**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, 2020

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: 001-38601

**LIQUIDIA TECHNOLOGIES, INC.**
(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **20-1926605** |
|---|---|
| (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 November 2, 2020, there were 37,752,882 shares of the registrant's common stock outstanding.

**LIQUIDIA TECHNOLOGIES, INC.**



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.



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**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 SEC, including, but not limited to (i) the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including potential FDA approval of the January 2020 filing of our New Drug Application, or NDA, for LIQ861; (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 or its *inter partes* review with 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;

- failing to obtain stockholder approval of the proposed acquisition of RareGen, LLC, or RareGen, by way of merger, or the Merger Transaction, pursuant to that certain Agreement and Plan of Merger, dated as of June 29, 2020, by and among our company, Liquidia Corporation, or HoldCo, RareGen and certain other parties thereto, or the Merger Agreement;

- satisfying the conditions to the closing of the Merger Transaction;

- the length of time necessary to complete the Merger Transaction;

- successfully integrating our and RareGen's businesses, and avoiding problems which may result in HoldCo not operating as effectively and efficiently as expected;

- the possibility that the expected benefits of 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 HoldCo's operations, and the anticipated tax treatment;
- the restrictions on our and RareGen's ability to pursue alternative transactions to the Merger Transaction and the possibility that, in specified circumstances, we could be required to pay a fee to RareGen;
- possible disruptions from the proposed Merger Transaction that could harm our or RareGen's business, including current plans and operations;
- the ability of us or RareGen 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 or RareGen 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, or the effects of acquisition accounting varying from our expectations;



- the risk that the credit ratings of HoldCo or its subsidiaries may be different from what the companies expect, which may increase borrowing costs and/or make it more difficult for HoldCo to pay or refinance its debts and require it to borrow or divert cash flow from operations in order to service debt payments;
- fluctuations in interest rates;
- the effects on the businesses of the companies resulting from uncertainty surrounding the Merger Transaction, including with respect to customers, suppliers, licensees, collaborators, business partners, employees, other third parties or the diversion of management's time and attention, that could affect our and/or RareGen's financial performance;
- adverse outcomes of pending or threatened litigation or governmental investigations, if any, unrelated to the Merger Transaction;
- potential litigation relating to the proposed Merger Transaction that could be instituted against us, RareGen or our and their respective officers or directors;
- the effects on the companies of future regulatory or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we or RareGen are subject;
- conduct of and changing circumstances related to third-party relationships on which we and RareGen 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 disaster, global pandemics such as COVID-19, or acts of war or terrorism;
- variations between the stated assumptions on which forward-looking statements are based and our and RareGen's 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 outbreak 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" and the "Company" refer to Liquidia Technologies, Inc., a Delaware corporation.*



**Liquidia Technologies, Inc.**
**Consolidated Balance Sheets**

| | September 30, 2020 (Unaudited) | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 79,551,041 | $ 55,796,378 |
| Prepaid expenses and other current assets | 1,095,331 | 590,251 |
| Total current assets | 80,646,372 | 56,386,629 |
| Property, plant and equipment, net | 7,388,376 | 9,253,965 |
| Operating lease right-of-use assets, net | 2,698,344 | 2,823,430 |
| Other assets | 378,043 | 378,043 |
| Total assets | $ 91,111,135 | $ 68,842,067 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,414,978 | $ 3,498,043 |
| Accrued compensation | 2,068,480 | 3,164,687 |
| Accrued stock offering expenses | — | 1,289,413 |
| Other accrued expenses | 1,409,976 | 1,525,919 |
| Current portion of operating lease liabilities | 638,862 | 566,390 |
| Current portion of finance lease liabilities | 1,113,670 | 1,244,229 |
| Current portion of long-term debt | 5,585,636 | 5,585,637 |
| Total current liabilities | 14,231,602 | 16,874,318 |
| Long-term operating lease liabilities | 5,183,539 | 5,670,971 |
| Long-term finance lease liabilities | 310,513 | 1,056,747 |
| Long-term debt | 6,104,374 | 10,292,484 |
| Total liabilities | 25,830,028 | 33,894,520 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock — 10,000,000 shares authorized as of September 30, 2020 and December 31, 2019, 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019 | — | — |
| Common stock — $0.001 par value, 60,000,000 and 40,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively, 37,752,261 and 28,231,267 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively | 37,752 | 28,231 |
| Additional paid-in capital | 324,159,065 | 250,158,766 |
| Accumulated deficit | (258,915,710) | (215,239,450) |
| Total stockholders' equity | 65,281,107 | 34,947,547 |
| Total liabilities and stockholders' equity | $ 91,111,135 | $ 68,842,067 |

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



**Liquidia Technologies, Inc.**
**Consolidated Statements of Operations and Comprehensive Loss (Unaudited)**

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

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



**Liquidia Technologies, Inc.**
**Consolidated Statements of Stockholders' Equity (Unaudited)**
**For the Three and Nine Months Ended September 30, 2020 and 2019:**

**For the Three and Nine Months Ended September 30, 2020:**

| | 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 |
| Exercise of common stock options | 2,035 | 2 | (2) | — | — |
| Stock-based compensation | — | — | 878,963 | — | 878,963 |
| Issuance of common stock under employee stock purchase plan | 3,269 | 3 | 11,488 | — | 11,491 |
| Issuance of common stock under stock incentive plan | 702 | 1 | (1) | — | — |
| Sale of common stock, net | 131,425 | 131 | 725,267 | — | 725,398 |
| 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 |
| Exercise of common stock options | 5,184 | 5 | 25,646 | — | 25,651 |
| Stock-based compensation | — | — | 988,119 | — | 988,119 |
| Issuance of common stock under stock incentive plan | 703 | 1 | (1) | — | — |
| 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 |
| Exercise of common stock options | 153 | — | 273 | — | 273 |
| Stock-based compensation | — | — | 1,081,000 | — | 1,081,000 |
| Issuance of common stock under employee stock purchase plan | 1,821 | 2 | 7,923 | — | 7,925 |
| Issuance of common stock under stock incentive plan | 702 | 1 | (1) | — | — |
| Sale of common stock, net | 9,375,000 | 9,375 | 70,281,625 | — | 70,291,000 |
| 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 |

**For the Three and Nine Months Ended September 30, 2019:**

| | Common Stock Shares | Common Stock Amount | Additional Paid in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| **Balance as of December 31, 2018** | 15,519,469 | $ 15,520 | $ 185,726,048 | $ (167,053,897) | $ 18,687,671 |
| Cumulative adjustment - adoption of ASC 842 | — | — | — | (602,098) | (602,098) |

| | | | | | |
|---|---|---|---|---|---|
| Exercise of common stock options | 52,914 | 53 | 63,099 | — | 63,152 |
| Exercise of common stock warrants | 64,629 | 64 | 649 | — | 713 |
| Stock-based compensation | — | — | 887,022 | — | 887,022 |
| Public offering of common stock, net | 3,000,000 | 3,000 | 32,427,000 | — | 32,430,000 |
| Public offering financing costs | — | — | (382,423) | — | (382,423) |
| Net loss | — | — | — | (13,766,790) | (13,766,790) |
| **Balance as of March 31, 2019** | 18,637,012 | $ 18,637 | $ 218,721,395 | $ (181,422,785) | $ 37,317,247 |
| Exercise of common stock options | 6,430 | 6 | 30,110 | — | 30,116 |
| Stock-based compensation | — | — | 821,770 | — | 821,770 |
| Public offering financing costs | — | — | (174,768) | — | (174,768) |
| Net loss | — | — | — | (5,901,165) | (5,901,165) |
| **Balance as of June 30, 2019** | 18,643,442 | $ 18,643 | $ 219,398,507 | $ (187,323,950) | $ 32,093,200 |
| Exercise of common stock options | 13,244 | 13 | 48,046 | — | 48,059 |
| Stock-based compensation | — | — | 830,502 | — | 830,502 |
| Net loss | — | — | — | (13,423,059) | (13,423,059) |
| **Balance as of September 30, 2019** | 18,656,686 | $ 18,656 | $ 220,277,055 | $ (200,747,009) | $ 19,548,702 |

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



**Liquidia Technologies, Inc.**
**Consolidated Statements of Cash Flows (Unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2020** | **2019** |
| **Operating activities** | | |
| Net loss | $ (43,676,260) | $ (33,091,014) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 2,948,082 | 2,539,294 |
| Depreciation and amortization | 2,178,402 | 1,857,070 |
| Non-cash lease expense | 125,086 | 190,784 |
| Amortization of discount and debt issuance costs on long-term debt | 47,183 | — |
| Non-cash interest expense | — | 32,180 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | — | 262,999 |
| Prepaid expenses and other current assets | (505,080) | (267,414) |
| Other non-current assets | — | 1,437,416 |
| Accounts payable | 133,521 | 1,353,762 |
| Accrued expenses | 203,833 | 77,630 |
| Accrued compensation | (1,096,207) | (252,436) |
| Deferred revenue | — | (8,071,920) |
| Operating lease liabilities | (414,960) | (290,492) |
| Net cash used in operating activities | (40,056,400) | (34,222,141) |
| **Investing activities** | | |
| Purchases of property, plant and equipment | (713,121) | (1,716,208) |
| Net cash used in investing activities | (713,121) | (1,716,208) |
| **Financing activities** | | |
| Principal payments on finance leases | (876,793) | (696,875) |
| Proceeds from issuance of long-term debt | — | 5,000,000 |
| Principal payments on long-term debt | (4,235,294) | — |
| Proceeds from sale of common stock, net of underwriting fees and commissions | 71,225,398 | 31,872,808 |
| Payments for offering costs | (1,634,467) | (610,007) |
| Proceeds from issuance of common stock under stock incentive plans | 45,340 | — |
| Proceeds from exercise of stock options and warrants | — | 142,002 |
| Net cash provided by financing activities | 64,524,184 | 35,707,928 |
| Net increase (decrease) in cash | 23,754,663 | (230,421) |
| Cash, beginning of period | 55,796,378 | 39,534,985 |
| Cash, end of period | $ 79,551,041 | $ 39,304,564 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 601,838 | $ 705,249 |
| Cash paid for operating lease liabilities | $ 875,229 | $ 790,688 |
| Right of use assets obtained with lease liabilities | $ — | $ 354,791 |
| Changes in purchases of property and equipment in accounts payable and accrued expenses | $ 400,308 | $ 187,086 |
| Accrued tenant improvements and receivable from landlord | $ — | $ 936,104 |
| Deferred offering costs incurred but not paid | $ — | $ 141,314 |

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

## 1. Business

Liquidia Technologies, Inc. ("Liquidia" or the "Company") is a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing the Company's proprietary PRINT technology to transform the lives of patients. PRINT is a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. The Company is currently focused on the development of two product candidates for which it holds worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension ("PAH") and LIQ865 for the treatment of local post-operative pain.

The development and commercialization activities are conducted at the Company's headquarters located in Morrisville, North Carolina. The Company was incorporated under the laws of the state of Delaware in 2004.

### Recent Developments and Subsequent Events

*Acquisition of RareGen, LLC*

On June 29, 2020, the Company entered into that certain Agreement and Plan of Merger with RareGen, LLC, a privately-held entity, Liquidia Corporation, a wholly owned subsidiary of the Company ("HoldCo"), Gemini Merger Sub I, Inc., a wholly owned subsidiary of HoldCo ("Liquidia Merger Sub"), Gemini Merger Sub II, LLC, a wholly owned subsidiary of HoldCo ("RareGen Merger Sub"), and PBM RG Holdings, LLC, as the Members' Representative (the "Merger Agreement"), pursuant to which, among other things, the Company and RareGen will each become a subsidiary of HoldCo (the "Merger Transaction"). RareGen provides strategy, investment, and commercialization for generic Treprostinil injection. RareGen has a small, targeted sales force focused on PAH. Pursuant to a Promotion Agreement, dated as of August 1, 2018, as amended (the "Promotion Agreement"), between RareGen and Sandoz Inc. ("Sandoz"), RareGen owns the exclusive rights to conduct any and all promotional and non-promotional activities to encourage the appropriate use of the first-to-file substitutable generic of treprostinil injection for the treatment of patients with PAH in the United States. The Merger Transaction is expected to close in the fourth quarter of 2020. If the Merger Transaction is completed, (i) each share of Company common stock, $0.001 par value per share ("Company Common Stock"), whether certificated or held in book-entry form, will automatically convert into one share of HoldCo common stock, $0.001 par value per share ("HoldCo Common Stock"), (ii) each option and warrant to purchase a share of Company Common Stock will entitle the holder to purchase one share of HoldCo Common Stock, and the exercise price per share will be identical to the Company option or warrant, and (iii) each Company restricted stock unit will entitle the holder to a HoldCo restricted stock unit, each to vest and settle into a share of HoldCo Common Stock. At the effective time of the Merger Transaction, an aggregate of 6,166,666 shares of HoldCo Common Stock, including 616,666 shares of HoldCo Common Stock which will be withheld from RareGen members to secure the indemnification obligations of RareGen members (the "Holdback Shares"), will be issued to RareGen members in exchange for all of the 10,000 outstanding RareGen common units, representing all of the issued and outstanding RareGen equity. RareGen members will be entitled to receive, on a pro rata basis, any Holdback Shares remaining on March 31, 2022. Additionally, RareGen members shall be entitled to a pro rata portion of any RareGen cash at closing in excess of $1 million. RareGen members will also be entitled to receive a pro rata portion of up to an additional 2,708,333 shares of HoldCo Common Stock in the aggregate in 2022, based on the amount of 2021 net sales of the generic treprostinil product owned by Sandoz, which RareGen markets pursuant to the Promotion Agreement. The fair value of the purchase consideration, or the purchase price is currently estimated to be approximately $23.9 million based on 6,166,666 shares of HoldCo Common Stock at a per share price of $3.34, which represents the closing price of Company Common Stock on November 2, 2020, and the estimated fair value of the contingent consideration liability of $3.3 million. The estimated purchase price is variable depending on the valuation of the Company Common Stock and the acquisition of RareGen is currently anticipated to be accounted for as a business combination in accordance with Accounting Standards Codification (ASC) 805, *Business Combinations*. The special meeting for stockholders to consider approval of the Merger Transaction is currently scheduled for November 13, 2020.



## 2. Basis of Presentation, Significant Accounting Policies and Going Concern

### Basis of Presentation and Significant Accounting Policies

The unaudited interim consolidated financial statements as of September 30, 2020 and for the three and nine months ended September 30, 2020 and 2019 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting. These 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"). Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2020. Certain information and footnote disclosures normally included in the annual 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 consolidated financial statements and related notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2019, which are included in the Company's Annual Report on Form 10-K.

There have been no material changes to the Company's significant accounting policies during the three and nine months ended September 30, 2020 compared with the significant accounting policies disclosed in Note 2 of the financial statements for the years ended December 31, 2019 and 2018.

#### *Going Concern*

The Company's consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company's operations have consisted primarily

of developing its technology, developing products, prosecuting its intellectual property and securing financing. The Company has incurred recurring losses and cash outflows from operations, has an accumulated deficit, and has debt principal payments that commenced in the first quarter of 2020. The Company expects to continue to incur losses in the foreseeable future and will require additional financial resources to continue to advance its products and intellectual property, in addition to repaying its maturing debt and other obligations. These conditions raise substantial doubt regarding the Company's ability to continue as a going concern.

