Chengdu to develop the RG Cartridge, which recently received FDA 510(k) clearance. The ability of patients to administer Treprostinil Injection through subcutaneous injection is dependent on the continued availability of the RG Cartridge. Our ability to sell the Treprostinil Injection for subcutaneous administration is dependent on market acceptance of the RG Cartridge by patients, health care providers and by third-party payors. If the RG Cartridge does not achieve an adequate level of acceptance or if the RG Cartridge experiences any quality problems, recalls or other adverse events, our ability to provide Treprostinil Injection to patients who receive Treprostinil through subcutaneous injection will be limited. The degree of market acceptance of the RG Cartridge will depend on a number of factors, including:

- the efficacy, safety, quality and potential advantages or disadvantages compared to alternative cartridges;
- Chengdu's ability to offer the RG Cartridge for sale at competitive prices;
- the strength of Chengdu's manufacturing and distribution support; and
- Chengdu's ability to maintain regulatory approvals necessary to manufacture and sell the RG Cartridge in the United States.

We are also seeking to work with third parties to develop or procure pumps that can be used to administer Treprostinil Injection in the future. Such pumps may require FDA 510(k) clearance before they can be sold. There is no guarantee that we or a third party will receive FDA 510(k) clearance. Failure by us or third parties to successfully develop or supply the medical equipment or to obtain or maintain regulatory approval or clearance of such medical equipment could negatively impact the market acceptance of and sales of Treprostinil Injection.

**Risks Related to the Commercialization of our Product Candidates and Generic Treprostinil Injection**

***United Therapeutics has initiated a lawsuit against us in which it claims that LIQ861 is infringing three of its patents, which may result in our company being delayed in its efforts to commercialize LIQ861.***

We are developing LIQ861 under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Accordingly, under the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, we were required to, in the NDA for LIQ861, certify that patents listed in the Orange Book for Tyvaso are invalid, unenforceable or will not be infringed by the manufacture, use or sale of LIQ861. Two of these patents are U.S. Patent No. 9,604,901 (the "'901 Patent"), entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", and U.S. Patent No. 9,593,066 (the "'066 Patent"), entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", both of which are owned by United Therapeutics. A notice of the paragraph IV certification was required to be provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for LIQ861 refers. On June 4, 2020, United Therapeutics, as the holder of such patents, asserted a patent challenge directed to the '901 Patent and the '066 Patent by filing a complaint against us in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-UNA) (the "Hatch-Waxman Litigation"), thereby triggering an automatic 30-month regulatory stay on final approval of the NDA for LIQ861. As a result of United Therapeutics' patent challenge, the FDA is prohibited from approving the NDA for LIQ861 until the earliest to occur of the expiration of the 30-month stay, which is projected to be in October 2022, expiration of the '901 Patent and '066 Patent, settlement of the lawsuit or a decision in the infringement suit that is favorable to us as the NDA applicant. Accordingly, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize LIQ861, if at all.

On July 21, 2020, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 10,716,793 (the "'793 Patent"), entitled "Treprostinil Administration by Inhalation", to United Therapeutics. On July 22, 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of LIQ861. The infringement allegations of the '793 Patent are 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. United Therapeutics' motion to dismiss our invalidity defenses and counterclaims concerning the '793 Patent was denied by the U.S. District Court for the District of Delaware on November 3, 2020.

On July 30, 2020, Judge Andrews, presiding over the Hatch-Waxman Litigation, conducted a scheduling conference and set a claim construction hearing, which was held in June 2021, and a date for the trial, which is currently scheduled to begin in March 2022. Following the claim construction hearing, the Court issued an order that two of the terms under consideration would be given their plain and ordinary meaning and ruling in our favor regarding a third term. Two of the terms that were under consideration at the claim construction hearing remain under consideration by the Court.

On June 4, 2021, United Therapeutics filed a motion seeking leave to amend its complaint in the Hatch-Waxman Litigation. United Therapeutics alleges that we and a former United Therapeutics employee who later joined us as an employee conspired to misappropriate certain trade secrets of United Therapeutics. We disagree with United Therapeutics' allegations, deny any liability for misappropriation of any trade secrets and intend to vigorously defend against these new allegations. The motion for leave to amend remains under consideration by the Court.

On March 30, 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (PTAB) of the USPTO. One petition was for *inter partes* review of the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid, and a second petition is for *inter partes* review of the '066 Patent, seeking a determination that the claims in the '066 Patent are invalid. Both the '901 Patent and '066 Patent are owned by United Therapeutics and are related to U.S. Patent No. 8,497,393 which was granted to United Therapeutics and subsequently invalidated by the USPTO in an *inter partes* review instituted in 2016 by SteadyMed Ltd. On October 13, 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. On March 1, 2021, PTAB denied a request from United Therapeutics for a rehearing regarding PTAB's decision to institute an *inter partes* review of the '901 patent. On October 8, 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were

unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium.

On January 7, 2021, we filed a petition with the PTAB for *inter partes* review of the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. On August 11, 2021, the PTAB instituted an inter partes review of the '793 Patent. A final written decision determining the validity of the challenged claims of the '793 Patent is expected within 12 months from institution.

If we are found to infringe, misappropriate or otherwise violate a United Therapeutics' intellectual property rights, we could be required to obtain a license from United Therapeutics to continue developing and marketing LIQ861. However, we may not be able to obtain any required license on commercially reasonable terms or at all. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or to have misappropriated a trade secret of United Therapeutics. A finding of infringement or misappropriation could also result in an injunction that prevents us from commercializing LIQ861, which could materially harm our business. In addition, we may be forced to redesign LIQ861 to avoid infringement.

***We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.***

We face significant competition from industry players worldwide, including large multi-national pharmaceutical companies, other emerging or smaller pharmaceutical companies, as well as universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff, and more experience in manufacturing and marketing, than we do. As a result, these companies may obtain marketing approval for their product candidates more quickly than we are able to and/or be more successful in commercializing their products, including generic treprostinil products, than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies. We may also face competition as a result of advances in the commercial applicability of new technologies and greater availability of capital for investment in such technologies. Our competitors may also invest heavily in the discovery and development of novel drug products that could make our product candidates less competitive or may file FDA citizen petitions which may delay the approval process for our product candidates. Furthermore, our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Our competitors may also succeed in asserting existing patents or developing new patents to which we do not have a license in an attempt to prevent us from marketing our products. These competitors may also compete with us in recruiting and retaining qualified sales personnel.

Any new drug product that competes with a prior approved drug product must demonstrate advantages in safety, efficacy, tolerability or convenience in order to overcome price competition and to be commercially successful. Our products, if and when approved, are expected to face competition from drug products that are already on the market, as well as those in our competitors' development pipelines. We expect that our lead program, LIQ861, an inhaled treprostinil therapy for the treatment of PAH, will face competition from the following inhaled treprostinil therapies that are either currently marketed or in clinical development:

- Tyvaso, marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009. Tyvaso is the reference listed drug in our NDA for LIQ861. Following patent litigation, United Therapeutics and Watson Pharmaceuticals reached a settlement whereby Watson Pharmaceuticals will be permitted to enter the market with a generic version of Tyvaso beginning on January 1, 2026. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA to include WHO group III PH-ILD patients.

- Ventavis®, marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004.

- Tyvaso DPI, licensed from MannKind as TreT by United Therapeutics, is currently in development in the United States for the treatment of PAH. Under the license agreement with MannKind, United Therapeutics is responsible for global development, regulatory and commercial activities. MannKind will manufacture clinical supplies and initial commercial supplies of the product while long-term commercial supplies will be manufactured by United Therapeutics. United Therapeutics announced that it had submitted an NDA in April 2021 to support FDA approval of Tyvaso DPI for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease. In October 2021, United Therapeutics announced the receipt of a complete response letter from the FDA with respect to its NDA for Tyvaso DPI, but expressed confidence that the issue raised in the complete response letter could be resolved quickly and that Tyvaso DPI could receive approval by the summer of 2022 or earlier. The NDA includes results from clinical studies evaluating safety and pharmacokinetics of switching PAH patients from Tyvaso to Tyvaso DPI and data comparing the pharmacokinetics of Tyvaso DPI to Tyvaso in healthy volunteers. United Therapeutics further reported that these are the only clinical studies necessary to support FDA approval and that the indicated population for Tyvaso DPI will mirror that of Tyvaso, which United Therapeutics announced in April 2021 was approved by FDA to include WHO group III PH-ILD patients. If Tyvaso DPI is approved by FDA before LIQ861 receives final approval from the FDA, then there is a possibility that the FDA could grant three years of market exclusivity to Tyvaso DPI as an inhaled dry-powder formulation of treprostinil that could delay the final approval of LIQ861 until said exclusivity expires.

- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmed initiated a Phase 2 trial in May 2021 studying patients diagnosed with PAH and intends to initiate trials to study PH-ILD and IPF. If the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to LIQ861 and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly.

In addition to these other inhaled treprostinil therapies, we expect that LIQ861 will also face competition from other treprostinil-based drugs, including Orenitram, which is administered orally, and Remodulin, which is administered parenterally, both of which are marketed by United Therapeutics. Branded pharmaceutical companies such as United Therapeutics continue to defend their products vigorously through, among other actions, life cycle management, marketing agreements with third-party payors, pharmacy benefits managers and generic manufacturers. These actions add increased competition in the generic pharmaceutical industry, including competition for Treprostinil Injection.

Additionally, even though Sandoz launched the first-to-file fully substitutable generic treprostinil for parenteral administration in March 2019 that is sold primarily through the specialty pharmacies, Teva Pharmaceutical Industries Ltd. launched a generic treprostinil for parenteral administration in October 2019 that is sold primarily through a specialty pharmacy and to hospitals, Par Pharmaceutical, Inc. launched a generic treprostinil for parenteral administration after receiving approval in September 2019 that is sold primarily to hospitals, Dr. Reddy’s Laboratories Inc. received approval in May 2020 for generic treprostinil for parenteral administration, and Alembic received approval in February 2021 for generic treprostinil for parenteral administration. Such increased competition may result in a smaller than expected commercial opportunity for us.

Generic drug prices may, and often do, decline, sometimes dramatically, especially as additional generic pharmaceutical companies (including low-cost generic producers outside of the United States) receive approvals and enter the market for a given product. The goals established under the Generic Drug User Fee Act, and increased funding of the FDA’s Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for generic products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. The FDA’s changes may benefit our competitors. Our ability to sell Treprostinil Injection and earn revenue is affected by the number of companies selling competitive products, including new market entrants, and the timing of their approvals.

In addition to treprostinil-based therapies, other classes of therapeutic agents for the treatment of PAH include the following:

- ***IP-agonists***, such as selexipag, marketed by Actelion, and ralinepeg, licensed from Arena Pharmaceuticals, Inc. by United Therapeutics, which is currently in clinical development;

- ***Endothelin receptor antagonists***, such as bosentan and macitentan, both marketed by Actelion, and ambrisentan, marketed by Gilead. Generic version of bosentan and ambrisentan are currently available.

- ***PDE-5 inhibitors***, such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc. Generic versions of both tadalafil and sildenafil are currently available.

- ***Soluble guanylate cyclase (sGC) stimulator,*** such as riociguat marketed by Bayer.

We are also aware of several other agents in clinical development that are exploring mechanisms of action which, if approved, could impact the standard of care for treating PAH in the United States, including programs from Acceleron Pharma, Inc., Gossamer Bio, Inc., PhaseBio Pharmaceuticals, Inc. and Sumitovant Biopharma Ltd, among others.

There are a number of competitors seeking marketing approval and/or regulatory exclusivity with respect to products that are or would be competitive to our product candidate. Thus, we face the risk that one of our competitors will be granted marketing approval and/or regulatory exclusivity before we are able to obtain FDA approval for our product candidate. In that case, as stated above, there is the possibility that such a competitor would be able to prevent us from obtaining approval of and marketing our product candidate until the expiration of the competitor's term of FDA regulatory exclusivity, which could be a term of three years for so-called New Clinical Study exclusivity, or could conceivably be for longer periods of time if the competitor is successful in being granted other forms of FDA regulatory exclusivity which might include, for example, Orphan Disease Designation exclusivity (seven years), New Chemical Entity exclusivity (five years), or Pediatric exclusivity (six months beyond other existing exclusivities or patent terms).

United Therapeutics has been granted New Clinical Study exclusivity for Tyvaso through March 31, 2024 for the indication of treatment of pulmonary hypertension associated with interstitial lung disease to improve exercise ability. Until the expiration of this exclusivity, we will be unable to receive FDA approval for LIQ861 for the indication of treatment of pulmonary hypertension associated with interstitial lung disease to improve exercise ability. Because United Therapeutics is also the sponsor of the NDA for Tyvaso DPI, the regulatory exclusivity granted to United Therapeutics with respect to Tyvaso will not limit the indications for which the FDA may approve Tyvaso DPI. Thus, if FDA approves Tyvaso DPI, Tyvaso DPI may have a broader label than the label for LIQ861 even if it is approved. If LIQ861 has a narrower label than other competitive products, it may affect our ability to compete with such products.

The ability of competitors to utilize other regulatory incentive programs could also expedite their FDA review and approval timeline, which could result in their products reaching the market before our product candidate, and which could create further potential implications on exclusivity as noted above. For example, when a Priority Review Voucher (PRV) is redeemed in connection with an NDA, the FDA's goal review period would generally be expedited to six months, although this timeframe is not guaranteed.

If we are unable to maintain our competitive position, our business and prospects will be materially and adversely affected.

***Our products may not achieve market acceptance.***

We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, which allows us to rely on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for approval in the United States.

While we believe that it will be less difficult for us to convince physicians, patients and other members of the medical community to accept and use our drug products as compared to entirely new drugs, our drug products may nonetheless fail to gain sufficient market acceptance by physicians, patients, other healthcare providers and third-party payors. If any of our drug products fail to achieve sufficient market acceptance, we may not be able to generate sufficient revenue to become profitable. The degree of market acceptance of our drug products, if and when they are approved for commercial sale, will depend on a number of factors, including but not limited to:

- the timing of our receipt of marketing approvals, the terms of such approvals and the countries in which such approvals are obtained;
- the safety, efficacy, reliability and ease of administration of our drug products;
- the prevalence and severity of undesirable side effects and adverse events;
- the extent of the limitations or warnings required by the FDA or comparable regulatory authorities in other countries to be contained in the labeling of our drug products;
- the clinical indications for which our drug products are approved;
- the availability and perceived advantages of alternative therapies;
- any publicity related to our drug products or those of our competitors;
- the quality and price of competing drug products;
- our ability to obtain third-party payor coverage and sufficient reimbursement;
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage; and
- the selling efforts and commitment of our commercialization collaborators.

If our drug products, if and when approved, fail to receive a sufficient level of market acceptance, our ability to generate revenue from sales of our drug products will be limited, and our business and results of operations may be materially and adversely affected.

***We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or enter into agreements with third parties to market and sell our drug products.***

In order to market and sell any of our drug products, if and when approved, we will be required to build our marketing and sales capabilities with respect to such products. With the acquisition of Liquidia PAH, we acquired a sales force to market generic treprostinil in accordance with the Promotion Agreement. We cannot assure you that we will be successful in further building our marketing and sales capabilities or be able to do so in a cost-effective manner. In addition, we may enter into collaboration arrangements with third parties to market our drug products. We may face significant competition for collaborators. In addition, collaboration arrangements may be time-consuming to negotiate and document. We cannot assure you that we will be able to negotiate collaborations for the marketing and sales of our drug products on acceptable terms, or at all. Even if we do enter into such collaborations, we cannot assure you that our collaborators will be successful in commercializing our products. If we or our collaborators are unable to successfully commercialize our drug products, whether in the United States or elsewhere, our business and results of operations may be materially and adversely affected.

As we seek to establish a commercial operation with respect to LIQ861 in anticipation of potential approval from the FDA, we also continue to evaluate additional drug candidates. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our commercial activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which include problems relating to managing manufacturing and supply, reimbursement, marketing problems, and other additional costs.

There are risks involved with building and expanding our sales, marketing, and other commercialization capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any drug launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these

commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may impact our efforts to commercialize our drug candidates on our own and generate product revenues include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel over a large geographic area;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- understanding and training relevant personnel on the limitations on, and the transparency and reporting requirements applicable to, remuneration provided to actual and potential referral sources;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- the inability of sales personnel to obtain access to physicians or to effectively promote any future drugs;
- our ability to appropriately market, detail and distribute products in light of healthcare provider facility closures, quarantine, travel restrictions and other governmental restrictions caused by COVID-19;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- any distribution and use restrictions imposed by the FDA or to which we agree;
- liability for sales and marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- our ability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

In the future, we may choose to participate in sales activities with collaborators for some of our drug candidates. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any drug candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

***We may be exposed to claims and may not be able to obtain or maintain adequate product liability insurance.***

Our business is exposed to the risk of product liability and other liability risks that are inherent in the development, manufacture, clinical testing and marketing of pharmaceutical products. These risks exist even if a product is approved for commercial sale by the FDA or comparable regulatory authorities in other countries and manufactured in licensed facilities. Our current product candidate, LIQ861, and Treprostinil Injection are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products could result in injury to a patient or even death.

Claims that are successfully brought against us could have a material and adverse effect on our financial condition and results of operations. Further, even if we are successful in defending claims brought against us, our reputation could suffer. Regardless of merit or eventual outcome, product liability claims may also result in, among others:

- a decreased demand for our products;
- a withdrawal or recall of our products from the market;

- a withdrawal of participants from our ongoing clinical trials;
- the distraction of our management's attention from our core business activities to defend such claims;
- additional costs to us; and
- a loss of revenue.