The Company believes that its existing cash will enable it to fund its operating expenses and capital expenditure requirements, make payments of interest and principal on its term loan facility with Pacific Western, and remain in compliance with its minimum cash covenant of $8.5 million pursuant to this term loan facility, into the first quarter of 2022. The Company has based these estimates on assumptions that may prove to be wrong, and it could utilize its available capital resources sooner than it expects. The Company will need to raise substantial additional capital to continue its business operations and remain in compliance with the minimum cash covenant of $8.5 million on its debt during and beyond the first quarter of 2022, in addition to commercializing LIQ861, if approved. Such capital may not be available on a timely basis, on terms that are favorable to the Company, or at all.

The pandemic caused by the outbreak of the novel coronavirus, or COVID-19, and the various governmental, industry and consumer actions related thereto, could have a material and adverse effect on the Company's business. The effect, which largely depends on future developments that cannot be accurately predicted and are uncertain, could include a negative impact on the availability of the Company's key personnel, temporary closures of the Company's facilities or the facilities of the Company's business partners, suppliers, third-party service providers or other vendors, delays in payments or purchasing decisions, and the interruption of domestic and global supply chains, distribution channels and financial markets. As the pandemic continues to spread, the Company has and may continue to experience disruptions that could severely impact the Company's business. Currently, most of the Company's employees are working remotely, with only essential personnel working on site as needed to produce LIQ861 and prepare for a pre-approval inspection by the FDA.

***Consolidation***

The accompanying consolidated financial statements include the Company's wholly owned subsidiary, Liquidia Corporation, and Liquidia Corporation's wholly owned subsidiaries, Gemini Merger Sub I, Inc. and Gemini Merger Sub II, LLC. All intercompany accounts and transactions have been eliminated.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual amounts could differ from those estimates.

***Reclassifications***

The Company has reclassified certain prior period amounts for comparative purposes. The Company reclassified certain prior period amounts to conform to the current period presentation, including the categorization of non-cash lease expense within the operating activities section of the Statements of Cash Flows. These reclassifications did not have any effect on the Company's previously reported financial condition, results of operations or cash flows.

***Revision of Previously Issued Financial Statements***

During the three months ended June 30, 2020, the Company identified an error in the matter in which it calculated diluted weighted common shares outstanding and diluted net loss per common share. While the Company has included common stock warrants whose exercise price is de minimis in the calculation of basic weighted average common shares outstanding and basic net loss per common share, these warrants were inappropriately excluded from the calculation of diluted weighted common shares outstanding and diluted net loss per common share, which resulted in an error in those previously reported amounts for the three and nine month periods ended September 30, 2019. The Company has evaluated this error and determined that this presentation error was not material to any prior annual or interim periods. However, the Company is revising the previously presented September 30, 2019 diluted weighted common shares outstanding and diluted net loss per common share as follows:

| | Three Months Ended September 30, 2019 | | Nine Months Ended September 30, 2019 | |
|---|---|---|---|---|
| | As Presented | As Revised | As Presented | As Revised |
| Net loss per common share: Diluted | $ (0.72) | $ (0.72) | $ (1.87) | $ (1.85) |
| Diluted weighted average shares outstanding | 18,650,965 | 18,757,166 | 17,737,737 | 17,856,826 |

**Summary of Significant Accounting Policies**

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash. The Company is exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding its cash to the extent of amounts recorded on the consolidated balance sheet. With regard to cash, 100% of the Company's cash is held on deposit with Pacific Western.

**Revenue Recognition**

The Company may derive revenue from licensing its proprietary PRINT technology and from performing research and development services. Revenue is recognized as services are performed in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services and technology.

The Company's research, development and licensing agreements provide for multiple promised goods and services to be satisfied by the Company and include a license to the Company's technology in a particular field of study, participation in collaboration committees, performance of certain research and development services and obligations for certain manufacturing services.

The transaction price for these contracts includes non-refundable fees and fees for research and development services. Non-refundable up-front fees which may include, for example, an initial payment upon effectiveness of the contractual relationship or payment to secure a right for a future license, are recorded as deferred revenue and recognized into revenue over time as the Company provides the research services under the contract required to advance the products to the point where the Company is able to transfer control of the licensed technology to the customer ("Technology Transfer"). The contract consideration may also include additional non-refundable payments due to the Company based on the achievement of research, development, regulatory or commercialization milestone events. In agreements involving multiple goods or services promised to be transferred to customers, the Company must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation. As these goods and services are considered to be highly interrelated, they may be considered to represent a single, combined performance obligation. The Company includes an estimate of the probable amount of milestone payments to which it will be entitled in the transaction price. The estimate requires evaluation of factors which are outside of the Company's control and significantly limit the Company's ability to achieve the remaining milestone payments. The Company revises the transaction price to include milestone payments once the specific milestone achievement is not considered to be subject to a significant reversal of revenue. At that time, the estimated transaction price is adjusted and a cumulative catch-up adjustment is recorded to adjust the amount of revenue to be recognized from the license inception to the date the milestone was deemed probable of achievement. The milestone is included with other non-refundable up-front fees and recognized into revenue over time as the Company continues to provide services under the contract through the Company's Technology Transfer. The amount of revenue recognized is based on the proportion of total research services performed to date to the expected services to be provided through the Technology Transfer.

The estimate of the research services to be provided through the Technology Transfer requires significant judgment to evaluate assumptions regarding the level of effort required for the Company to have performed sufficient obligations for the customer to be able to utilize the licensed technology without requiring further services from the Company. If the estimated level of effort changes, the remaining deferred revenue is recognized over the revised period in which the expected research services and Technology Transfer are required. Changes in estimates occur for a variety of reasons, including but not limited to (i) research and development acceleration or delays, (ii) customer prioritization of research projects, or (iii) results of research and development activities. The Company recognizes the consideration it is entitled to receive for research and development services, which are primarily billed quarterly in arrears on a time and materials basis, as the services are performed (under a proportional performance model) and collection is reasonably assured. Additionally, any up-front or development milestone payments received are also recognized as revenue, over time, under this same proportional performance model.

Royalties related to product sales will be recognized as revenue when the sale occurs since payments relate directly to products that will have been fully developed and for which the Company will have satisfied all of its performance obligations.

**Stock-Based Compensation**

The Company estimates the grant date fair value of its share-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 4). 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 and restricted stock units 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. Due to their anti-dilutive effect, the calculation of diluted net loss per share for the three and nine months ended September 30, 2020 and 2019 does not include the following common stock equivalent shares:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Stock Options | 2,747,538 | 2,037,003 | 2,516,604 | 2,037,003 |
| Restricted Stock Units | 123,369 | — | 98,355 | — |
| Total | 2,870,907 | 2,037,003 | 2,614,959 | 2,037,003 |

For the three and nine months ended September 30, 2020 and 2019, common stock warrants are included in the calculation of basic and diluted net loss per share since their exercise price is de minimis.

**Fair Value of Financial Instruments**

The carrying values of cash and accounts payable at September 30, 2020 and December 31, 2019 approximated their fair value due to the short maturity of these instruments.

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, 2020 and December 31, 2019:

| **September 30, 2020** | **Quoted Prices in Active Markets (Level 1)** | **Significant Other Observable Inputs (Level 2)** | **Significant Unobservable Inputs (Level 3)** | **Carrying Value** |
|---|---|---|---|---|
| Pacific Western Bank note - A&R LSA | $ — | $ 9,972,600 | $ — | $ 11,690,010 |

| **December 31, 2019** | **Quoted Prices in Active Markets (Level 1)** | **Significant Other Observable Inputs (Level 2)** | **Significant Unobservable Inputs (Level 3)** | **Carrying Value** |
|---|---|---|---|---|
| Pacific Western Bank note - A&R LSA | $ — | $ 14,094,792 | $ — | $ 15,878,121 |

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.

**Recent Accounting Pronouncements**

In October 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 ("ASU 2018-18"). The provisions of ASU 2018-18 clarify when certain transactions between collaborative arrangement participants should be accounted for under ASC 606 and incorporates unit-of-account guidance consistent with ASC 606 to aid in this determination. The guidance is effective for annual periods and interim periods within those annual periods beginning after December 15, 2019, with early adoption permitted. The Company adopted ASU 2018-18 effective January 1, 2020 and it did not have a material effect on the Company's consolidated financial statements for the three and nine months ended September 30, 2020.

**3. Stockholders' Equity**

**Authorized Capital**

As of September 30, 2020, the authorized capital of the Company consists of 70,000,000 shares of capital stock, $0.001 par value per share, of which 60,000,000 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 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, for continued development of LIQ865 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 Private Placement in December 2019*

On December 23, 2019, the Company entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with certain institutional accredited investors (the "Purchasers") for the sale by the Company in a private placement (the "Private Placement") of an aggregate of 7,164,534 shares (the "Private Placement Shares") of common stock, at a purchase price of $3.13 per Private Placement Share. The closing of the Private Placement occurred on December 27, 2019. The Company granted the Purchasers indemnification rights with respect to its representations, warranties, covenants and agreements under the Purchase Agreement. The gross proceeds from the sale of the Private Placement Shares were $22.4 million and net proceeds were $21.0 million, after deducting placement agent fees and offering expenses.

*Issuance of Common Stock from the ATM Agreement Commencing 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 will act as the Company's agent and/or principal. The Company pays 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, 2020, the Company sold 131,425 shares of common stock for net proceeds of $0.7 million after deducting underwriting discounts and other offering expenses under the ATM Agreement.

*Issuance of Common Stock from an Underwritten Public Offering in March 2019*

In March 2019, the Company closed an underwritten offering of 3,000,000 shares of its common stock at a public offering price of $11.50 per share. The gross proceeds from the offering were $34.5 million and net proceeds were $31.8 million, after deducting underwriting discounts and commissions and other offering expenses.

**Warrants**

During the three and nine months ended September 30, 2020 and 2019, no warrants to purchase shares of common stock were exercised. During the three and nine months ended September 30, 2020 and 2019, no warrants and 64,629 warrants to purchase shares of common stock were exercised, respectively. As of September 30, 2020 and December 31, 2019, there were outstanding warrants to purchase 106,274 shares of common stock with an exercise price of $0.0168 per share. The warrants expire on December 31, 2026.

**4. Stock-Based Compensation**

The Company's 2018 Long-Term Incentive Plan (the "2018 Plan") was approved by stockholders in July 2018. In addition to stock options, the 2018 Plan provides for the granting of stock appreciation rights, stock awards, stock units, and other stock-based awards. A total of 1,600,000 shares of the Company's common stock was initially authorized and reserved for issuance under the 2018 Plan. This reserve will automatically increase each subsequent anniversary of January 1 through 2028, 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, 2019, the number of shares of common stock available for issuance under the 2018 Plan automatically increased by 620,778 shares from 1,600,000 shares to 2,220,778 shares pursuant to the Evergreen Provision. On January 1, 2020, the number of shares of common stock available for issuance under the 2018 Plan automatically increased by 1,129,250 shares from 1,287,561 shares to 2,416,811 shares pursuant to the Evergreen Provision. The 2018 Plan provides for accelerated vesting under certain change of control transactions. As of September 30, 2020, there were 1,696,052 shares of common stock available for issuance under the 2018 Plan.



The 2018 Plan replaced the 2016 and 2004 Plans as the Company's primary long-term incentive program. The 2016 and 2004 Plans were discontinued following stockholder approval of the 2018 Plan, but the outstanding awards under the 2016 and 2004 Plans will continue to remain in effect in accordance with their terms. Shares that are returned under the 2016 and 2004 Plans upon cancellation, termination or otherwise of awards outstanding under the 2016 and 2004 Plans will not be available for grant under the 2018 Plan. As of September 30, 2020, the Company had reserved for issuance 656,927 shares of common stock under the 2016 Plan and 375,056 shares of common stock under the 2004 Plan, representing the remaining outstanding options granted under the 2016 and 2004 Plans.

***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 share-based compensation expense:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **By Expense Category:** | **2020** | **2019** | **2020** | **2019** |
| Research and development | $ 292,386 | $ 238,920 | $ 853,704 | $ 679,875 |
| General and administrative | 788,614 | 591,582 | 2,094,378 | 1,859,419 |
| Total stock-based compensation expense | $ 1,081,000 | $ 830,502 | $ 2,948,082 | $ 2,539,294 |

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **By Type of Award:** | **2020** | **2019** | **2020** | **2019** |
| Stock Options | $ 1,044,991 | $ 808,153 | $ 2,843,409 | $ 2,424,654 |
| Restricted stock awards | 36,009 | 22,349 | 104,673 | 114,640 |
| Total stock-based compensation expense | $ 1,081,000 | $ 830,502 | $ 2,948,082 | $ 2,539,294 |

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, 2020 | |
|---|---|---|
| | **Unamortized Expense** | **Weighted Average Remaining Recognition Period (Years)** |
| Stock Options | $ 7,000,498 | 2.53 |
| Restricted Stock Units | $ 443,913 | 3.38 |



***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, | |
|---|---|---|
| | **2020** | **2019** |
| Expected dividend yield | —% | —% |
| Risk-free interest rate | 0.40% - 1.60% | 1.44% - 2.54% |
| Expected Volatility | 87% - 90% | 83% - 85% |
| Expected life (years) | 6.32 | 6.04 |

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, 2020 and 2019 was $4.16 and $8.35 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, 2020:

| | **Number of** | **Weighted** | **Weighted** | **Aggregate** |
|---|---|---|---|---|

| | Shares | Average Exercise Price | Average Contractual Term (in years) | Intrinsic Value |
|---|---|---|---|---|
| **Outstanding as of December 31, 2019** | 2,052,976 | $ 9.33 | | |
| Granted | 963,191 | $ 5.63 | | |
| Exercised | (22,351) | $ 3.30 | | |
| Cancelled | (424,454) | $ 8.11 | | |
| **Outstanding as of September 30, 2020** | 2,569,362 | $ 8.20 | 7.20 | $ 1,030,161 |
| Exercisable as of September 30, 2020 | 1,274,181 | $ 8.34 | 5.55 | $ 444,747 |
| Vested and expected to vest as of September 30, 2020 | 2,392,942 | $ 8.26 | 7.05 | $ 901,226 |

The aggregate intrinsic value of stock options in the table above represents the difference between the $4.92 closing price of the Company's common stock as of September 30, 2020 and the exercise price of outstanding, exercisable, and vested and expected to vest in-the-money stock options.



***Restricted Stock Unit Awards***

During the nine months ended September 30, 2020, the Board of Directors approved grants of an aggregate of 138,614 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. RSUs can only be settled in shares of the Company's common stock.

A summary of nonvested RSU awards outstanding as of September 30, 2020 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, 2019 | 7,493 | $ 28.87 |
| Granted | 138,614 | 3.32 |
| Vested | (2,107) | 28.87 |
| Forfeited | (39,102) | 3.31 |
| Nonvested as of September 30, 2020 | 104,898 | $ 4.63 |

***Employee Stock Purchase Plan***

On May 8, 2019, the Company's stockholders approved the Liquidia Technologies, Inc. 2019 Employee Stock Purchase Plan (the "ESPP"). As of September 30, 2020, a total of 446,731 shares of the Company's common stock are reserved for issuance under the ESPP. Subject to any plan limitations, the ESPP allows eligible employees to contribute through payroll deductions up to $25,000 per year of their earnings for the purchase of the Company's common stock at a discounted price per share. The offering periods are six months each and begin in March and September of each year, with the initial offering period having commenced on September 3, 2019. Unless otherwise determined by the administrator, the Company's common stock will be purchased for the accounts of employees participating in the 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.