Our insurance may not provide adequate coverage against our potential liabilities. Furthermore, we, our collaborators or our licensees may not be able to obtain or maintain insurance on acceptable terms, or at all. In addition, our collaborators or licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. To the extent that they are uninsured or uninsurable, claims or losses that may be suffered by us, our collaborators or our licensees may have a material and adverse effect on our financial condition and results of operations.

**Risks Related to the Development and Regulatory Approval of our Product Candidates**

***We are primarily dependent on the success of our product candidate, LIQ861, for which we recently resubmitted an NDA with the FDA in response to a CRL received from the FDA in November 2020, and this product candidate may fail to receive marketing approval (in a timely manner or at all) or may not be commercialized successfully.***

We do not have any products approved for marketing in any jurisdiction and we have never generated any revenue from sales of our own products. Our ability to generate revenue from sales of our own products and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We expect that a substantial portion of our efforts and expenditure over the next few years will be devoted to our product candidate, LIQ861, a proprietary inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension (PAH). We do not anticipate generating revenue from sales of LIQ861 until 2022 at the earliest, if ever.

LIQ861 is being developed under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. We commenced a Phase 3 clinical trial of LIQ861, which we refer to as INSPIRE, in the first quarter of 2018. We completed the pivotal INSPIRE trial in August 2019. Final enrollment included 121 PAH patients to assess safety and tolerability through Month 2, the primary endpoint of the trial. Of the 121 patients enrolled in the study, 55 were Transition patients and 66 were Add-On patients. Add-On patients started on a dose of 26.5 mcg of LIQ861, with most (>80%) titrating to a 79.5 mcg dose or higher within the first two months of treatment. In April 2020, we reported final safety and tolerability results from the two-month primary endpoint of the INSPIRE study. Of the 121 PAH patients, 113, or 93%, completed their two-month visit. The most common reported TEAEs (reported in ≥ four percent) were cough (42%), headache (26%), throat irritation (16%), dizziness (11%), diarrhea (9%), chest discomfort (8%), nausea (7%), dyspnea (5%), flushing (5%) and oropharyngeal pain (4%).

We submitted an NDA for LIQ861 to the FDA in January 2020. 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. On November 25, 2020 we announced that the FDA issued a CRL for our NDA for LIQ861. On May 7, 2021, we resubmitted the NDA for LIQ861 to the FDA. In June of 2021, the FDA accepted our resubmitted NDA for LIQ861 for review and established a PDUFA goal date of November 7, 2021. The CRL did not cite the need to conduct further clinical studies, nor did the FDA indicate that additional studies related to toxicology or clinical pharmacology would be necessary. We believe that we have addressed the items raised in the CRL in the resubmitted NDA.

Expectations related to FDA approval and projected product launch timelines are impacted by ongoing Hatch-Waxman Litigation following a lawsuit filed by United Therapeutics on June 4, 2020. Under the Hatch-Waxman Act, as a result of the Hatch-Waxman Litigation commenced by United Therapeutics, the FDA may not issue a final approval for the LIQ861 NDA for up to 30 months, absent an earlier judgment unfavorable to United Therapeutics by the court. When the FDA is not permitted to issue an approval for a 505(b)(2) application due to a 30-month stay, it is generally possible that the agency could issue "tentative approval" if it determines that all regulatory requirements have been met. However, a drug product that is granted tentative approval may be subject to additional

review before final approval, particularly if tentative approval was granted more than three years before the earliest lawful approval date. The FDA's tentative approval of drug product would be based on information available to FDA at the time of the tentative approval letter (i.e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention. A new drug product may not be marketed until the date of final approval.

Expectations for LIQ861 also may be impacted by competing products, including Tyvaso® DPI. *See Item 1A. Risk Factors - We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.*

If we successfully complete the clinical development of LIQ861, we cannot assure you that we will receive marketing approval. The FDA or comparable regulatory authorities in other countries may delay, limit or deny approval of our product candidate for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials, or with our interpretation of data from our preclinical studies or clinical trials. Further, there are numerous FDA personnel assigned to review different aspects of an NDA, and uncertainties can be presented by their ability to exercise judgment and discretion during the review process. During the course of review, the FDA may request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC) or other data and information, and the development and information may be time-consuming and expensive. Status as a combination product, as is the case for LIQ861, may complicate or delay the FDA review process. Product candidates that the FDA deems to be combination products, such as LIQ861, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process. For example, the CRL for LIQ861 identified the need for additional information and clarification on CMC data pertaining to the drug product and device biocompatibility. Additionally, the FDA could delay approval of LIQ861 even if approvable after completing its review. For example, if a competing product comprised of an inhaled dry-powder formulation of treprostinil is approved by FDA before LIQ861 is approved, then there is a possibility that the FDA could grant three years of market exclusivity to the competitor that could delay the final approval of LIQ861 until said exclusivity expires. Moreover, the applicable requirements for approval may differ from country to country.

If we successfully obtain marketing approval for LIQ861, we cannot assure you that it will be commercialized in a timely manner or successfully, or at all. For example, LIQ861 may not achieve a sufficient level of market acceptance, or we may not be able to effectively build our marketing and sales capabilities or scale our manufacturing operations to meet commercial demand. The successful commercialization of LIQ861 will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such product, even if approved. Any delay or setback we face in the commercialization of LIQ861 may have a material and adverse effect on our business and prospects, which will adversely affect your investment in our company.

***Our preclinical studies and clinical trials may not be successful and delays in such preclinical studies or clinical trials may cause our costs to increase and significantly impair our ability to commercialize our product candidates. Results of previous clinical trials or interim results of ongoing clinical trials may not be predictive of future results.***

Before we are able to commercialize our drug products, we are required to undertake extensive preclinical studies and clinical trials to demonstrate that our drug products are safe and effective for their intended uses. However, we cannot assure you that our drug products will, in preclinical studies and clinical trials, demonstrate safety and efficacy as necessary to obtain marketing approval. Due to the nature of drug product development, many product candidates, especially those in early stages of development, may be terminated during development. Although we believe we have completed clinical development for LIQ861, we have not yet obtained approval for or commercialized any of our own product candidates and as a result do not have a track record of successfully bringing our own product candidates to market. Furthermore, LIQ861 has, to date, been tested only in relatively small study populations and, accordingly, the results from our earlier clinical trials may be less reliable than results achieved in

larger clinical trials, if required. Additionally, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary and interim results of a clinical trial do not necessarily predict final results.

Preclinical studies and clinical trials may fail due to factors such as flaws in trial design, dose selection and patient enrollment criteria. The results of preclinical studies and early clinical trials may not be indicative of the results of subsequent clinical trials. Product candidates may, in later stages of clinical testing, fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and earlier clinical trials. Moreover, there may be significant variability in safety or efficacy results between different trials of the same product candidate due to factors including, but not limited to, changes in trial protocols, differences in the composition of the patient population, adherence to the dosing regimen and other trial protocols and amendments to protocols and the rate of drop-out among patients in a clinical trial. If our preclinical studies or clinical trials are not successful and we are unable to bring our product candidates to market as a result, our business and prospects may be materially and adversely affected.

Furthermore, conducting preclinical studies and clinical trials is a costly and time-consuming process. The length of time required to conduct the required studies and trials may vary substantially according to the type, complexity, novelty and intended use of the product candidate. A single clinical trial may take up to several years to complete. Moreover, our preclinical studies and clinical trials may be delayed or halted due to various factors, including, among others:

- delays in raising the funding necessary to initiate or continue a clinical trial;
- delays in manufacturing sufficient quantities of product candidates for clinical trials;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining institutional review board approval at clinical trial sites;
- delays in recruiting suitable patients to participate in a clinical trial;
- delays in patients' completion of clinical trials or their post-treatment follow-up;
- regulatory authorities' interpretation of our preclinical and clinical data; and
- unforeseen safety issues, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar drug products or product candidates.

If our preclinical studies or clinical trials are delayed, the commercialization of our product candidates will be delayed and, as a result, we may incur substantial additional costs or not be able to recoup our investment in the development of our product candidates, which would have a material and adverse effect on our business.

***Clinical trials and data analysis can be expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for LIQ861, or any required clinical studies of LIQ861 do not provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business.***

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We cannot provide any assurance or certainty regarding when we might receive regulatory approval for LIQ861. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon an NDA filed with the FDA or repeat clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;

- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols or amendments to our protocols.

In addition, the FDA or an independent institutional review board (IRB) may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. Although clinical data is an essential part of NDA filings, NDAs must also contain a range of additional data including CMC data to meet FDA standards for approval. In the event we do not ultimately receive regulatory approval for LIQ861, we may be required to terminate development of our only product candidate.