During the Company's first offering period from September 1, 2019 to February 28, 2020, based upon 85% of the closing price of $4.13 on February 28, 2020, 3,269 shares were purchased based upon employee withholdings. During the Company's second offering period from March 1, 2020 to August 31, 2020, based upon 85% of the closing price of $5.12 on August 31, 2020, 1,821 shares were purchased based upon employee withholdings.

**5. 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 Letter Agreement"). As part of the UNC Letter 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 Letter Agreement, subject to industry standard contractual compliance. Under the UNC Letter 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 Letter Agreement. 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.

**6. Revenue From Contracts With Customers**

The Company derived its revenue during the nine months ended September 30, 2019 primarily from licensing its proprietary PRINT technology and from performing research and development services. Revenue was recognized as services were performed in an amount that reflected the consideration the Company expected to be entitled to in exchange for those services and technology.

The Company's research, development and licensing agreements provide for multiple promised goods and services to be satisfied by the Company and include a license to the Company's technology in a particular field of study, participation in collaboration committees, performance of certain research and development services and obligations for certain manufacturing services.

The transaction price for these contracts includes non-refundable fees and fees for research and development services. Non-refundable up-front fees which may include, for example, an initial payment upon effectiveness of the contractual relationship or payment to secure a right for a future license, are recorded as deferred revenue and recognized into revenue over time as the Company provides the research services under the contract required to advance the products to the point where the Company is able to transfer control of the licensed technology to the customer ("Technology Transfer"). The contract consideration may also include additional non-refundable payments due to the Company based on the achievement of research, development, regulatory or commercialization milestone events. In agreements involving multiple goods or services promised to be transferred to customers, the Company must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation. As these goods and services are considered to be highly interrelated, they were considered to represent a single, combined performance obligation. The Company includes an estimate of the probable amount of milestone payments to which it will be entitled in the transaction price. The estimate requires evaluation of factors which are outside of the Company's control and significantly limit the Company's ability to achieve the remaining milestone payments. Therefore, the Company has not included any future milestone payments in the transaction price allocated to research, development and licensing agreements as of September 30, 2020. The Company revises the transaction price to include milestone payments once the specific milestone achievement is not considered to be subject to a significant reversal of revenue. At that time, the estimated transaction price is adjusted and a cumulative catch-up adjustment is recorded to adjust the amount of revenue to be recognized from the license inception to the date the milestone was deemed probable of achievement. The milestone is included with other non-refundable up-front fees and recognized into revenue over time as the Company continues to provide services under the contract through the Company's Technology Transfer. The amount of revenue recognized is based on the proportion of total research services performed to date to the expected services to be provided through the Technology Transfer.

The estimate of the research services to be provided through the Technology Transfer requires significant judgment to evaluate assumptions regarding the level of effort required for the Company to have performed sufficient obligations for the customer to be able to utilize the licensed technology without requiring further services from the Company. If the estimated level of effort changes, the remaining deferred revenue is recognized over the revised period in which the expected research services and Technology Transfer are required. Changes in estimates occur for a variety of reasons, including but not limited to (i) research and development acceleration or delays, (ii) customer prioritization of research projects, or (iii) results of research and development activities. The Company recognizes the consideration it is entitled to receive for research and development services, which are primarily billed quarterly in arrears on a time and materials basis, as the services are performed (under a proportional performance model) and collection is reasonably assured. Additionally, any up-front or development milestone payments received are also recognized as revenue, over time, under this same proportional performance model.

No royalties have been recognized during the three and nine months ended September 30, 2020 or during the three and nine months ended September 30, 2019.

In September 2015, GSK Inhaled exercised the option to permanently license the technology for a non-refundable payment to the Company of $15.0 million. Pursuant to the license provisions of the collaboration agreement, GSK Inhaled is potentially required to pay the Company for certain milestones reached in addition to tiered royalties on the worldwide sales of the licensed products at percentages ranging from the mid-single digits to low-single digits depending on the total number of products developed and other royalty step-down events with a fixed low-single digit royalty floor. In February 2016, GSK Inhaled paid the Company a $3.0 million milestone payment pursuant to the collaboration agreement. The combined $18 million in up-front and milestone payments was subject to deferral pursuant to the adoption of ASC 606 and the revenue policy described herein.

In July 2018, GSK notified the Company of its plans to discontinue development of the inhaled antiviral for viral exacerbations in chronic obstructive pulmonary disease under the GSK Inhaled collaboration agreement after completion of the related Phase 1 clinical trial. In June 2019, the Company and GSK executed the third amendment to the collaboration agreement providing the Company rights to develop and commercialize additional inhaled programs at the Company's sole cost and development. This amendment granted the Company the right to develop three additional molecular entities for application in inhaled programs using the Company's PRINT technology and a mechanism to acquire further molecular entities for inhaled applications. New inhaled programs developed under this amendment would carry milestone and royalty payments due to GSK upon initiation of Phase 3 studies and subsequent commercialization, respectively. This amendment, among other factors including the lack of continued performance anticipated by the Company and GSK under the original agreement, led the Company to the belief that no further research and development services will be provided to GSK under the collaboration agreement and the earnings process related to the up-front and development milestone payments previously received under the collaboration agreement is completed under the proportional performance model. Therefore, the remaining deferred revenue of $8.1 million was recognized as revenue during the nine months ended September 30, 2019. If GSK were to request additional services under the original agreement, which the Company believes is a remote likelihood, the Company does not expect the value of any incremental efforts that the Company might agree to perform to be material. Any potential milestone or royalty payments from the Company to GSK associated with this amendment will be recorded as operating expenses.

The following tables represent a disaggregation of revenue by each significant research, development and licensing agreement and payment type for the nine months ended September 30, 2019:

| | Revenue for the Nine Months Ended September 30, 2019 From | | | |
|---|---|---|---|---|
| | Non-Refundable Payments | | Research and Development Services | Total |
| | Milestones | Up-front Payments | | |
| GSK Inhaled | $ 1,345,320 | $ 6,726,600 | $ — | $ 8,071,920 |
| Other | — | — | 200 | 200 |
| **Total** | $ 1,345,320 | $ 6,726,600 | $ 200 | $ 8,072,120 |

**Deferred Sublicense Payments**

Sublicense payments to UNC are considered direct and incremental fulfillment costs of the Company's research, development and licensing agreements as the PRINT technology resources used by the Company are continually researched by UNC. These costs are deferred and then amortized into Cost of Sales over the same estimated period of benefit as the period of the underlying revenue recognition. In conjunction with the June 2019 amendment to the GSK collaboration agreement, the balance of deferred sublicense payments were expensed to Cost of revenue in the nine months ended September 30, 2019.

**7. Property, Plant and Equipment**

Property, plant and equipment consisted of the following:

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Lab and build-to-suit equipment | $ 8,071,881 | $ 7,562,263 |
| Office equipment | 128,669 | 128,669 |
| Furniture and fixtures | 294,689 | 237,951 |
| Computer equipment | 896,022 | 804,046 |
| Leasehold improvements | 11,524,739 | 11,762,351 |
| Construction-in-progress | — | 91,797 |
| Total property, plant and equipment | 20,916,000 | 20,587,077 |
| Accumulated depreciation and amortization | (13,527,624) | (11,333,112) |
| Property, plant and equipment, net | $ 7,388,376 | $ 9,253,965 |

The Company recorded depreciation and amortization expense of $722,325 and $604,164 for the three months ended September 30, 2020 and 2019, respectively, and $2,178,402 and $1,857,070 for the nine months ended September 30, 2020 and 2019, respectively.

**8. Income Taxes**

The Company did not record a federal or state income tax expense or benefit for the three or nine months ended September 30, 2020 and 2019 as a result of the establishment of a full valuation allowance being required against the Company's net deferred tax assets.

**9. Commitments and Contingencies**

**Commitments**

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 on net sales totaling no more than $1,500,000, none of which has been earned as of September 30, 2020.



**Contingencies**

**Merger Termination Fee and Merger Transaction Fees**

In the event the Merger Agreement is terminated by the Company on account of its acceptance of a Superior Proposal or by RareGen, if the Board of Directors shall have made a change in recommendation to its stockholders following the receipt of a Superior Proposal, then, in the case of a termination by the Company pursuant to (i), the Company shall pay to RareGen by wire transfer a one-time termination fee equal to $7.5 million immediately before and as a condition to such termination, and in the case of a termination by RareGen pursuant to (ii), within two business days after the date of such termination.

The Company estimates it will incur $5.0 million of fees in connection with the Merger Transaction.

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.

**10. Long-Term Debt**

Long-term debt consisted of the following as of September 30, 2020 and December 31, 2019:

| | Maturity Date | September 30, 2020 | December 31, 2019 |
|---|---|---|---|
| Pacific Western Bank term loan outstanding | October 25, 2022 | $ 11,690,010 | $ 15,878,121 |
| Less current portion | | (5,585,636) | (5,585,637) |
| Long-term debt, less current portion | | $ 6,104,374 | $ 10,292,484 |

***Pacific Western Bank***

In October 2018, the Company and Pacific Western entered into the A&R LSA in which the Company received an initial tranche of $11.0 million to extinguish its existing debt of $8.0 million under the LSA, repay in full the $1.8 million in outstanding indebtedness under the UNC Promissory Note and for general corporate purposes. The indebtedness under the A&R LSA bears interest at the greater of the Prime rate or 5% and has a four-year term maturing in October 2022. The A&R LSA provided for access to a second tranche of up to $5.0 million available to be drawn at the Company's option through June 30, 2019. The second tranche became accessible as a result of the full enrollment of the Company's LIQ861 INSPIRE clinical trial, without observing any materially adverse data through the two week endpoint. The entire second tranche of $5.0 million was drawn by the Company in May 2019 bringing the total amount outstanding to $16.0 million. Both tranches required payments of interest-only through December 31, 2019.

The A&R LSA carries a one-time success fee of $375,000 and a prepayment penalty of 1% if the drawn tranche is prepaid prior to October 27, 2020. The success fee was triggered in December 2019 by the sale of common stock and this was recorded as interest expense of $375,000 during the year ended December 2019. Accrued interest is included in Other accrued expenses in the Balance Sheet as of December 31, 2019. The minimum cash covenant is $8.5 million. Pacific Western maintains a blanket lien on all assets excluding intellectual property, for which it has been provided a negative pledge. Pursuant to the A&R LSA, the Company is also obligated to comply with various other customary covenants, including, among others, restrictions on its ability to dispose of assets, replace or suffer the departure of the CEO or CFO without delivering ten days' prior written notification to Pacific Western, suffer a change on the Board of Directors which would result in the failure of at least one partner of Canaan Partners or their respective affiliates to serve as a voting member in each case without having used best efforts to deliver at least 15 days' prior written notification to Pacific Western, make acquisitions, be acquired, incur indebtedness, grant liens, make distributions to its stockholders, make investments, enter into certain transactions with affiliates or pay down subordinated debt, subject to specified exceptions.

In May 2019, the Company and Pacific Western entered into a First Amendment to A&R LSA to provide for a limit of $2.5 million of the Company's capital expenditures during the year ended December 31, 2019. As of September 30, 2020, the Company was in compliance with all covenants under the A&R LSA. The Company received a waiver of covenant compliance from Pacific Western for non-timely submissions of monthly financial statements for the January and February 2020 periods.



*Joinder and Second Amendment to Amended and Restated Loan and Security Agreement on July 3, 2020*

On July 3, 2020, the Company, HoldCo, Liquidia Merger Sub and RareGen Merger Sub entered into a Joinder and Second Amendment (the "Second Amendment") to Amended and Restated Loan and Security Agreement, dated as of October 26, 2018 (the "A&R LSA"), with Pacific Western Bank ("Pacific Western"), pursuant to which, among other things, (i) HoldCo, Liquidia Merger Sub and RareGen Merger Sub have executed a joinder to the A&R LSA for the purpose of acknowledging that it shall be a "Borrower" along with the Company thereunder and, in connection therewith, collaterally assign and transfer to Pacific Western, and grant the Bank a continuing security interest in, all of such parties' now owned and existing or hereafter acquired and arising assets of "Collateral" (as defined in the A&R LSA), (ii) the Borrowers shall not make any payments pursuant to that certain Litigation Funding and Indemnification Agreement, to be entered into by and between RareGen and the Members' Representative prior to closing the Merger Transaction, without Pacific Western's consent unless such payments are reimbursed within 30 days and do not exceed $250,000 at any time and (iii) the definition of "Permitted Indebtedness" was amended to accommodate the transactions contemplated by the Litigation Funding and Indemnification Agreement.

Scheduled annual maturities of long-term debt as of September 30, 2020 are as follows:

| **Year ending December 31:** | |
|---|---|
| 2020 – three months remaining | $ 1,411,766 |
| 2021 | 5,647,059 |
| 2022 | 4,705,881 |
| Thereafter | — |
| Total | 11,764,706 |
| Less: Unamortized discount | (52,336) |
| Less: Unamortized debt issuance costs | (22,360) |
| Less: Current portion of long-term debt | (5,585,636) |
| Long-term debt, noncurrent | $ 6,104,374 |



**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 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**

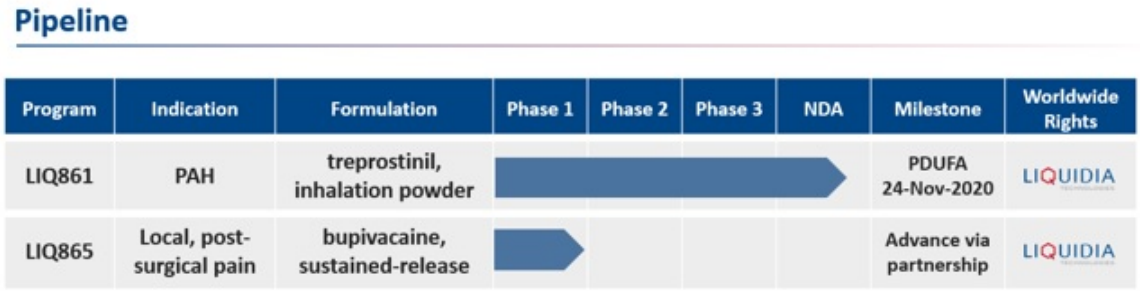
We are a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing our proprietary PRINT® technology to transform the lives of patients. PRINT is a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. We are currently focused on the development of two product candidates for which we hold worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension, or PAH, and LIQ865 for the treatment of local post-operative pain. LIQ861, for which we recently filed a New Drug Application, or NDA, with the FDA, 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. We have applied our PRINT technology to enable us to deliver LIQ861 through a convenient, palm-sized dry powder inhaler, or DPI. We have also applied our PRINT technology to our second product candidate, LIQ865, for which we have completed two Phase 1 clinical trials and have conducted toxicology studies in order to support Phase 2 clinical studies. LIQ865 is designed to deliver sustained-release particles of bupivacaine, a non-opioid anesthetic, to treat local post-operative pain for three to five days through a single administration. Additionally, we recently initiated a pre-clinical program to develop an inhaled product leveraging the benefits of our PRINT technology to engineer particles with precise, uniform, aerodynamic size and shape for deep lung delivery.

Our primary objective has been to pursue marketing approval of LIQ861 and to commercialize such product if approved by FDA. We will need to raise substantial additional capital to commercialize LIQ861, if approved, pursue our other research and development stage programs, and remain in compliance with the minimum cash requirement covenant on our debt. Such capital may not be available to us on a timely basis, on terms that are favorable to us, or at all.

**Product Pipeline**

We are currently focused on the development of two product candidates for which we hold worldwide commercial rights: LIQ861 for the treatment of PAH and LIQ865 for the treatment of local post-operative pain.

The following table summarizes our clinical-stage product candidates being developed using PRINT technology:






**LIQ861**

In January 2020, we submitted an NDA to the FDA for LIQ861, our lead product candidate, as a potential treatment for patients with PAH. Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function, which is deficient in patients with PAH. We believe that LIQ861 has the potential to improve the therapeutic profile of existing formulations of treprostinil by enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies. We are developing LIQ861 under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug, which allows us to rely in part on the FDA's previous findings of efficacy and safety of Tyvaso and the active ingredient treprostinil, which has been approved in four different products administered through the oral, inhaled and continuous infusion (parenteral) routes.

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. Under the Hatch-Waxman Act, as a result of the Hatch-Waxman Litigation commenced by United Therapeutics on June 4, 2020, 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 precluded from approving 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 requirements for approval 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.

Our NDA submission is based in part upon the results of our open-label Phase 3 clinical trial, INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, for LIQ861, the initiation of which we announced in January 2018. The primary objective of the INSPIRE study was to evaluate the long-term safety and tolerability of LIQ861. The study was designed to evaluate patients who have either been under stable treatment with Tyvaso (nebulizer-delivered treprostinil) for at least three months and were transitioned to LIQ861 under the protocol, or Transition patients, or patients who had been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and then had their treatment regimen supplemented with LIQ861 under the protocol, or Add-On patients.

In August 2019, we completed the pivotal INSPIRE trial. 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. Consistent with preliminary data presented in the second quarter of 2019, LIQ861 was observed to be well-tolerated and treatment-emergent adverse events, or TEAEs, were mostly mild to moderate in nature at Month 2 up to doses of 159 mcg of LIQ861, the highest dose studied at Month 2. Durability of therapy with LIQ861 appeared to be favorable, with 96% of Transition patients and 91% of Add-On patients remaining on study drug at the Month 2 timepoint.

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%).

Analysis of the exploratory endpoints from the INSPIRE study indicates that LIQ861 may provide functional and quality-of-life benefits to PAH patients in New York Heart Association, or NYHA, functional classes II and III. More than 70% of patients were able to titrate to a LIQ861 dose greater than or equal to 79.5 mcg, the LIQ861 dose-level comparable to 54 mcg of nebulized treprostinil, the maximum recommended dose in the Tyvaso® package insert. More than 95% of all patients who completed two months of treatment maintained (75.9%) or improved (20.5%) their NYHA functional class. We observed improvements in median six-minute-walk-distance (+10.1 meter increase). Quality-of-life as measured by the MLHFQ showed an improved total score (>5-point reduction), as well as improvements in both emotional and physical dimensions. We observed a greater percentage of subjects who met two or three PAH low-risk criteria at month 2 compared to baseline. We did not see clinically meaningful changes in N-terminal pro b-type natriuretic peptide (NT-proBNP). The majority of Transition patients preferred the LIQ861 dry-powder inhaler to the Tyvaso® Inhalation System.

In September 2019, we reported results from pharmacokinetic (PK) studies indicating that the 79.5 mcg dose of LIQ861 correlates with nine breaths of Tyvaso, the maximum recommended label dose of Tyvaso. To accurately characterize the pharmacokinetics of LIQ861, we conducted two PK studies in healthy volunteers. In the first of these studies, we observed unexpected variability in PK levels. Post-hoc analysis showed that plasma levels of treprostinil were tightly correlated to the LIQ861 dose delivered. Based upon additional non-clinical and clinical work, we believe the unexpected variability seen in this healthy volunteer study was due to an administration technique unique to the conduct of the study in the Phase 1 setting. In August 2019, we completed a second PK study in healthy volunteers in which the proper administration technique was followed. This study demonstrated significantly reduced variability, and we believe we have established comparative bioavailability to the reference listed drug.

Results from the INSPIRE trial have been presented at various international scientific meetings such as the American Thoracic Society (ATS), International Society of Heart Lung Transplantation (ISHLT), Pulmonary Vascular Research Institute (PVRI), American College of Chest Physicians (ACCP) in 2019 and 2020.

We continued to treat patients who chose to remain on LIQ861 beyond the Month 2 timepoint of the primary endpoint. At the completion of the INSPIRE study, the patient with the longest duration of treatment had been on LIQ861 therapy for 18 months and the highest dosing reached in the INSPIRE study was 212 mcg of treprostinil given four times per day. To provide for continuity of treatment, patients from INSPIRE were provided the opportunity to continue receiving treatment in an extension study, which is currently ongoing (LTI-302). Currently, more than 70 patients have now received therapy with LIQ861 for more than two years. We have also observed that more than 70 percent of patients who have been enrolled in the INSPIRE and extension studies have received LIQ861 doses of 100 mcg or more.

Prior to submission of the NDA in January 2020, the FDA visited our manufacturing site in June 2019 as a qualifying participant in the Emerging Technology Program sponsored by the Center for Drug Evaluation and Research (CDER). The program supports innovation by providing a forum for sponsors to engage the FDA early in development and ensures consistency, continuity, and predictability in review and inspection. The program has allowed us to discuss PRINT® technology with Emerging Technology Team members, including personnel who may be involved in the prior approval inspection (PAI) and review of the Chemistry Manufacturing Controls section of the NDA to support LIQ861.



The FDA communicated in August 2020 that inspections of two sites involved in the manufacturing of LIQ861, both of which are located in the United States, would be required before the FDA can approve the NDA for LIQ861. The FDA also informed us that because of restrictions on travel due to COVID-19, the FDA may be unable to conduct inspections of these two sites prior to the User Fee Date of November 24, 2020. We will continue to work closely with the FDA with regard to the PAIs; however, the FDA has not yet conducted these inspections as of the date of this Quarterly Report on Form 10-Q.

In addition to the studies submitted in the NDA for FDA review, we are conducting a clinical study at certain investigational sites in France and Germany to characterize the hemodynamic dose-response relationship to LIQ861 (LTI-201). After pausing enrollment due to the COVID-19 pandemic in the second quarter of 2020, we resumed enrollment in September 2020 at sites in Germany as allowed by local regulatory authorities. We intend to resume enrollment at French sites as soon as feasible in cooperation with French regulatory authorities.

We are considering conducting other clinical trials to generate additional data on LIQ861, including a clinical trial in pediatric patients. We will continue to conduct development work in support of potential approval and commercialization of LIQ861, including label and patient-use assessments.

**LIQ865**

LIQ865 is our proprietary injectable, sustained-release formulation of bupivacaine, a non-opioid pain medication. We have engineered the size and composition of the LIQ865 PRINT particles to release bupivacaine over three to five days through a single administration for the management of local post-operative pain after a surgical procedure. We completed a Phase 1a clinical trial of LIQ865 in Denmark in 2017 and a Phase 1b clinical trial in the United States in 2018.

We initiated Phase 2-enabling toxicology studies in 2019 to assess LIQ865 in multiple non-clinical tissue models. Results from a study to assess incision tensile strength after healing were acceptable and not statistically different from controls. A nonclinical study to examine soft tissue healing was also completed, and the results were acceptable and comparable to vehicle-treated, saline-treated, and Marcaine-treated sites. We believe this data supports progression to Phase 2 hernia repair studies.

In a toxicology study to assess bone fracture healing, we observed dose-dependent delayed healing at the two LIQ865 doses studied; however, there were no adverse effects noted on surrounding soft tissues. We have completed an additional non-Good Laboratory Practice (GLP) study to investigate bone fracture healing using the same animal model with lower doses of LIQ865. This additional non-GLP study has established a no adverse effect level, or NOAEL, on bone healing and provides evidence that LIQ865 could proceed into a GLP toxicology study to support Phase 2 clinical activities.

Considering our focus in advancing our lead asset, LIQ861, we will seek to advance LIQ865 through a strategic collaboration with an external partner. We believe LIQ865, if successfully developed and approved, has the potential to provide significantly longer local post-operative pain relief compared to currently marketed formulations of bupivacaine.

**Other Potential Applications of PRINT**

We believe that our PRINT technology can be applied to a wide range of therapeutic areas, molecule types and routes of administration. We are currently focused on developing product candidates that we believe are eligible to be approved under the 505(b)(2) regulatory pathway, which can be capital efficient and potentially enable a shorter time to approval, as it allows us to rely in part on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for approval in the United States. If any of our product candidates are approved, we intend to conduct initial commercial manufacturing of drug product using in-house capabilities, and to outsource packaging and distribution to third parties. Where appropriate, we may also transition the commercial manufacture of our drug product to third parties. In addition to developing our two product candidates, we have provided specific field-limited licenses to our PRINT technology to pharmaceutical companies seeking to develop their own potential drugs and biological therapies.



**Proposed Acquisition of RareGen, LLC**

On June 29, 2020, we entered into that certain Agreement and Plan of Merger with RareGen, LLC, a privately-held entity, Liquidia Corporation, a wholly owned subsidiary of our company, or HoldCo, Gemini Merger Sub I, Inc., a wholly owned subsidiary of HoldCo, or Liquidia Merger Sub, Gemini Merger Sub II, LLC, a wholly owned subsidiary of HoldCo, or RareGen Merger Sub, and PBM RG Holdings, LLC, as the Members' Representative, pursuant to which, among other things, we and RareGen will each become a subsidiary of HoldCo, which we refer to as the Merger Transaction. RareGen provides strategy, investment, and commercialization for generic Treprostinil injection. RareGen has a small, targeted sales force focused on PAH. Pursuant to a Promotion Agreement, dated as of August 1, 2018, as amended, or the Promotion Agreement, between RareGen and Sandoz Inc., or Sandoz, RareGen owns the exclusive rights to conduct any and all promotional and non-promotional activities to encourage the appropriate use of the first-to-file substitutable generic of treprostinil injection for the treatment of patients with PAH in the United States. The Merger Transaction is expected to close in the fourth quarter of 2020. If the Merger Transaction is completed, (i) each share of common stock, $0.001 par value per share, of our company, whether certificated or held in book-entry form, will automatically convert into one share of HoldCo common stock, $0.001 par value per share, or HoldCo Common Stock, (ii) each option and warrant to purchase a share of our common stock will entitle the holder to purchase one share of HoldCo Common Stock, and the exercise price per share will be identical to the option or warrant issued by our company, and (iii) each restricted stock unit issued by our company will entitle the holder to a HoldCo restricted stock unit, each to vest and settle into a share of HoldCo Common Stock. At the effective time of the Merger Transaction, an aggregate of 6,166,666 shares of HoldCo Common Stock, including 616,666 shares of HoldCo Common Stock which will be withheld from RareGen members to secure the indemnification obligations of RareGen members, or the Holdback Shares, will be issued to RareGen members in exchange for all of the 10,000 outstanding RareGen common units, representing all of the issued and outstanding RareGen equity. RareGen members will be entitled to receive, on a pro rata basis, any Holdback Shares remaining on March 31, 2022. Additionally, RareGen members shall be entitled to a pro rata portion of any RareGen cash at closing in excess of $1 million. RareGen members will also be entitled to receive a pro rata portion of up to an additional 2,708,333 shares of HoldCo Common Stock in the aggregate in 2022, based on the amount of 2021 net sales of the generic treprostinil product owned by Sandoz, which RareGen markets pursuant to the Promotion Agreement. The fair value of the purchase consideration, or the purchase price is currently estimated to be approximately $23.9 million based on 6,166,666 shares of HoldCo Common Stock at a per share price of $3.34, which represents the closing price of our common stock on November 2, 2020, and the estimated fair value of the contingent consideration liability of $3.3 million. The estimated purchase price is variable depending on the valuation of our common stock and the acquisition of RareGen is currently anticipated to be accounted for as a business combination in accordance with Accounting Standards Codification (ASC) 805, *Business Combinations*.

On November 2, 2020, we announced that we have rescheduled our special meeting of stockholders, which was originally scheduled for October 21, 2020, to be held at 4:30 p.m., Eastern Time, on November 13, 2020, or the Special Meeting. The Special Meeting will be a virtual meeting conducted solely online via live webcast and can be attended by visiting www.meetingcenter.io/287587626. On October 16, 2020, we received an unsolicited offer to enter into a License Agreement for LIQ861, or the Alternative Proposal. The Alternative Proposal was conditioned upon us terminating the Merger Agreement. On November 1, 2020, our board of directors determined that the Alternative Proposal does not constitute a "Superior Proposal" under the Merger Agreement and we subsequently informed the counterparty that we are terminating discussions with respect to such Alternative Proposal. Accordingly, our board of directors has unanimously reaffirmed its recommendations that our stockholders vote "FOR" each proposal being submitted to a vote of our stockholders at the Special Meeting. Closing of the Merger Transaction is expected to occur within a few business days following the Special Meeting.

**Financial Overview**

We have not generated any revenue to date from the sale of pharmaceutical products, and we have historically financed our operations in large part with an aggregate of $311.0 million of gross proceeds from sales of our capital stock and convertible promissory notes, $16.0 million in term loans from a bank and a $2.1 million loan from The University of North Carolina at Chapel Hill, or UNC. We do not expect to generate significant product revenue unless and until we obtain marketing approval for and commercialize LIQ861, LIQ865 or one of our other future product candidates.

Since our inception, we have incurred significant operating losses. Our net loss was $43.7 million for the nine months ended September 30, 2020 and $47.6 million, $53.1 million and $29.2 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of September 30, 2020, we had an accumulated deficit of $258.9 million. 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. 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.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital

sources, including potential collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed, on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

As of September 30, 2020, we had $79.6 million of cash. On July 2, 2020, we received $70.3 million in net proceeds from the issuance of 9,375,000 shares of our common stock through a public offering. We believe that our existing cash will enable us to fund our operating expenses and capital expenditure requirements, make payments of interest and principal on our term loan facility with Pacific Western Bank, or PWB, and remain in compliance with the minimum cash covenant of $8.5 million pursuant to this term loan facility, into the first quarter of 2022. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. See “Liquidity and Capital Resources.”



As of September 30, 2020, we do not have any material capital expenditure commitments.

**Going Concern**

Our consolidated financial statements have been prepared assuming we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. Our operations have consisted primarily of developing our technology, developing products, prosecuting our intellectual property and securing financing. We have incurred recurring losses and cash outflows from operations, have an accumulated deficit, and have debt principal payments that commenced in the first quarter of 2020. We expect to continue to incur losses in the foreseeable future and will require additional financial resources to continue to advance our products and intellectual property, in addition to repaying our maturing debt and other obligations. These circumstances raise substantial doubt about our ability to continue as a going concern.