***The marketing approval processes of the FDA and comparable regulatory authorities in other countries are unpredictable and our product candidates may be subject to multiple rounds of review or may not receive marketing approval.***

Pursuing marketing approval for a pharmaceutical product candidate (for example, through the NDA process) is an extensive, lengthy, expensive and inherently uncertain process. We cannot assure you that any of our product candidates will receive marketing approval. Regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including, but not limited to, the following:

- the FDA or comparable regulatory authorities may, for a variety of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate;

- the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers do not sufficiently demonstrate compliance with cGMP to support approval of a product candidate, or that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities in other countries that our product candidate is safe and effective for its proposed indication, or that its clinical and other benefits outweigh its safety risks;

- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

Even if we obtain marketing approval, the FDA or comparable regulatory authorities in other countries may approve our product candidates for fewer or more limited indications than those for which we requested approval or may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other studies or the conduct of an expensive REMS, which could significantly reduce the potential for commercial success or viability of our product candidates. We also may not be able to find acceptable collaborators to manufacture our drug products, if and when approved, in commercial quantities and at acceptable prices, or at all.

***We may encounter difficulties in enrolling patients in our clinical trials.***

We may not be able to commence or complete clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials.

Patient enrollment may be affected by, among others:

- the severity of the disease under investigation;
- the design of the clinical trial protocol and amendments to a protocol;

- the size and nature of the patient population;
- eligibility criteria for the clinical trial in question;
- the perceived risks and benefits of the product candidate under clinical testing, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar products or product candidates;
- the existing body of safety and efficacy data in respect of the product candidate under clinical testing;
- the proximity of patients to clinical trial sites;
- the number and nature of competing therapies and clinical trials; and
- other environmental factors such as the ongoing COVID-19 pandemic or other natural or unforeseen disasters.

Any negative results we may report in clinical trials of our product candidates may also make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate.

We expect that if we initiate, as we are currently contemplating, a clinical trial of LIQ861 in pediatric patients, we may encounter difficulties enrolling patients in such a trial because of the limited number of pediatric patients with this disease. Furthermore, we are aware of a number of therapies for PAH that are being developed or that are already available on the market, and we expect to face competition from these investigational drugs or approved drugs for potential subjects in our clinical trials, which may delay enrollment in our planned clinical trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays, or both. We may, as a result of such delays or failures, be unable to carry out our clinical trials as planned or within the timeframe that we expect or at all, and our business and prospects may be materially and adversely affected as a result.

***Product candidates that the FDA deems to be combination products, such as LIQ861, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process.***

The FDA has indicated that it considers LIQ861, which is delivered by a DPI, to be a drug-device combination product. Accordingly, the DPI was evaluated as part of our original NDA filing, and the CRL we received from FDA, as announced November 25, 2020, identified the need for additional information pertaining to device biocompatibility. When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. We rely on third parties for the design and manufacture of the delivery systems for our products, including the DPI for LIQ861, and in some cases for the right to refer to their data on file with the FDA or other regulators. Quality or design concerns with the delivery system, or commercial disputes with these third parties, could delay or prevent regulatory approval and commercialization of our product candidates.

***We are pursuing the FDA 505(b)(2) pathway for our current product candidate. If we are unable to rely on the 505(b)(2) regulatory pathway to apply for marketing approval of our product candidates in the United States, seeking approval of these product candidates through the 505(b)(1) NDA pathway would require full reports of investigations of safety and effectiveness, and the process of obtaining marketing approval for our product candidates would likely be significantly longer and more costly.***

We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, which permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us for a particular product candidate, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the

FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We plan to pursue this pathway for our current product candidate, LIQ861, and have submitted a 505(b)(2) NDA. Even if the FDA allows us to rely on the 505(b)(2) regulatory pathway, we cannot assure you that such marketing approval will be obtained in a timely manner, or at all.

The FDA may require us to perform additional clinical trials to support any change from the reference listed drug, which could be time-consuming and substantially delay our receipt of marketing approval. Also, as has been the experience of others in our industry, our competitors may file citizens' petitions with the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505(b)(2) regulatory pathway. If an FDA decision or action relative to our product candidate, or the FDA's interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for our product candidates. Even if we are able to utilize the 505(b)(2) regulatory pathway, a drug approved via this pathway may be subject to the same post-approval limitations, conditions and requirements as any other drug.

In addition, we may face Hatch-Waxman litigation in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the approval of our product candidates. The pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. If the previously approved drugs referenced in an applicant's 505(b)(2) NDA are protected by patent(s) listed in the Orange Book, the 505(b)(2) applicant is required to make a claim after filing its NDA that each such patent is invalid, unenforceable or will not be infringed. The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30-month delay (or the shorter of dismissal of the lawsuit or expiration of the patent(s)) in approval of the 505(b)(2) NDA application. For example, the LIQ861 NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Under the Hatch-Waxman Act, as a result of the Hatch-Waxman Litigation commenced by United Therapeutics on June 4, 2020, the FDA is automatically precluded from approving the LIQ861 NDA for up to 30 months, absent an earlier judgment unfavorable to United Therapeutics by the court. It is not uncommon for a manufacturer of an approved product, such as United Therapeutics, to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

If the FDA determines that our product candidates, including LIQ861, do not qualify for the 505(b)(2) regulatory pathway, we would need to reconsider our plans and might not be able to commercialize our product candidates in a cost-efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects.

***We may be unable to continually develop a pipeline of product candidates, which could affect our business and prospects.***

A key element of our long-term strategy is to continually develop a pipeline of product candidates by developing proprietary innovations to FDA-approved drug products using our PRINT technology. If we are unable to identify off-patent drug products for which we can develop proprietary innovations using our PRINT technology or otherwise expand our product candidate pipeline, whether through licensed or co-development opportunities, and obtain marketing approval for such product candidates within the timeframes that we anticipate, or at all, our business and prospects may be materially and adversely affected.

***We have conducted, and may in the future conduct, clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials.***

Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for our product candidates, if not conducted under an IND, this is subject to certain conditions set out in 21 C.F.R. § 312.120. For example, in order for the FDA to accept data from such a foreign clinical trial, the study must have been conducted in accordance with Good Clinical Practice (GCP) including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The FDA must also be able to validate the data from the study through an onsite inspection if the agency deems it necessary. In addition, foreign clinical data submitted to support FDA applications should be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.

**Risks Related to Our Dependence on Third Parties**

***We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of LIQ861.***

We depend on third-party suppliers for clinical and commercial supplies for the supply of materials and components necessary for clinical and commercial production of LIQ861, including the active pharmaceutical ingredients which are used in our product candidates. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, our manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted and our business and prospects may be materially and adversely affected as a result.

For example, we currently rely on a sole supplier for treprostinil, the active pharmaceutical ingredient of LIQ861, which sources treprostinil from a manufacturer in South Korea, with whom we have a long-term supply agreement. If our supplier is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, or if it ceases its relationship with us, we may not be able to obtain alternative supplies of treprostinil from other suppliers on acceptable terms, in a timely manner, or at all. We also rely on a sole supplier for encapsulation and packaging services, with whom we have a long-term contract. Furthermore, LIQ861 is administered using the RS00 Model 8 DPI, which is manufactured by Plastiape, which is located in Italy. We purchase our RS00 Model 8 DPI supply pursuant to purchase orders and do not have a long-term contract with Plastiape. In the event of any prolonged disruption to our supply of treprostinil, the encapsulation and packaging services, or the manufacture and supply of RS00 Model 8 DPI or, our ability to develop and commercialize, and the timeline for commercialization of, LIQ861 may be adversely affected.

Additionally, in December 2019, a novel strain of COVID-19 (coronavirus) was reported to have surfaced in Wuhan, China and continues to be a global pandemic as of the date of this Quarterly Report on Form 10-Q. The full impact of the coronavirus is unknown and continues to rapidly evolve. Both South Korea, the country from which our supplier sources treprostinil, and Italy, the country in which Plastiape is headquartered, have had significant outbreaks of this disease, which, in the case of Italy, led to a lockdown of the entire country. The extent to which the coronavirus impacts our ability to procure sufficient supplies for the development and commercialization of our products and product candidates will depend on the severity, location and duration of the spread of the coronavirus, and the actions undertaken to contain the coronavirus or treat its effects.

***If we are unable to establish or maintain licensing and collaboration arrangements with other pharmaceutical companies on acceptable terms, or at all, we may not be able to develop and commercialize additional product candidates using our PRINT technology.***

We have collaborated, and may consider collaborating, with, among others, pharmaceutical companies to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. In

addition, if we are able to obtain marketing approval for our product candidates from regulatory authorities, we may enter into strategic relationships with collaborators for the commercialization of such products.

Collaboration and licensing arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish collaboration or other alternative arrangements should we so choose to enter into such arrangements. In addition, the terms of any collaboration or other arrangements that we may enter into may not be favorable to us or may restrict our ability to enter into further collaboration or other arrangements with third parties. For example, collaboration agreements may contain exclusivity arrangements which limit our ability to work with other pharmaceutical companies to expand the applications for our PRINT technology, as is the case in our collaboration agreement with GSK.

If we are unable to establish licensing and collaboration arrangements or the terms of such agreements we enter into are unfavorable to us or restrict our ability to work with other pharmaceutical companies, we may not be able to expand the applications for our PRINT technology or commercialize our products, if and when approved, and our business and prospects may be materially and adversely affected.

***Our collaboration and licensing arrangements may not be successful.***

Our collaboration and licensing arrangements, as well as any future collaboration and licensing arrangements that we may enter into, may not be successful. The success of our collaboration and licensing arrangements will depend heavily on the efforts and activities of our collaborators, which are not within our control. We may, in the course of our collaboration and licensing arrangements, be subject to numerous risks, including, but not limited to, the following:

- our collaborators may have significant discretion in determining the efforts and resources that they will contribute;
- our collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing. For example, in July 2018, GSK notified us of its decision to discontinue development of the inhaled antiviral for viral exacerbations in COPD, part of the GSK ICO Agreement, after completion of its related Phase 1 clinical trial and we do not believe that GSK is currently advancing any program under our collaboration;
- our collaborators may independently, or in conjunction with others, develop products that compete directly or indirectly with our product candidates;
- we may grant exclusive rights to our collaborators that would restrict us from collaborating with others. For example, we are currently subject to certain restrictions with regard to our ability to enter into collaboration arrangements for the development of inhaled therapeutics based upon our PRINT technology with third parties pursuant to our collaboration with GSK;
- our collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and our collaborators, which may cause a delay in or the termination of our research, development or commercialization activities;
- our collaboration and licensing arrangements may be terminated, and if terminated, may result in our need for additional capital to pursue further drug product development or commercialization. For example, our development and licensing agreement with G&W Laboratories, Inc., was mutually terminated in April 2018 and we are currently seeking the termination or amendment of our collaboration with GSK;
- our collaborators may own or co-own certain intellectual property arising from our collaboration and licensing arrangements with them, which may restrict our ability to develop or commercialize such intellectual property; and
- our collaborators may alter the strategic direction of their business or may undergo a change of control or management, which may affect the success of our collaboration arrangements with them.

**Risks Related to our Intellectual Property**

***We may be subject to claims from third parties that our products infringe their intellectual property rights.***

The pharmaceutical industry has experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay any introduction of new drug products or related technologies by, among others, establishing intellectual property rights over their drug products or technologies and aggressively enforcing these rights against potential new entrants into the market. We expect that we and other industry participants will be increasingly subject to infringement claims as the number of competitors and drug products grows.

Our commercial success depends in large part upon our ability to develop, manufacture, market and sell our drug products or product candidates without infringing on the patents or other proprietary rights of third parties. It is not always clear to industry participants, including us, what the scope of a patent covers. Due to the large number of patents in issue and patent applications filed in our industry, there is a risk that third parties will claim that our products or technologies infringe their intellectual property rights.

Claims for infringement of intellectual property which are brought against us, whether with or without merit, and which are generally uninsurable, could result in time-consuming and costly litigation, diverting our management's attention from our core business and reducing the resources available for our drug product development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being issued. We also may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Uncertainties resulting from the initiation and continuation of litigation or other proceedings could also have a material and adverse effect on our ability to compete in the market. Third parties making claims against us could obtain injunctive or other equitable relief against us, which could prevent us from further developing or commercializing our product candidates.

In particular, under the Hatch-Waxman Act, the owner of patents listed on the Orange Book and referenced by an NDA applicant may bring patent infringement suit against the NDA applicant after receipt of the NDA applicant's notice of paragraph IV certification. On June 4, 2020, United Therapeutics asserted a patent challenge directed to the Orange Book listed patents for Tyvaso by filing a complaint against us in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-UNA), thereby triggering an automatic 30-month regulatory stay on final approval of the NDA for LIQ861. As a result of United Therapeutics' patent challenge, the FDA is prohibited from approving the NDA for LIQ861 until the earliest to occur of the expiration of the 30-month stay, which is currently in October 2022, expiration of the Orange Book listed patents, settlement of the lawsuit or a decision in the infringement suit that is favorable to us as the NDA applicant. Accordingly, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize LIQ861, if at all.

In the event of a successful infringement claim against us, including an infringement claim filed in response to a paragraph IV certification, we may be required to pay damages, cease the development or commercialization of our drug products or product candidates, re-engineer or redevelop our drug products or product candidates or enter into royalty or licensing agreements, any of which could have a material and adverse impact on our business, financial condition and results of operations. Any effort to re-engineer or redevelop our products would require additional monies and time to be expended and may not ultimately be successful.

Infringement claims may be brought against us in the future, and we cannot assure you that we will prevail in any ensuing litigation given the complex technical issues and inherent uncertainties involved in intellectual property litigation. Our competitors may have substantially greater resources than we do and may be able to sustain the costs of such litigation more effectively than we can.

***Our commercial success depends largely on our ability to protect our intellectual property.***

Our commercial success depends, in large part, on our ability to obtain and maintain patent protection and trade secret protection in the United States and elsewhere in respect of our product candidates and PRINT technology. If we fail to adequately protect our intellectual property rights, our competitors may be able to erode, negate or preempt any competitive advantage we may have. To protect our competitive position, we have filed and will continue to file for patents in the United States and elsewhere in respect of our product candidates and PRINT technology. The process of identifying patentable subject matter and filing a patent application is expensive and time-consuming. We cannot assure you that we will be able to file the necessary or desirable patent applications at a reasonable cost, in a timely manner, or at all. Further, since certain patent applications are confidential until patents are issued, third parties may have filed patent applications for subject matters covered by our pending patent applications without us being aware of such applications, and our patent applications may not have priority over patent applications of others. In addition, we cannot assure you that our pending patent applications will result in patents being obtained. Once published, all patent applications and publications throughout the world, including our own, become prior art to our new patent applications and may prevent patents from being obtained or interfere with the scope of patent protection that might be obtained. The standards that patent offices in different jurisdictions use to grant patents are not always applied predictably or uniformly and may change from time to time.

Even if we have been or are able to obtain patent protection for our product candidates or PRINT technology, if the scope of such patent protection is not sufficiently broad, we may not be able to rely on such patent protection to prevent third parties from developing or commercializing product candidates or technology that may copy our product candidates or technology. The enforceability of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Accordingly, we cannot assure you that third parties will not successfully challenge the validity, enforceability or scope of our patents. A successful challenge to our patents may lead to generic versions of our drug products being launched before the expiry of our patents or otherwise limit our ability to stop others from using or commercializing similar or identical products and technology. A successful challenge to our patents may also reduce the duration of the patent protection of our drug products or technology. In addition, we cannot assure you that we will be able to detect unauthorized use or take appropriate, adequate and timely actions to enforce our intellectual property rights. If we are unable to adequately protect our intellectual property, our business, competitive position and prospects may be materially and adversely affected.

Even if our patents or patent applications are unchallenged, they may not adequately protect our intellectual property or prevent third parties from designing around our patents or other intellectual property rights. If the patent applications we file or may file do not lead to patents being granted or if the scope of any of our patent applications is challenged, we may face difficulties in developing our product candidates, companies may be dissuaded from collaborating with us, and our ability to commercialize our product candidates may be materially and adversely affected. We are unable to predict which of our patent applications will lead to patents or assure you that any of our patents will not be found invalid or unenforceable or challenged by third parties. The patents of others may prevent the commercialization of product candidates incorporating our technology. In addition, given the amount of time required for the development, clinical testing and regulatory review of new product candidates, any patents protecting our product candidates may expire before or shortly after such product candidates might become approved for commercialization.

Moreover, the issuance of a patent is not conclusive as to the inventorship of the patented subject matter, or its scope, validity or enforceability. We cannot assure you that all of the potentially relevant prior art, that is, any evidence that an invention is already known, relating to our patents and patent applications, has been found. If such prior art exists, it may be used to invalidate a patent or may prevent a patent from being issued.

In addition, we, our collaborators or our licensees may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. As a result, we may miss potential opportunities to seek patent protection or strengthen our patent position.

***If we are unable to protect our trade secrets, the value of our PRINT technology and product candidates may be negatively impacted, which would have a material and adverse effect on our competitive position and prospects.***

In addition to patent protection, we rely on trade secret protection to protect certain aspects of our intellectual property. While we require parties who have access to any portion of our trade secrets, such as our employees, consultants, advisers, CROs, CMOs, collaborators and other third parties, to enter into non-disclosure and confidentiality agreements with us, we cannot assure you that these parties will not disclose our proprietary information, including our trade secrets, in breach of their contractual obligations. Enforcing a claim that a party has illegally disclosed or misappropriated a trade secret is difficult, costly and time-consuming, and we may not be successful in doing so. If the steps we have taken to protect our trade secrets are deemed by the adjudicating court to be inadequate, we may not be able to obtain adequate recourse against a party for misappropriating our trade secrets.