Management’s plans with regard to this matter include continuing attempts to obtain additional financing to sustain our operations. However, there is no assurance that we will be successful in obtaining sufficient financing on terms acceptable to us, and the failure to obtain sufficient funds on acceptable terms, when needed, could have a material adverse effect on our business, results of operations and financial condition. If sufficient financing is not obtained, this may necessitate other actions by us. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Our Collaborations**

We recognized no revenue during the three and nine months ended September 30, 2020. Revenue has been derived from collaborating with, and licensing our proprietary PRINT technology to, pharmaceutical companies, and amounted to $8.1 and $2.7 million for the years ended December 31, 2019 and 2018, respectively. GlaxoSmithKline plc, or GSK, accounted for $8.1 and $0.4 million of our revenue for the years ended December 31, 2019 and 2018, respectively, or 100% and 15% respectively, of our total revenue during these years. We have received upfront fees for technology access, milestone payments, and fees to develop drug products through research and development services, such as particle formulation and manufacturing.

In addition to advancing our own product candidates, LIQ861 and LIQ865, we have collaborated, and may consider collaborating, with pharmaceutical companies to develop their own product candidates across a wide range of therapeutic areas, molecule types and routes of administration, leveraging our PRINT technology. These collaborations are intended to help advance new PRINT capabilities and build upon our competitive advantage in the pharmaceutical industry, while adding to our intellectual property portfolio.

We have exclusively licensed our PRINT technology to (i) GSK for applications broadly across inhaled delivery of their small molecule and biologic chemical entities, although we retained the ability to develop LIQ861, inhaled vaccines and other rights, subject to certain contractual obligations, to apply our PRINT technology to certain inhaled molecules; and (ii) Aerie Pharmaceuticals, Inc., which in 2017 acquired most of the assets of Envisia Therapeutics, Inc., an entity which we formed in 2013, for broad usage in the design and commercialization of small molecule and biologic ophthalmic therapies.

***GlaxoSmithKline***

Previously, we had collaborated with GSK on the use of our PRINT technology in respiratory disease. In June 2012, we entered into an Inhaled Collaboration and Option Agreement, or the GSK ICO Agreement, with GSK to collaborate on research regarding the application of our PRINT technology to specified inhaled therapies. Pursuant to the GSK ICO Agreement, we granted GSK exclusive options and licenses to further develop and commercialize such inhaled therapies using our PRINT technology. In partial consideration of the rights granted to GSK under the GSK ICO Agreement, we received a one-time up-front payment of $4.0 million.

In September 2015, GSK exercised its option to obtain an exclusive, worldwide license to certain of our know-how and patents relating to our PRINT technology, for the purpose of, among others, preclinical studies of inhaled therapeutics developed, manufactured or otherwise produced using our PRINT technology. In connection with the grant of this license, we received a one-time option exercise fee of $15.0 million. Under the terms of the GSK ICO Agreement, we were also entitled to continued research and development funding and certain milestone payments aggregating up to $158 million upon the achievement of specified events for new non-rescue therapeutic products. Rescue therapeutic products are therapeutics that GSK develops with our PRINT technology that had previously been discontinued from development. We are also entitled to tiered royalties on the worldwide sales of the licensed products at percentages ranging from the mid-single digits to low-single digits depending on the total number of products developed and other royalty step-down events with a fixed low-single digit royalty floor. In February 2016, we received a $3.0 million payment from GSK upon the achievement of a clinical development milestone related to the development of an inhaled antiviral for viral exacerbations in chronic obstructive pulmonary disease. However, in July 2018, GSK notified us of its plans to discontinue development of this compound after completion of the related Phase 1 clinical trial.



GSK has the right to terminate the GSK ICO Agreement in its entirety or on a product-by-product basis upon a specified period of prior written notice. Upon termination of the GSK ICO Agreement, each party will continue to have the right to practice and/or license its interest in any know-how developed

during the collaboration without seeking the consent of, or accounting to, the other party.

In June 2019, we and GSK executed the third amendment to the collaboration agreement providing us with rights to develop and commercialize three specified molecular entities for application in inhaled programs using our PRINT technology at our sole expense. This amendment also provided a mechanism for us to acquire rights to develop and commercialize further molecular entities for inhaled applications. New inhaled programs developed under this amendment would carry milestone and royalty payments due to GSK upon initiation of Phase 3 studies and subsequent commercialization, respectively.

This amendment, among other factors, including the lack of continued performance anticipated by us and GSK under the original agreement, led us to believe that no further research and development services will be provided to GSK under the collaboration agreement. Accordingly, in January 2020, we notified GSK of our intent to terminate the GSK ICO Agreement based upon GSK's lack of performance under the agreement, which we believe constitutes a material breach of the agreement. In February 2020, we received a letter from GSK disputing our basis for termination. The parties are currently attempting to resolve the dispute pursuant to the terms of the GSK ICO Agreement.

**Components of Consolidated Statements of Operations**

***Revenue***

In prior years, our revenue has been primarily derived from collaborating with and licensing our proprietary PRINT technology to pharmaceutical companies. In the future, we also expect to derive our revenue from our own pharmaceutical products. We recognized no revenue during the three and nine months ended September 30, 2020. We manage our operations and reporting structure under a single reportable segment.

All long-lived assets are domiciled and all revenue was earned within the United States.

***Research and Development Expenses***

Research and development expense consists 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.



Research and development activities are central to our business model. 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. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our ongoing clinical trial and other development work for LIQ861, continue the development of LIQ865, conduct additional clinical trials, continue manufacturing process development and scale up and prepare for regulatory filings for our product candidates and regulatory inspection of facilities utilizing our PRINT manufacturing process. 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, travel expenses and recruiting expenses. Other general and administrative expenses include costs for efforts to prepare for commercialization, facility related costs, patent filing and prosecution costs and professional fees for marketing, legal, auditing and tax services and insurance costs.

***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 the 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 2019 Annual Report on Form 10-K. There have been no material changes during the nine months ended September 30, 2020 to our critical accounting policies, significant judgments and estimates disclosed in our 2019 Annual Report on Form 10-K.



**COVID-19**

The pandemic caused by the outbreak of the novel coronavirus, or COVID-19, and the various governmental, industry and consumer actions related thereto, could have a material and adverse effect on our business. The effect, which largely depends on future developments that cannot be accurately predicted and are uncertain, could include a negative impact on the availability of our key personnel, temporary closures of our facilities or the facilities of our business partners, suppliers, third-party service providers or other vendors, delays in the conduct of our clinical trials, delays in payments or purchasing decisions, and the interruption of domestic and global supply chains, distribution channels and financial markets. As the pandemic continues to spread, we have and may continue to experience disruptions that could severely impact our business. Currently, most of our employees are working remotely, with only essential personnel working on site as needed to produce LIQ861 and prepare for a pre-approval inspection by the FDA. As a result of the pandemic, we paused enrollment in our hemodynamic study, which is being conducted in France and Germany. In September 2020, we resumed enrollment in the hemodynamic study at a site in Germany with the expectation that additional sites will resume enrollment in the fourth quarter 2020. As such, the results for the three and nine months ended September 30, 2020 may not be indicative of results for the full year.

**Results of Operations**

***Comparison of the Three and Nine Months Ended September 30, 2020 with the Three and Nine Months Ended September 30, 2019***

The following table summarizes the results of our operations for each of the three- and nine-month periods ended September 30, 2020 and 2019, 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, | | $ | % |
|---|---|---|---|---|---|---|---|---|
| | 2020 | 2019 | Change | Change | 2020 | 2019 | Change | Change |
| | | | | (in thousands) | | | | |
| Revenue | $ — | $ — | $ — | * | $ — | $ 8,072 | $ (8,072) | * |
| Costs and expenses: | | | | | | | | |
| Cost of revenue | — | — | — | * | — | 807 | (807) | * |
| Research and development | 7,661 | 10,942 | (3,281) | (30.0)% | 26,975 | 32,330 | (5,355) | (16.6)% |
| General and administrative | 7,152 | 2,378 | 4,774 | 200.8% | 16,201 | 7,808 | 8,393 | 107.5% |
| Total costs and expenses | 14,813 | 13,320 | 1,493 | 11.2% | 43,176 | 40,945 | 2,231 | 5.4% |
| Loss from operations | (14,813) | (13,320) | (1,493) | (11.2)% | (43,176) | (32,873) | (10,303) | (31.3)% |
| Interest income | 35 | 162 | (127) | (78.6)% | 156 | 520 | (364) | (70.0)% |
| Interest expense | (191) | (265) | 74 | 28.1% | (656) | (738) | 82 | 11.0% |
| Net loss | $ (14,969) | $ (13,423) | $ (1,546) | (11.5)% | $ (43,676) | $ (33,091) | $ (10,585) | (32.0)% |

* Not meaningful

**Revenue**

We recognized no revenue for the nine months ended September 30, 2020, compared with $8.1 million for the nine months ended September 30, 2019. Revenue during the nine months ended September 30, 2019 was due to the recognition of $8.1 million of deferred revenue from the GSK ICO Agreement resulting from the third amendment to such agreement that was entered into in June 2019.

**Cost of Revenue**

We recognized no cost of revenue for the nine months ended September 30, 2020, compared to $0.8 million for the nine months ended September 30, 2019. As noted above, the decrease of $0.8 million was due to the decrease in revenue. Cost of revenue represents sub-licensing fees paid to UNC when licensing revenue is recognized from the use of the intellectual property that we in-licensed from UNC.

**Research and Development Expenses**

Research and development expenses were $7.7 million for the three months ended September 30, 2020 compared with $10.9 million for the three months ended September 30, 2019, a decrease of $3.3 million or 30.0%. Clinical trial related expenses for the development of LIQ861 and LIQ865 decreased by $2.5 million and $0.6 million, respectively, during the three months ended September 30, 2020 compared with the three months ended September 30, 2019. The decrease in clinical trial expenses was a result of our company substantially completing our clinical trial activity prior to filing the NDA in 2020. Research and development expenses for the three months ended September 30, 2020 consisted of $5.3 million and $0.2 million attributable to our development of LIQ861 and LIQ865, respectively, and $2.2 million from general research and development that was not directly related to LIQ861 and LIQ865. This compares with $7.9 million and $0.8 million which were attributable to our development of LIQ861 and LIQ865, respectively, and $2.2 million from general research and development that was not directly related to either LIQ861 or LIQ865 during the three months ended September 30, 2019.

Research and development expenses were $27.0 million for the nine months ended September 30, 2020 compared with $32.3 million for the nine months ended September 30, 2019, a decrease of $5.4 million or 16.6%. Clinical trial related expenses for the development of LIQ861 and LIQ865 decreased by $4.1 million and $2.1 million, respectively, during the nine months ended September 30, 2020 compared with the nine months ended September 30, 2019. The decrease in clinical trial expenses was a result of our company substantially completing our clinical trial activity prior to filing the NDA in 2020. These decreases were partially offset by an increase in general research and development expenses not specifically associated with the LIQ861 and LIQ865 development programs. Research and development expenses for the nine months ended September 30, 2020 consisted of $18.6 million and $1.0 million attributable to our development of LIQ861 and LIQ865, respectively, and $7.4 million from general research and development that was not directly related to either LIQ861 or LIQ865 during the nine months ended September 30, 2020. This compares with $23.7 million and $3.1 million which were attributable to our development of LIQ861 and LIQ865, respectively, and $5.5 million from general research and development that was not directly related to either LIQ861 or LIQ865 during the nine months ended September 30, 2019.

**General and Administrative Expenses**

General and administrative expenses were $7.2 million for the three months ended September 30, 2020, compared with $2.4 million for the three months ended September 30, 2019. The increase of $4.8 million, or 200.8%, was primarily due to $1.7 million in expenses related to our pending acquisition of RareGen, $1.1 million in legal and patent expenses from our ongoing litigation with United Therapeutics, an increase of $1.1 million in employee compensation and outside consulting expenses and $0.9 million from a reclassification during 2020 of expenses for directors' and officers' insurance and certain commercial activities to general and administrative expenses from research and development expenses. General and administrative expenses consist primarily of personnel expenses, including stock-based compensation, as well as directors' and officers' insurance, and fees for audit, legal, consulting and other service fees.

General and administrative expenses were $16.2 million for the nine months ended September 30, 2020, compared with $7.8 million for the nine months ended September 30, 2019. The increase of $8.4 million, or 107.5%, was due to $2.7 million in expenses related to our pending acquisition of RareGen, $1.1 million in legal and patent expenses from our ongoing litigation with United Therapeutics, an increase of $2.1 million in employee compensation and outside consulting expenses and $2.3 million from a reclassification during 2020 of expenses for directors' and officers' insurance and certain commercial activities to general and administrative expenses from research and development expenses.

**Interest Income (Expense)**

Interest income was $35,000 for the three months ended September 30, 2020, compared with $162,000 for the three months ended September 30, 2019. The decrease in interest income of $127,000 was primarily due to lower interest rates in 2020 compared with 2019, partially offset by an increase in cash balances held in interest bearing accounts during 2020 compared with 2019.

Interest income was $156,000 for the nine months ended September 30, 2020, compared with $520,000 for the nine months ended September 30, 2019. The decrease in interest income of $364,000 was primarily due to lower interest rates in 2020 compared with 2019.



Interest expense was $(191,000) for the three months ended September 30, 2020, compared with $(265,000) for the three months ended September 30, 2019. The decrease in interest expense of $74,000 was primarily due to lower levels of debt during the three months ended September 30, 2020 compared with the three months ended September 30, 2019.

Interest expense was $(656,000) for the nine months ended September 30, 2020, compared with $(738,000) for the nine months ended September 30, 2019. The decrease in interest expense of $82,000 was primarily due to lower levels of debt during the nine months ended September 30, 2020 compared with the nine months ended September 30, 2019.

**Net Loss**

Net loss was $15.0 million for the three months ended September 30, 2020, compared with $13.4 million for the three months ended September 30, 2019. The increase in net loss of $1.5 million, or 11.5%, was primarily due to an increase in general and administrative expenses, partially offset by a decrease in research and development expenses during the three months ended September 30, 2020 compared with the three months ended September 30, 2019. See the discussion above for further information.

Net loss was $43.7 million for the nine months ended September 30, 2020, compared with $33.1 million for the nine months ended September 30, 2019. The increase in net loss of $10.6 million, or 32.0%, was primarily due to the decrease in revenue, partially offset by the decrease in cost of revenue recognized during the nine months ended September 30, 2020 compared with the nine months ended September 30, 2019. Additionally, an increase in general and administrative expenses was partially offset by a decrease in research and development expenses during the nine months ended September 30, 2020 compared with the nine months ended September 30, 2019. See the discussion above for further information.

**Liquidity and Capital Resources**

We have financed our growth and operations through a combination of funds generated from our licensing revenue, the issuance of convertible preferred stock and common stock, finance leases, bank borrowings and the issuance of convertible notes. Our principal uses of cash have been for working capital requirements and capital expenditures. As of September 30, 2020, we had a cash balance of $79.6 million, stockholders' equity of $65.3 million and an accumulated deficit of $258.9 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 December 2019, we entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with certain institutional accredited investors, or the Purchasers, for the sale by us in a private placement, or the Private Placement, of an aggregate of 7,164,534 shares, or the Private Placement Shares, of our common stock, at a purchase price of $3.13 per Private Placement Share. The gross proceeds from the sale of the Private Placement Shares were $22.4 million and net proceeds were $21.0 million, after placement agent fees and offering expenses.

In August 2019, we entered into a sales agreement, or 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 will act as our agent and/or principal. We pay 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, 2019, we sold 2,409,356 shares of our common stock for gross proceeds of $8.4 million and net proceeds were $8.1 million, after deducting underwriting discounts and other offering expenses under the ATM Agreement. During the nine months ended September 30, 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.

In March 2019, we closed an underwritten follow-on offering of 3,000,000 shares of our common stock at a public offering price of $11.50 per share. The gross proceeds from the offering were $34.5 million and net proceeds were $31.8 million, after deducting underwriting discounts and commissions and other offering expenses.



In October 2018, we and PWB entered into an Amended and Restated Loan and Security Agreement, or the A&R LSA, in which we received an initial tranche of $11.0 million to extinguish our then-current debt of $8.0 million under the LSA, repay in full the outstanding indebtedness under the UNC Promissory Note (as defined below) and to utilize for general corporate purposes. The indebtedness under the A&R LSA bears interest at the greater of the Prime rate or 5% and has a four-year term and maturity. The A&R LSA provided for access to a second tranche of up to $5.0 million, the full amount of which we drew in June 2019. The second tranche became accessible as a result of the full enrollment of the Company's LIQ861 INSPIRE clinical trial, without observing any materially adverse data through the two-week endpoint. Both tranches required payments of interest-only through December 31, 2019. The A&R LSA carries a one-time success fee of $375,000 and a prepayment penalty of 1% if the drawn tranche is prepaid prior to October 27, 2020. The success fee was triggered in December 2019 by the sale of our common stock and this was recorded as interest expense of $375,000 during the year ended December 2019. The minimum cash covenant is $8.5 million. In May 2019, we and PWB entered into an amendment to the A&R LSA to, among others, amend our negative covenant related to capitalized expenditures to increase the aggregate amount of capitalized expenditures we are permitted to make without PWB's prior written consent during the fiscal year ending December 31, 2019 from $1.25 million to $2.5 million. The Company received a waiver of covenant compliance from PWB for non-timely submissions of monthly financial statements for the February and March 2020 periods.

The A&R LSA with PWB, as amended, contains restrictions that limit our flexibility in operating our business. We may not, among other things, without the prior written consent of PWB, (a) pay any dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock except in certain prescribed circumstances, (b) create, incur, assume, guarantee or be or remain liable with respect to any indebtedness except certain permitted indebtedness or prepay any indebtedness, (c) replace or suffer the departure, as defined, of our Chief Executive Officer or Chief Financial Officer without delivering written notification to PWB within ten days of such change or (d) suffer a change on our Board which results in the failure of at least one partner of Canaan Partners or their respective affiliates to serve as a voting member, in each case without having used best efforts to deliver at least 15 days' prior written notification to PWB. PWB maintains a blanket lien on all assets excluding intellectual property, for which it has been provided a negative pledge.

***Cash Flows***

The following table summarizes our sources and uses of cash:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Net cash (used in) provided by: | | |
| Operating activities | $ (40,056) | $ (34,222) |
| Investing activities | (713) | (1,716) |
| Financing activities | 64,524 | 35,708 |
| Net increase (decrease) in cash | $ 23,755 | $ (230) |

***Operating Activities***

Net cash used in operating activities increased $5.8 million to $40.1 million for the nine months ended September 30, 2020 from $34.2 million for the nine months ended September 30, 2019. The increase was mainly due to an increase in our general and administrative expenses partially offset by a decrease in our research and development expenses during the nine months ended September 30, 2020 compared with 2019. For the nine months ended September 30, 2020, the net cash used in operating activities of $40.1 million was comprised of operating cash outflows before working capital changes of $38.4 million and net working capital outflows of $1.7 million. For the nine months ended September 30, 2019, the net cash used in operating activities of $34.2 million was comprised of operating cash outflows before working capital changes of $28.4 million and net working capital outflows of $5.8 million.

***Investing Activities***

Net cash used in investing activities consisting of property, plant and equipment was $0.7 million during the nine months ended September 30, 2020 compared with $1.7 million during the nine months ended September 30, 2019.

***Financing activities***

Net cash provided by financing activities was $64.5 million during the nine months ended September 30, 2020 compared with $35.7 million provided by financing activities during the nine months ended September 30, 2019. During the nine months ended September 30, 2020, we received $70.3 million from the public offering of common stock in July 2020 and $0.7 million from the sale of our common stock under our ATM facility, which was offset by $4.2 million in principal payments on our long-term debt, $1.4 million for expenses related to our sale of Private Placement Shares that closed in December 2019 and $0.9 million in principal payments on our finance leases. During the nine months ended September 30, 2019, cash provided by financing activities consisted primarily of $31.9 million in net proceeds from a follow-on sale of our common stock and a $5.0 million draw under the A&R LSA.



**Funding Requirements**

We plan to focus in the near-term on the development, regulatory approval and potential commercialization of LIQ861. We anticipate we will incur net losses for the next several years as we complete clinical development of these product candidates and continue research and development of additional product candidates. In addition, we plan to commercialize LIQ861, if approved, continue sales of generic Remodulin® through our RareGen acquisition, if the Merger Transaction is successfully completed, expand our corporate infrastructure and continue to invest in research and development efforts to explore additional product candidates. We may not be able to complete the development and initiate commercialization of these programs if, among others, our clinical trials are not successful or if the FDA does not approve our product candidates arising out of our current clinical trials 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, administrative and overhead costs and debt service. Our future funding requirements will be heavily determined by the resources needed to support development of our product candidates.

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, or Nasdaq, require public companies to implement specified corporate governance practices. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe that our current cash balance will enable us to fund our operating expenses and capital expenditure requirements and remain in compliance with the minimum cash covenant of $8.5 million pursuant to our term loan facility with PWB into the first quarter of 2022. We are in the process of implementing a more cost-efficient operating plan to further improve our cashflow. In addition, a successful close of the Merger Transaction has the potential to improve our cashflow going forward. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to complete NDA regulatory review of LIQ861 and commercialize our product candidates, if we receive regulatory approval, and to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for LIQ861 or LIQ865, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. 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 licensing activities, other business arrangements or the sale of equity or convertible debt securities. In such an event, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder 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.

**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 Interim 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, or COSO, of the Treadway Commission, and concluded that our internal control over financial reporting was not effective as of September 30, 2020 as a result of material weaknesses in our 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, 2020:

During 2019, 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 consolidated 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. Additionally, 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 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 implementing and demonstrating that the new or improved controls are designed appropriately and operate effectively for a reasonable period of time. Although we have not fully remediated the material weaknesses described in our 2019 Annual Report on Form 10-K, we believe that we have made progress on the remediation plans described in Item 9A *Controls and Procedures* in our 2019 Annual Report on Form 10-K. The following remediation steps were taken by the Company during the quarter ended September 30, 2020:

- We have engaged an external accounting firm to provide controller and other financial consulting services to strengthen the finance team.

- We have also engaged an accounting and consulting firm to assist us with the strengthening and monitoring of our internal controls processes and documentation. In addition, we have worked with the consulting firm on the following:

    - Modified user rights to our accounting system to ensure that journal entries cannot be created and posted by the same user.

    - Modified the user rights to our accounting system to ensure that no accounting personnel have “Super User” rights.

    - Implemented procedures to ensure that account reconciliations are reviewed and approved by qualified accounting personnel

independent from the personnel that prepared the reconciliation and related journal entry.

In addition, we expect to provide enhanced training to existing and new employees in order to increase the level of understanding of controls with individuals that provide key information and perform key roles within our financial accounting and reporting group.

The material weaknesses described in our 2019 Annual Report on Form 10-K will not be considered remediated, until the applicable controls operate for a sufficient period of time and management has concluded that these controls operate effectively.

**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 Interim 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, 2020, 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, or persons performing similar functions, 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, 2020, our Chief Executive Officer and Interim 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 above 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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Subsequent to our December 31, 2019 year end, we began taking a number of actions, including designing and implementing new controls and revising existing controls, in order to remediate the material weaknesses described above. We expect to continue our remediation efforts, including testing of operating effectiveness of new controls, as described above under "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations – Internal Controls and Procedures – Remedial Actions to Address Material Weaknesses", and we plan to provide an update on the status of our remediation activities on a quarterly basis.



**PART II.**

**Item 1. Legal Proceedings.**

On June 4, 2020, United Therapeutics Corporation, a Delaware corporation, or 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), or 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®", or the '901 Patent, and 9,593,066, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", or the '066 Patent, relating to United Therapeutics' Tyvaso®, a nebulized treprostinil solution for the treatment of pulmonary arterial hypertension, or PAH. On July 16, 2020, we filed an answer to United Therapeutics' complaint and also included 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, or the LIQ861 NDA, filed with the U.S. Food and Drug Administration, or the 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, or the USPTO, issued U.S. Patent No. 10,716,793, or 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. We are required to make a certification with respect to the '793 Patent in our NDA for LIQ861. 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 in May 2021 and set the trial to begin in March 2022.

On March 30, 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board, or the PTAB, of the U.S. Patent and Trademark Office, or 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 Corporation, or 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. A final written decision determining the validity of the challenged claims of the '901 Patent is expected within 12 months from institution.

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 consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," 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.*

**Risks Related to the Merger Transaction**

***We may not achieve the benefits expected from the proposed acquisition of RareGen, LLC, or RareGen, by way of merger, or the Merger Transaction, pursuant to that certain Agreement and Plan of Merger, dated as of June 29, 2020, by and among our company, Liquidia Corporation, or HoldCo, RareGen and certain other parties thereto, or the Merger Agreement, which may harm our business and could result in the loss of key suppliers, licensees, collaborators, business partners and personnel.***

Achieving the benefits of the Merger Transaction will depend in part on the successful integration of the technology, platforms, capabilities, operations and personnel of our company and RareGen in a timely and efficient manner to minimize the impact on suppliers, licensees, collaborators, business partners, employees and management. The integration of our company and RareGen will be a complex, time-consuming and expensive process and may harm our business, financial condition and results of operations. The challenges involved in this integration include, but are not limited to, the following:

- retaining existing suppliers, licensees, collaborators and business partners of both our company and RareGen;
- retaining and integrating directors, executive management and other key employees of both our company and RareGen;
- onboarding RareGen employees to our company's benefit plans and payroll;
- managing the RareGen field sales team;
- consolidating the companies' promotional, sales and commercialization efforts so that the industry receives useful information about HoldCo's product candidates and services;
- identifying and eliminating redundant operations and assets;
- coordinating research and development activities to integrate existing technologies and enhance introduction of new products and technologies;
- persuading employees that the business cultures of our company and RareGen are compatible; and
- maintaining and upgrading uniform standards, controls, procedures and policies for compliance with rules and regulations customary in our line of business, including but not limited to federal and state healthcare requirements and internal controls and procedures that we will be required to maintain under the Sarbanes-Oxley Act of 2002.

We cannot assure you that we can successfully integrate our business with that of RareGen in a timely manner or that all or any of the anticipated benefits of the Merger Transaction will be realized.

The Merger Transaction involves the integration of two companies that previously have operated independently. Risks to the successful integration of the two companies include:

- the impairment of relationships with employees, suppliers, licensees, collaborators and business partners;
- the potential disruption of our business and distraction of our management;
- the difficulty of incorporating acquired technology, platforms and relationships from RareGen into our offerings;



- not achieving expected synergies as a result of a number of factors, including, but not limited to, the failure of the FDA to timely approve our NDA for LIQ861 and/or the failure of Sandoz Inc.'s treprostinil pursuant to the Promotion Agreement between RareGen and Sandoz Inc. to be administered subcutaneously; and
- unanticipated expenses related to integration of the two companies.

We may not succeed in addressing these risks or any other problems encountered in connection with the Merger Transaction.

***Any delay in completing the Merger Transaction may reduce or eliminate the benefits expected to be achieved thereunder.***

The Merger Transaction is subject to a number of conditions beyond our and RareGen's control that may prevent, delay or otherwise materially adversely affect its completion. Neither we nor RareGen can predict whether and when these conditions will be satisfied. Any delay in completing the Merger Transaction could cause us not to realize some or all of the operational and revenue synergies and other benefits that we and RareGen expect to achieve if the merger is successfully completed within its expected time frame.

***We may incur substantial transaction fees and merger-related costs in connection with the Merger Transaction.***

We expect to incur a number of substantial expenses, totaling approximately $5.0 million, associated with completing the Merger Transaction, including the costs and expenses of filing, printing and mailing the notice of internet availability of the definitive proxy statement/prospectus and all filing and other fees paid to the SEC and Nasdaq in connection with the Merger Transaction, investment banking fees and expenses, and combining the operations of the two companies. While we have assumed that a certain level of transaction and coordination expenses will be incurred, there are a number of factors beyond our control that could affect the total amount or the timing of these transaction and coordination expenses. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately. Additional unanticipated costs may be incurred in the integration of the businesses of our company and RareGen, and such costs could become substantial. Although it is expected that the elimination of certain duplicative costs, as well as the realization of other efficiencies related to the integration of the two businesses, will offset the incremental transaction and merger-related costs over time, this net benefit may not be achieved in the near term, or at all. Further, if the Merger Transaction is not completed, we would have to recognize these expenses without realizing the expected benefits of the Merger Transaction. These costs could adversely affect our financial condition and results of operations prior to the Merger Transaction and of HoldCo following completion of the Merger Transaction.

***Our stockholders may not realize a benefit from the Merger Transaction commensurate with the ownership dilution they will experience in connection with the Merger Transaction.***

If we are unable to realize the strategic and financial benefits currently anticipated from the Merger Transaction, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect our business, financial results, financial condition and stock price following completion of the Merger Transaction. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

***We and RareGen will be subject to business uncertainties and contractual restrictions while the Merger Transaction is pending that may cause disruption from the transaction and may make it more difficult to maintain relationships with employees, suppliers, business partners or licensees.***

Uncertainties about the effect of the Merger Transaction on employees, suppliers, business partners, licensees and other persons with whom we or RareGen has a business relationship may have an adverse effect on our business or RareGen prior to the Merger Transaction and on HoldCo following completion of the Merger Transaction. In connection with the pendency of the Merger Transaction, as well as during times of significant change and uncertainty such as the period following completion of the Merger Transaction, suppliers, business partners, licensees and other persons with whom we or RareGen have a business relationship may delay or defer business decisions, decide to terminate, modify or renegotiate their relationships with our company or RareGen, or take other actions as a result of the Merger Transaction that could negatively affect our or RareGen's respective revenue, earnings and cash flows, as well as the market price or fair market value of their respective securities. The ability of us or RareGen to raise additional capital through the debt markets, and the associated borrowing costs, may also be negatively impacted. These disruptions could have an adverse effect on the results of operations, cash flows and financial position of us or RareGen, including an adverse effect on HoldCo's ability to realize the expected cost savings and other benefits of the Merger Transaction. The risk, and adverse effect, of any disruption could be exacerbated by a delay in completion of the Merger Transaction or termination of the Merger Agreement.



***During the pendency of the Merger Transaction, we may not be able to enter into a business combination with another party because of restrictions in the Merger Agreement.***

Covenants in the Merger Agreement impede our ability to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger Transaction, even if such transactions might be favorable to our stockholders. As a result, if the Merger Transaction is not completed, we may be at a disadvantage to our competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, we are discouraged from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a strategic collaboration agreement involving LIQ861, or a sale of our assets, an acquisition of our common stock, a tender offer for our common stock, a merger or other business combination outside the ordinary course of business, as the termination of the Merger Agreement of (i) by us if our board of directors decides to accept a superior proposal or (ii) by RareGen if our board of directors changes its recommendation following the receipt of an alternative proposal would result in us paying to RareGen a termination fee of $7.5 million.