Trade secrets can be difficult to protect as they may, over time, be independently discovered by our competitors or otherwise become known despite our trade secret protection. If any of our trade secrets were to be lawfully obtained or independently developed by our competitors, we would have no right to prevent such competitors, or those to whom they communicate such technology or information, from using that technology or information to compete with us. Such competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights.

If our trade secrets were to be disclosed to or independently developed by our competitors, our competitors may be able to exploit our PRINT technology to develop competing product candidates, and the value of our PRINT technology and our product candidates may be negatively impacted. This would have a material and adverse effect on our competitive position and prospects.

***We rely on licenses to intellectual property that are owned by third parties.***

We have entered and may, in the future, enter into license agreements with third parties to license the rights to use their technologies in our research, development and commercialization activities. License agreements generally impose various diligence, milestone payments, royalty, insurance and other obligations on us, and if we fail to comply with these obligations, our licensors may have the right to terminate these license agreements. Termination of these license agreements or the reduction or elimination of our licensed rights or the exclusivity of our licensed rights may have an adverse impact on, among others, our ability to develop and commercialize our product candidates. We cannot assure you that we will be able to negotiate new or reinstated licenses on commercially acceptable terms, or at all.

In addition, we license certain patent rights for our PRINT technology from UNC under the UNC License. Under the UNC License, UNC has the right to terminate our license if we materially breach the agreement and fail to cure such breach within the stipulated time. In the event that UNC terminates our license and we have a product that relies on that license, it may bring a claim against us, and if they are successful, we may be required to compensate UNC for the unauthorized use of their patent rights through the payment of royalties.

Also, the agreements under which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain or successfully enforce necessary or desirable patent protection from those patent rights. We do not have primary control over patent prosecution and maintenance for certain of the patents we license, and therefore cannot assure you that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We also cannot assure you that patent prosecution and maintenance activities by our licensors, if any, will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

Pursuant to the terms of some of our license agreements with third parties, some of our third-party licensors have the right, but not the obligation, in certain circumstances, to control the enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense,

we will require the cooperation of our licensors, and we cannot assure you that we will receive such cooperation on commercially acceptable terms, or at all. We also cannot assure you that our licensors will allocate sufficient resources or prioritize their or our enforcement of these patents or defense of these claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position, business and prospects may be materially and adversely affected.

Further, licenses to intellectual property may not always be available to us on commercially acceptable terms, or at all. In the event that the licenses we rely on are not available to us on commercially acceptable terms, or at all, our ability to commercialize our PRINT technology or product candidates, and our business and prospects, may be materially and adversely affected.

***We may not be able to enforce our intellectual property rights throughout the world.***

Filing, prosecuting, enforcing and defending patents on our PRINT technology and our product candidates throughout the world may be prohibitively expensive and may not be financially or commercially feasible. In countries where we have not obtained patent protection, our competitors may be able to use our proprietary technologies to develop competing product candidates.

Also, the legal systems of non-U.S. jurisdictions may not protect intellectual property rights to the same extent or in the same manner as the laws of the United States, and we may face significant difficulty in enforcing our intellectual property rights in these jurisdictions. The legal systems of certain developing countries may not favor the enforcement of patents and other intellectual property rights. We may therefore face difficulty in stopping the infringement or misappropriation of our patents or other intellectual property rights in those countries.

***We need to protect our trademark, trade name and service mark rights to prevent competitors from taking advantage of our name recognition.***

We believe that the protection of our trademark, trade name and service mark rights, such as Liquidia, the Liquidia logo and PRINT, is an important factor in product recognition, protecting our brand, maintaining goodwill and maintaining or increasing market share. We may expend substantial cost and effort in an attempt to register new trademarks, trade names and service marks and maintain and enforce our trademark, trade name and service mark rights. If we do not adequately protect our rights in our trademarks, trade names and service marks from infringement, any name recognition that we have developed in those trademarks could be lost or impaired.

Third parties may claim that the sale or promotion of our products, when and if approved, may infringe on the trademark, trade name and service mark rights of others. Trademark, trade name and service mark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark, trade name and service mark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time-consuming litigation that could harm our business. If the trademarks, trade names and service marks we use are found to infringe upon the trademarks, trade names or service marks of another company, we could be liable for damages and be forced to stop using those trademarks, trade names or service marks, and as a result, we could lose all the name recognition that has been developed in those trademarks, trade names or service marks.

**Risks Related to the Manufacturing of our Product Candidates**

***Our product candidates are based on our proprietary, novel technology, PRINT, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.***

Our future success depends on the successful development of our novel PRINT technology and products based on it, including LIQ861. To our knowledge, no regulatory authority has granted approval to market or commercialize drugs made using our PRINT technology. We may never receive approval to market and commercialize any product candidate that uses our PRINT technology.

***Our operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural disasters or other unforeseen events could materially and adversely affect our operations.***

Most of our current operations are concentrated in Morrisville, North Carolina. A fire, flood, hurricane, earthquake or other disaster or unforeseen event resulting in significant damage to our facilities could significantly disrupt or curtail or require us to cease our operations. It would be difficult, costly and time-consuming to transfer resources from one facility to another or to repair or replace our facility in the event that it is significantly damaged. In addition, our insurance may not be sufficient to cover all of our losses and may not continue to be available to us on acceptable terms, or at all. In addition, if one of our suppliers experiences a similar disaster or unforeseen event, we could face significant delays in obtaining our supplies or be required to source supplies from an alternative supplier and may incur substantial costs as a result. Any significant uninsured loss, prolonged or repeated disruption to operations or inability to operate, experienced by us or by our suppliers, could materially and adversely affect our business, financial condition and results of operations.

**Risk Related to our Employees**

***We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel.***

Our ability to continue our operations and manage our potential future growth depends on our ability to hire and retain suitably skilled and qualified employees, including those in senior management, in the long-term. Due to the specialized nature of our work, there is a limited supply of suitable candidates. We compete with other biotechnology and pharmaceutical companies, educational and research institutions and government entities, among others, for research, technical, clinical and sales and marketing personnel. In addition, in order to manage our potential future growth effectively, we will need to improve our financial controls and systems and, as necessary, recruit sales, marketing, managerial and finance personnel. The loss of the services of members of our sales team could seriously harm our ability to successfully implement our business strategy. If we are unable to attract and retain skilled personnel, including in particular Damian deGoa, our Chief Executive Officer, our business and prospects may be materially and adversely affected.

**Risks Related to our Common Stock**

***Future sales of our common stock or securities convertible into our common stock in the public market could cause our stock price to fall.***

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

On April 13, 2021, the Company sold 8,626,037 shares of the Company's common stock in a private placement. The purchasers of such shares of common stock have agreed not to offer, sell, transfer or otherwise dispose of any such shares during the 6-month period following the closing. The 6-month lock-up period recently expired, allowing such shares to be freely sold in the public market which could cause our stock price to decline.

Upon consummation of the Merger Transaction, we issued to RareGen's former members an aggregate of 5,550,000 shares of our common stock. Additionally, 616,666 shares of our common stock, which are referred to in the Merger Agreement as "Holdback Shares", are being withheld to satisfy potential indemnification obligations of former RareGen members. In addition, we may issue up to 2,708,333 shares of our common stock in 2022, which are referred to in the Merger Agreement as "Net Sales Earnout Shares", if Liquidia PAH achieves at least $32.9 million of 2021 net sales (as calculated by Sandoz net sales), with the number of Net Sales Earnout Shares to be issued to depend upon the actual amount of the 2021 net sales. The shares issued to former RareGen members on the closing date of the Merger Transaction were subject to a six-month lock-up that expired on May 18, 2021. In the event that

Holdback Shares are released or Net Sales Earnout Shares are issued, such shares will not have a lock-up restriction and may be freely sold in the public market which could cause our stock price to decline.

As of October 15, 2021, 51,977,992 shares of our common stock were outstanding, of which 40,705,936 shares of common stock, or 78.3% of our outstanding shares as of October 15, 2021, are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act ("Rule 144"). The resale of the remaining 11,272,056 shares held by our stockholders as of October 15, 2021 is currently prohibited or otherwise restricted as a result of securities law provisions. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

As of October 15, 2021, the holders of 10,513,974 shares, or 20.2%, of our outstanding shares as of October 15, 2021, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, including the employee stock purchase plan. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance or resale (as applicable), subject to lock-up agreements, if any.