***The future results of HoldCo will suffer if it does not effectively manage its expanded operations following the completion of the Merger Transaction.***

Following the completion of the Merger Transaction, the size and complexity of HoldCo's business will increase beyond the current size of either our or RareGen's business. HoldCo's future success depends, in part, upon its ability to manage this expanded business, which will pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. If HoldCo is unsuccessful in managing its integrated operations, or if it does not realize the expected operating efficiencies, cost savings and other benefits currently anticipated from the Merger Transaction, HoldCo's operations and financial condition could be adversely affected and it may not be able to take advantage of business development opportunities.

***Our internal financial forecasts regarding RareGen may not prove accurate.***

In connection with the Merger Transaction, our management prepared internal, stand-alone, pre-transaction financial forecasts of RareGen. These forecasts were based on numerous variables and assumptions that are inherently uncertain and are beyond our control, including assumptions with respect to macro-economic trends, interest rates and anticipated growth rates, and is not necessarily indicative of what RareGen's actual results of operations, cash flows or financial position would be on the dates indicated. The assumptions used in preparing these forecasts may not prove to be accurate and other factors may affect HoldCo's actual results and financial condition after the completion of the Merger Transaction, which may cause HoldCo's actual results and financial condition to differ materially from our estimates contained in the unaudited prospective financial information for RareGen. These forecasts were not prepared with a view to public disclosure, are subject to significant economic, competitive, industry and other uncertainties and may not be achieved in full, at all, or within projected timeframes. The failure of our or RareGen's businesses to achieve projected results could have a material adverse effect on the price of HoldCo common stock, HoldCo's financial position, and HoldCo's operating results and cash flows.

***The Merger Agreement may be terminated in accordance with its terms and the Merger Transaction may not be completed.***

We and RareGen may terminate the Merger Agreement under certain circumstances, including, among other reasons, if the Merger Transaction is not completed by December 31, 2020. In addition, if the Merger Agreement is terminated (i) by us if our board of directors decides to accept a superior proposal or (ii) by RareGen if our board of directors changes its recommendation to our stockholders following receipt of an alternative proposal, then we shall pay to RareGen a termination fee of $7.5 million.

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

***Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.***

Our consolidated financial statements for the nine months ended September 30, 2020 include a statement that our recurring losses and cash outflows from operations, our accumulated deficit and our debt maturing within twelve months raise substantial doubt about our ability to continue as a going concern. As of September 30, 2020, we had $79.6 million of cash. We believe that our existing cash will enable us to fund our operating expenses and capital expenditure requirements, make payments of interest and principal on our term loan facility with Pacific Western Bank, or PWB, and remain in compliance with the minimum cash covenant of $8.5 million pursuant to this term loan facility, into the first quarter of 2022. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we are unable to obtain sufficient funding or execute on strategic initiatives to generate sufficient cash, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. Future financial statements may also include statements expressing substantial doubt about our ability to continue as a going

concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.



***We have a history of losses, have not commenced commercial operations to date and our future profitability is uncertain.***

We have incurred net losses of $43.7 million during the nine months ended September 30, 2020 and $47.6 million, $53.1 million and $29.2 million during the years ended December 31, 2019, 2018 and 2017, respectively. We also had negative operating cash flows for each of these periods. As of September 30, 2020, we had an accumulated deficit of $258.9 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. These up-front fees and milestone payments have been, and 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. 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 and LIQ865 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.

***We may acquire businesses, products or product candidates, or form strategic alliances or create joint ventures, in the future, and we may not realize the benefits of such transactions.***

We may acquire additional businesses, products or product candidates, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business, although we have no current agreements, commitments or understandings to do so. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products or product candidates resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, strategic alliance or joint venture, we will achieve the expected synergies to justify the transaction.



***Our credit facility with Pacific Western Bank, or PWB, contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in PWB 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 amended and restated loan and security agreement dated as of October 26, 2018, as amended, or the A&R LSA, with PWB, pursuant to which PWB extended a $16.0 million term loan facility to us, of which $11.0 million was received in October 2018 in an initial tranche and $5.0 million was received in May 2019, we may not, among others, without the prior written consent of PWB, (a) pay any dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock except in certain prescribed circumstances, (b) create, incur, assume, guarantee or be or remain liable with respect to any indebtedness except certain permitted indebtedness or prepay any indebtedness, (c) replace or suffer the departure of our Chief Executive Officer or Chief Financial Officer without delivering written notification to PWB within ten days of such change or (d) suffer a change on our board of directors, or Board, which results in the failure of at least one partner of Canaan Partners or their respective affiliates to serve as a voting member, without having used best efforts to deliver at least 15 days' prior written notification to PWB. Our facility with PWB is collateralized by all of our assets excluding our intellectual property, on which we have granted a negative pledge.

We have, in the past, breached multiple covenants in our loan and security agreement dated as of January 6, 2016, as amended, with PWB related to cash levels, reporting requirements and required periodic deliverables to PWB, but have obtained waivers from PWB in relation to all such breaches. 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 our facility agreements, giving lenders the right to require us to repay the then outstanding debt immediately, and the lenders 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. A breach of covenants in the A&R LSA and the acceleration of our repayment obligations by PWB could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Although we have historically depended on GSK for a significant portion of our revenue, we do not expect to receive any additional revenue from our GSK collaboration.***

We are party to a licensing agreement with GSK pursuant to which GSK has exercised an option to exclusively license our PRINT technology for applications in certain inhaled therapies, or the GSK ICO Agreement. We previously entered into a separate licensing agreement with GSK relating to the field of vaccines, which lapsed in April 2016. We have historically received a significant portion of our revenue from GSK pursuant to these licensing agreements. We recorded no revenue attributable to our collaboration and licensing agreements with GSK during the nine months ended September 30, 2020. For the year ended December 31, 2019, our revenue attributable to our collaboration and licensing arrangements with GSK, which included a combination of billings for particle formulations, manufacturing, milestone payments and amortization of deferred revenue from up-front fees, accounted for 100% of our total revenue.

During the second quarter of 2019 we concluded that no further research and development services will be provided to GSK under the collaboration agreement and the earnings process related to the license fees previously received under the collaboration agreement has been completed under the proportional performance model. Therefore, the remaining deferred revenue of $8.1 million was recognized as revenue during the second quarter of 2019, and we do not expect to receive any additional revenue from GSK pursuant to our collaboration. Because GSK is no longer actively advancing any programs under our collaboration, we entered into the Third Amendment to the GSK ICO Agreement during the second quarter of 2019, pursuant to which we have the right to develop three products for delivery via inhalation, subject to specified milestone payments and royalties due to GSK. Additionally, under certain circumstances GSK has a right of first negotiation with respect to these programs. Although a large proportion of our revenue has historically been obtained from our collaboration with GSK, we do not expect this collaboration to continue. To that end, in January 2020 we notified GSK of our intent to terminate the collaboration because we believe that GSK's inactivity with respect to the collaboration constitutes a material breach and GSK has rebutted our notice of termination. We are currently attempting to resolve the dispute with GSK pursuant to the terms of the GSK ICO Agreement.

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

We expect to use the net proceeds of our July 2020 public offering and prior public and private equity offerings for ongoing commercial development of LIQ861, for continued development of LIQ865 and for general corporate purposes. The net proceeds are not being used to fund the acquisition of RareGen and we do not expect to use any material proceeds from this offering to fund the operations of RareGen. 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, or 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 July 2020 equity offering, our December 2019 private placement, recent issuances under our ATM facility, our March 2019 follow-on equity offering and our July 2018 initial public offering, as well as other past transactions, we believe that we have already triggered an “ownership change” limitation, or will likely trigger an “ownership change” following the consummation of the Merger Transaction. 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 product revenue, 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. Drug product development involves a substantial degree of uncertainty. Our operations to date have been limited to developing our PRINT technology, undertaking preclinical studies and clinical trials for our product candidates and collaborating with pharmaceutical companies, including GlaxoSmithKline plc and/or its subsidiaries, collectively, 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 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.

***The TCJA could adversely affect our business and financial condition.***

In December 2017, the TCJA was enacted into law. The TCJA includes significant changes to the U.S. corporate income tax system, including a permanent reduction in the corporate income tax rate from 35% to 21%, limitations on the deductibility of interest expense and executive compensation and the transition of U.S. international taxation from a worldwide system to a territorial tax system. For taxpayers with revenue over a certain threshold, the TCJA also limits interest expense deductions to 30% of taxable income before interest, depreciation and amortization from 2018 to 2021 and then taxable income before interest thereafter. The TCJA permits disallowed interest expense to be carried forward indefinitely. We calculated our best estimate of the impact of the TCJA in our income tax provision for the year ended December 31, 2017 in accordance with our understanding of the TCJA and guidance available at the time. The overall impact of the TCJA resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of $14.1 million. We completed our accounting for the TCJA during the third quarter of 2018. No changes to the provisional amounts as of December 31, 2017 were recorded. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our

stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

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

***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 FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or 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, or the '901 Patent, entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®", and U.S. Patent No. 9,593,066, or 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), or 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, 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, or the USPTO, issued U.S. Patent No. 10,716,793, or 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 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. We are required to make a certification with respect to the '793 Patent in our NDA for LIQ861. 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 on May 24, 2021 and set the trial to begin on March 28, 2022.

On March 30, 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board, or the 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. A final written decision determining the validity of the challenged claims of the '901 Patent is expected within 12 months from institution.

***We face significant competition from large pharmaceutical companies, among others, 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 be more successful in commercializing their 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.

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.



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

2004.

- TreT, licensed from MannKind, by United Therapeutics, is currently in late-stage clinical development in the United States for the treatment of PAH. Under the license agreement, 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. In September, 2019, United Therapeutics commenced a clinical study (BREEZE) to evaluate the safety and pharmacokinetics of switching PAH patients from Tyvaso to TreT and announced that a second clinical study is expected to be completed by the end of 2020 to compare the pharmacokinetics of TreT to Tyvaso in healthy volunteers. United Therapeutics further reported that the two studies, if successful, are the only clinical studies necessary to support FDA approval.

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.

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.

In addition, we are also aware of several other agents currently in clinical development in the United States for the treatment of PAH, including those in development by Insmed, Inc. and Acceleron Pharma, Inc.

We expect LIQ865 to face competition from EXPAREL®, an existing injectable version of bupivacaine. The early success of EXPAREL may make it difficult for us to convince physicians, patients and other members of the medical community to accept and use LIQ865 over EXPAREL. Generic equivalents of EXPAREL may also enter the market following the expiry of EXPAREL's patent in 2021.

While EXPAREL is currently the only direct competitor to LIQ865 on the market, in October 2018 Heron Therapeutics, Inc., or Heron, announced the submission of its NDA to the FDA for HTX-011, an investigational long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the management of postoperative pain. HTX-011 was granted both breakthrough therapy and fast track designations from the FDA as well as priority review by the FDA. On May 1, 2019, Heron announced that it received a complete response letter, or CRL, for HTX-011 from the FDA. On October 1, 2019, Heron announced that it had resubmitted its NDA for HTX-011 to the FDA and expected a six-month review. On June 26, 2020, Heron announced that it received a CRL from the FDA for HTX-011. In addition to Heron, Durect Corporation and Innocoll Holdings plc each also have products in clinical development that are potential competitors to LIQ865.

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

***If a competitor obtains orphan drug designation from the FDA for the same drug and same indication as we are seeking for a product candidate, and then obtains approval of that drug for that condition before we do, the resulting FDA exclusivity would significantly delay our ability to commercialize that product candidate. Similarly, if a competitor obtains marketing approval for a new condition of use that required new clinical investigations for support, the competitor may obtain three-year marketing exclusivity for that condition of use, and thereby delay our ability to receive marketing approval for that drug product for that condition of use by three years form the date of that approval.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition — generally a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA.



After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first applicant to receive FDA approval for a particular active ingredient to treat a particular disease or condition with orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product in that indication. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

During the exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease or condition, except in limited circumstances, such as if the second applicant demonstrates clinical superiority of its product to the product with orphan drug exclusivity through a demonstration of superior safety, superior efficacy or a major contribution to patient care, or if the manufacturer of the product with orphan exclusivity is not able to assure sufficient quantities of the product. "Same drug" means a drug that contains the same identity of the active moiety if it is a drug composed of small molecules, or of the principal molecular structural features if it is composed of macromolecules and is intended for the same use as a previously approved drug, except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug. Drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

***The commercial success of our drug products depends on the availability and sufficiency of third-party payor coverage and reimbursement.***

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, market acceptance of our drug products is dependent on the extent to which third-party coverage and reimbursement is available from government health administration authorities (including in connection with government healthcare programs, such as Medicare and Medicaid in the United States), private healthcare insurers and other healthcare funding organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we may obtain regulatory approval. Coverage decisions may not favor new drug products when more established or lower-cost therapeutic alternatives are already available. Even if we obtain coverage for a given drug product, the associated reimbursement rate may not be adequate to cover our costs, including research, development, intellectual property, manufacture, sale and distribution expenses, or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless reimbursement is adequate to cover all or a significant portion of the cost of our drug products.

Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly, which will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. It is difficult to predict at this time what government authorities and third-party payors will decide with respect to coverage and reimbursement for our drug products.

The market for our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Competition to be included in such formularies often leads to downward pricing pressures. In particular, third-party payors may refuse to include a particular drug in their formularies or otherwise restrict patient access to a drug when a less costly generic equivalent or other alternative is available. In particular, given that several therapeutically similar drug products to LIQ861, including inhaled, oral and parenteral prostacyclins, are available on the market, managed care organizations may minimize the utilization of a new to market product and accordingly, we expect that LIQ861, if and when approved, will operate in a highly cost-constrained environment. Similarly, as there are a number of generic and branded therapeutic alternatives to LIQ865 in the post-operative pain market, there is a significant risk that LIQ865 may not be placed on the formularies of key institutions and/or receive favorable reimbursement, if and when approved.

The U.S. government, state legislatures and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drug products from coverage and limit payments for pharmaceuticals.



In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities will continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for our drug products, the commercial success of our drug products may be greatly hindered and our financial condition and results of operations may 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.

***The pharmaceutical industry is subject to rapid technological change, which could affect the commercial viability of our products.***

The pharmaceutical industry is subject to rapid and significant technological change. Research, discoveries or inventions by others may result in medical insights or breakthroughs that render our products less competitive or even obsolete. Furthermore, there may be breakthroughs of new pharmaceutical technologies which may become superior to our PRINT technology that may result in the loss of our commercial advantage. Our future success will depend in part upon our ability to, among others:

- develop or license new technologies that address the changing needs of the medical community; and
- respond to technological advances and changing industry standards and practices in a cost-effective and timely manner.

Developing technology entails significant technical and business risks and substantial costs. We cannot assure you that we will be able to utilize new technologies effectively or that we will be able to adapt our existing technologies to changing industry standards in a timely or cost-effective manner, or at all. If we are unable to keep up with advancements in technology, our competitive position may suffer and our business and prospects may be materially and adversely affected.