***We expect that the market price of our common stock may be volatile, and you may lose all or part of your investment.***

The trading prices of the securities of pharmaceutical and biotechnology companies have been highly volatile. As such, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The market price for our common stock may be influenced by many factors, including:

- results of any clinical trials of LIQ861 or any product candidate we may develop, or those of our competitors;
- the success of Sandoz's generic version of Remodulin to which we have commercial rights to pursuant to the Promotion Agreement;
- the success of Chengdu's launch of the RG Cartridge and the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection;
- our cash resources;
- the success of competitive products or technologies;
- potential approvals of any product candidate we may develop for marketing by the FDA or equivalent foreign regulatory authorities or any failure to obtain such approvals;
- our involvement in significant lawsuits, including stockholder or patent litigation, including *inter partes* review proceedings and Hatch-Waxman litigation with originator companies or others which may hold patents, including United Therapeutics;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize any product candidate we may develop;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;

- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

The stock market in general, and market prices for the securities of pharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned 36.2% of our capital stock as of October 15, 2021. Accordingly, our executive officers, directors and principal stockholders have significant influence in determining the composition of the Board, and voting on all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as one of our stockholders. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the Board or management.

***As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares. The results of our assessment of the effectiveness of internal control over financial reporting (ICFR) indicate that we had multiple material weaknesses which have not been fully remedied as of September 30, 2021.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act) or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

As required by the Sarbanes Oxley Act of 2002 and commencing with the fiscal year ended December 31, 2019, we were required to furnish a report by management on, among other things, the effectiveness of our ICFR. In connection with the assessment of the effectiveness of our ICFR, our management identified material weaknesses that existed as of December 31, 2019 and December 31, 2020 which have not been fully remedied as of September 30, 2021. See Item 4. Controls and Procedures for additional information.

***We are an "emerging growth company," as defined in the JOBS Act, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more, (ii) the last day of 2023, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price.***

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

- permit the Board to issue up to 10 million shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- create a staggered board of directors such that all members of our Board are not elected at one time;
- allow for the issuance of authorized but unissued shares of our capital stock without any further vote or action by our stockholders; and
- establish advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon at stockholders' meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL") which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any stockholder owning in excess of 15% of our outstanding stock for a period of three years following the date on which the stockholder obtained such 15% equity interest in us.

The terms of our authorized preferred stock selected by our Board at any point could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and powers, including voting rights, of holders of our common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock.

Any provision of our certificate of incorporation or bylaws or Delaware corporate law that has the effect of delaying or deterring a change in control could limit opportunities for our stockholders to receive a premium for their shares of common stock, and could also affect the price that investors are willing to pay for our common stock.

***Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.***

Our certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (d) any action asserting a claim against us governed by the internal affairs doctrine; *provided*, that, this provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or Exchange Act. Furthermore, our bylaws designate the federal district courts of the United States as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors or officers. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, prospects or results of operations.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our equity securities. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our existing LSA with SVB preclude us, and the terms of any future debt agreement may preclude us, from paying dividends. As a result, capital appreciation, if any, of our equity securities will likely be your sole source of gain for the foreseeable future.

***An impairment of our long-lived contract acquisition cost and intangible assets, including goodwill, could have a material non-cash adverse impact on our results of operations.***

In connection with the accounting for our RareGen acquisition, we have recorded significant amounts of contract acquisition costs, intangible assets, and goodwill. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill has been impaired. Contract acquisition costs and amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. The valuation of goodwill depends on a variety of factors, the success of the Company's business, including our ability to obtain regulatory approval for LIQ861, global market and economic conditions, earnings growth and expected cash flows. Impairments may be caused by factors outside the Company's control, such as actions by the FDA, increasing competitive pricing pressures, and various other factors. Significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for LIQ861, could require a non-cash charge for impairment in a future period, which may significantly affect the Company's results of operations in the period of such charge.

**General Risk Factors**

**General Risks Related to the Commercialization of our Product Candidates**

***Our business and operations are likely to be adversely affected by the evolving and ongoing COVID-19 global pandemic.***

Our business and operations are likely to be adversely affected by the effects of the recent and evolving COVID-19 virus, which was declared by the World Health Organization as a global pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States that, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and our research and development activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements may result in control deficiencies in the preparation of our financial reports, which could be material. Currently, many of our employees are continuing to work remotely, with only essential personnel required to work on site as needed to produce LIQ861 and conduct other activities that cannot be conducted remotely.

Such orders may also impact personnel at third-party contract research organizations that conduct clinical trials or research activities, which could impact our ability to continue or commence such activities, or contract manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Quarterly Report on Form 10-Q, such as the ultimate geographic spread of the disease, the severity and duration of future outbreaks (including from the spread of COVID-19 variants or mutant strains), the duration and effect of business disruptions and the short-term effects, the administration, availability and efficacy of vaccination programs and the ultimate effectiveness of travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. We expect the impact of COVID-19 on the FDA's operations will continue to evolve. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section and the "Risk Factors" sections of the documents incorporated by reference herein.

***The marketing approval processes of the FDA and comparable regulatory authorities in other countries are unpredictable and our product candidates may be subject to multiple rounds of review or may not receive marketing approval.***

Pursuing marketing approval for a pharmaceutical product candidate (for example, through the NDA process) is an extensive, lengthy, expensive and inherently uncertain process. We cannot assure you that any of our product candidates will receive marketing approval. Regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including, but not limited to, the following:

- the FDA or comparable regulatory authorities may, for a variety of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate;

- the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers do not sufficiently demonstrate compliance with current good manufacturing practices (cGMP) to support approval of a product candidate; or that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities in other countries that our product candidate is safe and effective for its proposed indication, or that its clinical and other benefits outweigh its safety risks;

- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

Even if we obtain marketing approval, the FDA or comparable regulatory authorities in other countries may approve our product candidates for fewer or more limited indications than those for which we requested approval or may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other studies or the conduct of an expensive REMS, which could significantly reduce the potential for commercial success or viability of our product candidates. We also may not be able to find acceptable collaborators to manufacture our drug products, if and when approved, in commercial quantities and at acceptable prices, or at all.

***If the FDA or comparable regulatory authorities in other countries approve generic versions of our product candidates, or do not grant our product candidates a sufficient period of market exclusivity before approving their generic versions, our ability to generate revenue may be adversely affected.***

Once an NDA is approved, the drug product covered will be listed as a reference listed drug in the FDA's Orange Book. In the United States, manufacturers of drug products may seek approval of generic versions of reference listed drugs through the submission of abbreviated new drug applications (ANDAs). In support of an ANDA, a generic manufacturer is generally required to show that its product has the same active pharmaceutical ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug. Generic drug products may be significantly less expensive to bring to market than the reference listed drug, and companies that produce generic drug products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug product, a significant percentage of the sales of any reference listed drug may be lost to the generic drug product.

The FDA will not approve an ANDA for a generic drug product until the applicable period of market exclusivity for the reference listed drug has expired. The applicable period of market exclusivity varies depending on the type of exclusivity granted. A grant of market exclusivity is separate from the existence of patent protection and manufacturers may seek to launch generic versions of our drug products following the expiry of their respective marketing exclusivity periods, even if our drug products are still under patent protection at the relevant time.

Any competition that our product candidates may face, if and when such product candidates are approved for marketing and commercialized, from generic versions could substantially limit our ability to realize a return on our investment in the development of our product candidates and have a material and adverse effect on our business and prospects.

**General Risk Related to the Development and Regulatory Approval of our Product Candidates**

***Even if we obtain marketing approval for our product candidates in the United States, we or our collaborators may not obtain marketing approval for the same product candidates elsewhere.***

We may enter into strategic collaboration arrangements with third parties to commercialize our product candidates outside of the United States. In order to market any product candidate outside of the United States, we or our collaborators will be required to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be recognized or accepted by regulatory authorities in other countries, and obtaining marketing approval in one country does not mean that marketing approval will be obtained in any other country. Approval processes vary among countries and additional product testing and validation, or additional administrative review periods, may be required from one country to the next.

Seeking marketing approval in countries other than the United States could be costly and time-consuming, especially if additional preclinical studies or clinical trials are required to be conducted. We currently do not have any product candidates approved for sale in any jurisdiction, including non-U.S. markets, and we do not have experience in obtaining marketing approval in non-U.S. markets. We currently also have not identified any collaborators to market our products outside of the United States and cannot assure you that such collaborators, even if identified, will be able to successfully obtain marketing approval for our product candidates outside of the United States. If we or our collaborators fail to obtain marketing approval in non-U.S. markets, or if such approval is delayed, our target market may be reduced, and our ability to realize the full market potential of our products will be adversely affected.

**General Risk Related to Healthcare Regulation**

***The pharmaceutical industry is subject to a range of laws and regulations in areas including healthcare program requirements and fraud, waste, and abuse; healthcare and related marketing compliance and transparency; and privacy and data security. Our failure to comply with these laws and regulations as they are, or in the future become, applicable to us may have an adverse effect on our business.***

Healthcare providers, physicians and third-party payors often play a primary role in the recommendation and prescription of any drug products for which we may obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell, or distribute drug products.

In addition, we may be subject to transparency laws and patient privacy regulation by both the federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include, but are not limited to, the following examples:

- The federal Anti-Kickback Statute (AKS) prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for or the purchase, lease, or order of, or the

arranging for an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs.

- The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act (FCA) prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS constitute a false or fraudulent claim for purposes of the federal False Claims Act. Promotion that is deemed to be "off label" can be the basis of FCA exposure.

- Federal law includes provisions (established under the Health Insurance Portability and Accountability Act of 1996) addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs.

- Privacy and data security laws may apply to our business. Under the Federal Trade Commission Act (the FTCA) Section 5(a), the FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements, for example the California Consumer Privacy Act (CCPA) went into effect in January 2020 creating data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information.

- The federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services (CMS) information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Payments and transfers of value made to certain other providers such as nurse practitioners and physician assistants beginning in 2021 will need to be reported under the Sunshine Act in 2022.

- For both investigational and commercialized products, interactions with or communications directed to healthcare professionals (HCPs), patients or patient- or disease-advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to nonpromotional communications, for example, there are specific and limited FDA accommodations for nonpromotional, truthful and non-misleading sharing of information regarding products in development and off-label uses including dissemination of peer-reviewed reprints, support of independent continuing medical education (CME), and healthcare economic discussions with payors. In a competitive environment, a company's communications about products in development may also be subject to heightened scrutiny.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases may apply regardless of payor (i.e., even for self-pay scenarios). Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and

other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives. Many of these state laws differ from each other in significant ways and may not have the same effect, and may apply more broadly or be stricter than their federal counterparts, thus complicating compliance efforts; and

- Price reporting laws require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursements or discounts on our drug products. Participation in such programs and compliance with their requirements may subject us to increased infrastructure costs and potentially limit our ability to price our drug products.

Ensuring that our business and business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business, even if the government ultimately finds that no violation has occurred.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws or government regulations that apply to us, we may be subject to penalties and potentially, the curtailment or restructuring of our operations as well as additional governmental reporting obligations and oversight, any of which could adversely affect our ability to operate our business and our results of operations.

**General Risk Related to Our Dependence on Third Parties**

***We rely on third parties to conduct our preclinical studies and clinical trials.***

We currently rely on, and plan to continue to rely on, third-party contract research organizations (CROs) to monitor and manage data for our preclinical studies and clinical trials. However, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable regulatory standards and our reliance on CROs does not relieve us of our regulatory responsibilities.

The CROs on which we rely are required to comply with FDA regulations (and the regulations of comparable regulatory authorities in other countries) regarding GCP. Regulatory authorities enforce GCP standards through periodic inspections. If any of the CROs on which we rely fail to comply with the applicable GCP standards, the clinical data generated in our clinical trials may be deemed unreliable. While we have contractual agreements with these CROs, we have limited influence over their actual performance and cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical trials. A failure to comply with the applicable regulations in the conduct of the preclinical studies and clinical trials for our product candidates may require us to repeat such studies or trials, which would delay the process of obtaining marketing approval for our product candidates and have a material and adverse effect on our business and prospects.

Some of our CROs have the ability to terminate their respective agreements with us if, among others, it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination. If any of our agreements with our CROs is terminated, and if we are not able to enter into agreements with alternative CROs on acceptable terms or in a timely manner, or at all, the clinical development of our product candidates may be delayed and our development expenses could be increased.

**General Risks Related to Legal Compliance Matters**

***Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review.***

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, drug supply chain security surveillance and tracking, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and comparable requirements outside

of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we may receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We will also be required to report certain adverse reactions and production problems, if any, to the FDA or other regulatory agencies and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA or other regulatory agency approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a clinical study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us or our strategic partners;
- restrict the marketing or manufacturing of our products;
- seize or detain products, or require a product recall;
- refuse to permit the import or export of our product candidates; or
- refuse to allow us to enter into government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

**General Risks Related to our Intellectual Property**

***We may become involved in litigation to protect our intellectual property or enforce our intellectual property rights, which could be expensive, time-consuming and may not be successful.***

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may engage in litigation to, among others, enforce or defend our intellectual property rights, determine the validity or scope of our intellectual property rights and those of third parties, and protect our trade secrets. Such actions may be time-consuming and costly and may divert our management's attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome.

In addition, in an infringement proceeding, a court may decide that a patent owned by, or licensed to, us is invalid or unenforceable, or may refuse to stop the other party from using the technology in question on the ground that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information may be compromised by disclosure.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

We intend to seek extensions of patent terms in the United States and, if available, in other countries where we prosecute patents. In the United States, the Hatch-Waxman Act permits patent owners to request a patent term extension, based on the regulatory review period for a product, of up to five years beyond the normal expiration of the patent, which is limited to one patent claiming the approved drug product or use in an indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO, in the United States, and comparable regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or grant more limited extensions than we had requested. In such event, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our preclinical and clinical data in their marketing approval applications with the FDA to launch their drug product earlier than might otherwise be the case.

**General Risk Related to the Manufacturing of our Product Candidates**

***Our facilities are subject to extensive and ongoing regulatory requirements and failure to comply with these regulations may result in significant liability.***

Our company and our facilities are subject to payment of fees, registration and listing requirements, ongoing review and periodic inspections by the FDA and other regulatory authorities for compliance with quality system regulations, including the FDA's cGMP requirements. These regulations cover all aspects of the manufacturing, testing, quality control and record-keeping of our drug products. Furthermore, the facilities where our product candidates are manufactured may be subject to additional inspections by the FDA before we can obtain marketing approval and remain subject to periodic inspection even after our product candidates have received marketing approval. Suppliers of components and materials, such as active pharmaceutical ingredients, used to manufacture our drug products are also required to comply with the applicable regulatory standards.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and any contract manufacturers that we may engage in the future must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Compliance with these regulatory standards often requires significant expense and effort. If we or our suppliers are unable to comply with the applicable regulatory standards or take satisfactory corrective steps in response to adverse results of an inspection, this could result in enforcement action, including, among others, the issue of a public warning letter, a shutdown of or restrictions on our or our suppliers' manufacturing operations, delays in approving our drug products and refusal to permit the import or export of our drug products. Any adverse regulatory action taken against us could subject us to significant liability and harm our business and prospects.

**Item 6. Exhibits**

The exhibits listed on the Exhibit Index hereto are filed or furnished (as stated therein) as part of this Quarterly Report on Form 10-Q.

**EXHIBIT INDEX**

| Exhibit No. | Document |
|---|---|
| 10.1 | First Loan Modification Agreement, dated as of August 26, 2021, by and among Silicon Valley Bank, Liquidia Corporation, Liquidia Technologies, Inc. and Liquidia PAH, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on August 30, 2021). |
| 31.1* | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act. |
| 31.2* | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act. |
| 32.1** | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes- Oxley Act. |
| 32.2** | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes- Oxley Act. |
| 101* | The following materials from Liquidia Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2021 (unaudited) and December 31, 2020, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2021 and 2020, (iii) Condensed Consolidated Statement of Stockholders' Equity (Deficit) (unaudited) for the three and nine months ended September 30, 2021 and 2020, (iv) Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2021 and 2020 and (v) Notes to Condensed Consolidated Financial Statements (unaudited). |
| 104* | Cover Page Interactive Data File (formatted as Inline XBRL and Contained in Exhibit 101). |

* Filed herewith.

** Furnished herewith.

**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 thereunto duly authorized.

DATE: November 3, 2021

**LIQUIDIA CORPORATION**
By:/s/ Damian deGoa
Damian deGoa
Chief Executive Officer

DATE: November 3, 2021

**LIQUIDIA CORPORATION**
By:/s/ Michael Kaseta
Michael Kaseta
Chief Financial Officer

**Exhibit 31.1**

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Damian deGoa, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Liquidia Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2021

By: /s/ Damian deGoa
Name: Damian deGoa
Title: Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael Kaseta, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Liquidia Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2021

By: /s/ Michael Kaseta
Name: Michael Kaseta
Title: Chief Financial Officer
(Principal Financial Officer)

**Exhibit 32.1**

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Liquidia Corporation, a Delaware corporation (the "Company"), on Form 10-Q for the three months ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Damian deGoa, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2021

By: /s/ Damian deGoa
Name: Damian deGoa
Title: Chief Executive Officer
(Principal Executive Officer)

**Exhibit 32.2**

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER**
**PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Liquidia Corporation, a Delaware corporation (the "Company"), on Form 10-Q for the three months ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Kaseta, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2021

By: /s/ Michael Kaseta
Name: Michael Kaseta
Title: Chief Financial Officer
(Principal Financial Officer)