***Disruptions at the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including global pandemics, natural disasters, geopolitical actions, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in December 2019, a novel strain of COVID-19, or coronavirus, was reported to have surfaced in Wuhan, China and has become a global pandemic as of the date of this Quarterly Report on Form 10-Q. The full impact of the coronavirus is unknown and rapidly evolving. For example, after generally suspending in-person inspections due to COVID-19, the FDA recently announced it would resume domestic facility inspections, although the agency continues its general suspension of foreign facility inspections (although “mission-critical” inspections may be considered on a case-by-case basis). Because of the global pandemic, decision-making around facility inspections by the FDA (including preapproval inspections) continues to evolve. Additionally, over the last several years, including from December 22, 2018 until January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA and other government employees and stop critical activities. In addition, there may be personnel and other changes following the 2020 Presidential election and other developments, the impact of which is currently unknown. If a prolonged government disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, prolonged government disruptions, global pandemics and other natural disasters or geopolitical actions could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***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, most of our employees are working remotely, with only essential personnel working on site as needed to produce LIQ861 and prepare for a pre-approval inspection by the FDA.

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. For example, as a result of the pandemic, we have paused enrollment in our hemodynamic study, which has been conducted in Europe.

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 duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. For example, during the course of the pandemic the FDA has at points delayed both domestic and foreign facility inspections. The agency announced in July 2020 that domestic facility inspections will be conducted but prioritized through a risk-based approach, while foreign facility inspections remain delayed unless the FDA determines they can be conducted based on an assessment of whether it is “mission-critical.” 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.

***Our products may be subject to reduced prices negotiated by certain group purchasing organizations that could adversely impact our product revenue.***

Our customers may organize with each other or with third parties, such as distributors, manufacturers or hospitals, to negotiate prices that are lower than we may have been able to obtain from each of them individually. In such event, our ability to generate product revenue, and consequently our 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. We cannot assure you that we will be successful in doing so 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 in anticipation of potential approval from the FDA, we also continue to develop 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 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.

***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, or 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.



***The off-label use or misuse of our products may harm our image in the marketplace, result in injuries that lead to costly product liability suits, or result in costly investigations and regulatory agency sanctions under certain circumstances if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.***

We are developing LIQ861 for the treatment of PAH and LIQ865 for the treatment of local post-operative pain. If our product candidates receive marketing approval from the FDA for these specific indications, we may only promote or market our product candidates for their specifically approved indications and make promotional claims consistent with the FDA-required product labeling. We will train our marketing and sales force against promoting our product candidates for "off-label uses" that would be inconsistent with FDA law and guidance. With respect to whether communications are consistent with the FDA-required product labeling, we cannot predict whether the FDA will agree with our assessment. We also cannot prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products for uses for which they are not approved. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA determines that our promotional materials or training constitute promotion of an off-label or other improper use, it could request that we modify our training or promotional materials, or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, mandatory compliance programs under corporate integrity agreements, debarment, refusal of government contracts, and the curtailment of our operations.

These regulations or codes may limit our ability to effectively market our products, or we could run afoul of the requirements imposed by these regulations, causing reputational harm. These regulations or codes may also impose potentially substantial costs on us.

***We may not be able to respond effectively to changing consumer preferences and demand.***

Our success depends, in part, on our ability to anticipate and respond to changing consumer trends and preferences in the pharmaceutical industry. We may not be able to respond to these changes in a timely or commercially effective manner or at all. Our failure to accurately predict these trends could negatively impact our inventory levels, sales and reputation. The commercial success of our drug products will depend upon a number of factors, including our ability to, among others:

- anticipate consumers' therapeutic needs;
- innovate, develop and commercialize new drug products in a timely manner;
- competitively price our drug products;
- procure and maintain our drug products in sufficient volumes and in a timely manner; and
- differentiate our drug products from those of our competitors.

If we are unable to introduce new drug products, develop improvements to our existing drug products or maintain the appropriate inventory levels to meet our customers' demand in a timely manner or at all, our business and prospects could be materially and 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 candidates, LIQ861 and LIQ865, 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.

***If our product candidates are approved for commercialization outside of the United States, we may be exposed to a number of risks associated with international business operations.***

If our product candidates are approved for commercialization outside of the United States, we may market our drug products ourselves, or we may enter into agreements with third parties to market the aforesaid drug products outside of the United States. In such event, we may be subject to risks related to international business operations, including, but not limited to:

- varying levels of protection for intellectual property rights;
- changes in tariffs and the imposition of trade barriers;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- compliance with tax, employment, immigration and labor laws in respect of employees living or traveling abroad;
- foreign tax laws;
- currency fluctuations; and
- business interruptions resulting from geopolitical actions, such as wars and terrorist attacks, among others, or global pandemics or natural disasters, such as fires, floods, earthquakes and hurricanes, among others.

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

***We are primarily dependent on the success of our lead product candidate, LIQ861, for which we have recently filed an NDA with the FDA, and to a lesser degree, LIQ865, which is still in clinical development, and these product candidates may fail to receive marketing approval 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 product sales. Our ability to generate revenue from product sales 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 candidates, LIQ861, a proprietary inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension, or PAH, and LIQ865, a sustained-release formulation of bupivacaine for the management of local post-operative pain. 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. Consistent with preliminary data presented in the second quarter of 2019, LIQ861 was observed to be well-tolerated and treatment-emergent adverse events, or TEAEs, were mostly mild to moderate in nature at Month 2 up to doses of 159 mcg of LIQ861, the highest dose studied at Month 2. Durability of therapy with LIQ861 appeared to be favorable, with 96% of Transition patients and 91% of Add-On patients remaining on study drug at the Month 2 timepoint.

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%).

In August 2019, one of the clinical investigators in the INSPIRE study reassessed a serious adverse event, preliminarily identified as hypersensitivity pneumonitis, as being possibly related to LIQ861, whereas the clinical investigator had previously, in May and June 2019, characterized the event as not related to LIQ861. Based on the patient's medical history, two other potential alternative causes of this event noted by the clinical investigator, and the fact that the patient has been taking LIQ861 since October 2018, we do not agree with the clinical investigator's assessment. However, we reported the event to the FDA, as required, and we will continue to monitor and assess this event for any change.



In September 2019, we reported results from pharmacokinetic (PK) studies indicating that the 79.5 mcg dose of LIQ861 correlates with nine breaths of Tyvaso, the maximum recommended label dose of Tyvaso. To accurately characterize the pharmacokinetics of LIQ861, we conducted two PK studies in healthy volunteers. In the first of these studies, we observed unexpected variability in PK levels. Post-hoc analysis showed that plasma levels of treprostinil were tightly correlated to the LIQ861 dose delivered. Based upon additional non-clinical and clinical work, we believe the unexpected variability seen in this healthy volunteer study was due to an administration technique unique to the conduct of the study in the Phase 1 setting. In August 2019, we completed a second PK study in healthy volunteers in which the proper administration technique was followed. This study demonstrated significantly reduced variability, and we believe we have established comparative bioavailability to the reference listed drug.

We continued to treat patients who chose to remain on LIQ861 beyond the Month 2 timepoint of the primary endpoint. More than 80% of INSPIRE patients remained on study drug at Month 4 with no significant changes in safety or tolerability observed compared to Month 2. At the completion of the INSPIRE study, the patient with the longest duration of treatment had been on LIQ861 therapy for 18 months. To provide for continuity of treatment, patients from INSPIRE were provided the opportunity to continue receiving treatment in an extension study, which is currently ongoing. Currently, more than 70 patients have now received therapy with LIQ861 for more than two years. In addition, we are enrolling patients in a clinical study at certain investigational sites in Europe to characterize the hemodynamic dose-response relationship to LIQ861. Enrollment was paused in the second quarter 2020 due to concerns related to the COVID-19 pandemic, but has resumed in September 2020. We are also considering conducting other clinical trials to

generate additional data on LIQ861, including a clinical trial in pediatric patients. We also continue to conduct development work in support of potential approval and commercialization of LIQ861, including label and patient-use assessments.

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. Expectations related to this PDUFA date as originally set are impacted by ongoing Hatch-Waxman Litigation following a lawsuit filed by United Therapeutics Corporation on June 4, 2020. Prior to submission of the NDA in January 2020, the FDA visited our manufacturing site in June 2019 as a qualifying participant in the Emerging Technology Program sponsored by the CDER. The program supports innovation by providing a forum for sponsors to engage FDA early in development and ensures consistency, continuity, and predictability in review and inspection. The program has allowed us to discuss PRINT® technology with Emerging Technology Team members, including personnel who would be involved in the PAI and review of the Chemistry Manufacturing Controls section of the NDA to support LIQ861.

The FDA communicated in August 2020 that inspections of two domestic sites involved in the manufacturing of LIQ861 would be required before the FDA can approve our NDA for LIQ861. Due to restrictions on travel due to COVID-19, the FDA may be unable to conduct inspections of these two sites prior to the User Fee Date of November 24, 2020. We will continue to work closely with the FDA with regard to the PAIs; however, as of the date of this Quarterly Report on Form 10-Q, the FDA has not yet conducted these inspections.

With respect to LIQ865, we initiated Phase 2-enabling toxicology studies in March 2019 in both soft tissue and bone models. The soft tissue toxicology study showed favorable results; however, our bone toxicology study showed delayed bone healing at the dose tested. We have completed an additional non-GLP study to investigate bone fracture healing using the same animal model with lower doses of LIQ865. This additional non-GLP study has established a NOAEL on bone healing and provides evidence that LIQ865 could proceed into a GLP toxicology study to support Phase 2 clinical activities. Considering our focus in advancing our lead asset, LIQ861, we will seek to advance LIQ865 through a strategic collaboration with an external partner. We cannot assure you that our toxicology studies or clinical trials, if commenced, will be successful or meet their endpoints, that the endpoints for any future Phase 3 trials that we may conduct will be sufficient to receive marketing approval, or that we will be successful in entering a strategic collaboration to further advance the program.

If we successfully complete the clinical development of LIQ861 and LIQ865, we cannot assure you that they will receive marketing approval. The FDA or comparable regulatory authorities in other countries may delay, limit or deny approval of our product candidates 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, CMC (chemistry, manufacturing, and control), 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. Moreover, the applicable requirements for approval may differ from country to country.



Under the Hatch-Waxman Act, as a result of the Hatch-Waxman Litigation commenced by United Therapeutics on June 4, 2020, 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.

If we successfully obtain marketing approval for LIQ861 and LIQ865, we cannot assure you that they will be commercialized in a timely manner or successfully, or at all. For example, LIQ861 and LIQ865 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 and LIQ865 will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such products, even if approved. Any delay or setback we face in the commercialization of LIQ861 or LIQ865 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 product candidates and as a result do not have a track record of successfully bringing product candidates to market. Furthermore, LIQ861 and LIQ865 have, 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. 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 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.

***LIQ861, for which we submitted an NDA, requires regulatory review, and, subject to feedback from the FDA, may require additional clinical testing and data analysis. LIQ865, for which we have only completed Phase 1 studies, requires additional clinical testing, data analysis, and regulatory review. 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 LIQ865, or any of our product candidates 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 or LIQ865. 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, or 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. In the event we do not ultimately receive regulatory approval for LIQ861 and LIQ865, we may be required to terminate development of our only product candidates.

***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.***

We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable regulatory authorities in other countries for any product candidate, and we cannot assure you that any of our product candidates will receive marketing approval. Filing an application and obtaining marketing approval for a pharmaceutical product candidate is an extensive, lengthy, expensive and inherently uncertain process, and 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 in other countries may refuse to file an NDA or similar drug approval filing if they deem the application to be incomplete;
- the FDA or comparable regulatory authorities in other countries may disagree with the number, design, size, conduct or statistical analysis of one or more of our clinical trials;
- 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 results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable regulatory authorities in other countries;
- the data collected from our clinical trials may not be sufficient to support the submission of an NDA or similar drug approval filing to the FDA or comparable regulatory authorities in other countries;
- the FDA or comparable regulatory authorities in other countries may disagree with our interpretation of data from our preclinical studies or clinical trials;
- our manufacturing processes and facilities have not been inspected by the FDA, and the FDA or comparable regulatory authorities in other countries may not ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers sufficiently demonstrate compliance with cGMP to support NDA approval;
- our product candidates may not meet the level of quality and control required by the FDA or comparable regulatory authorities in other countries;

- our product candidates may not demonstrate sufficient long-term stability to support an NDA filing or obtain approval, or the product shelf life may be limited by stability results;
- the FDA or comparable regulatory authorities in other countries may require development of a costly and extensive risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the success or further approval of competing products approved in indications similar to those of our product candidates may change the standards for approval of our product candidates in their proposed indications; and
- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our clinical data insufficient for approval.

In addition, the FDA or comparable regulatory authorities in other countries may, in their sole discretion, change their views in respect of regulatory pathways they had previously affirmed or clinical trial protocols to which they were previously not opposed. While we have consulted with the FDA on the appropriate regulatory pathway and clinical trial protocols for our product candidates, LIQ861 and LIQ865, we cannot assure you that the FDA will not revise its position significantly at a later date. In the event that this occurs, the clinical development and commercialization of our product candidates may be delayed or even derailed.

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 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.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.***

If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon our development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Any serious adverse or undesirable side effects identified during the development of our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenue from their sale. In addition, if any of our product candidates receive regulatory approval and we or others later identify undesirable adverse effects caused by the product, we could face one or more of the following consequences:

- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication, or other safety labeling changes;
- regulatory authorities may require a REMS;
- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may seize the product;
- we may be required to change the way that the product is administered;
- we may be required to conduct additional clinical trials;
- we may be required to recall the product;
- we may be subject to litigation or product liability claims, fines, injunctions or criminal penalties; and
- our reputation may suffer.

***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.

In particular, we will be required to identify and enroll a sufficient number of patients with PAH for our clinical trials and studies of LIQ861. PAH is a rare disease with a relatively small patient population, and our enrollment of clinical trial participants may be slow as a result. Additionally, 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 and, accordingly, the DPI will be evaluated as part of our NDA filing. 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 all of our current product candidates. 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 candidates, LIQ861 and LIQ865, and have submitted a 505(b)(2) NDA for LIQ861. 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 FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, or the Orange Book, the 505(b)(2) applicant is required to make a claim after filing their 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, or 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.

We conducted the early Phase 1a clinical trial of LIQ865 in Denmark, and not under an IND, we plan to conduct an additional clinical trial in Europe that explores the hemodynamic effects of LIQ861 in PAH patients when we are able to resume enrolling patients following the end of the COVID-19 pandemic, and we may, in the future, conduct clinical trials of our product candidates outside the United States. The FDA may not accept such foreign clinical data, and in such event, we may be required to re-conduct relevant clinical trials within the United States, which would be costly and time-consuming, and which could have a material and adverse effect on our ability to carry out our business plans.



***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.

**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. If our supplier is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise default 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. Furthermore, LIQ861 is administered using the RS00 Model 8 DPI, or dry powder inhaler, which is manufactured by Plastiape S.p.A., or Plastiape, which is located in Italy. We also rely on a sole supplier for encapsulation and packaging services. We purchase treprostinil, our DPI supply and encapsulation and packaging services pursuant to purchase orders and do not have long-term contracts with these suppliers. In the event of any prolonged disruption to our supply of treprostinil, the manufacture and supply of RS00 Model 8 DPI or encapsulation and packaging services, 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, or coronavirus, was reported to have surfaced in Wuhan, China and has become a global pandemic as of the date of this Quarterly Report on Form 10-Q. The full impact of the coronavirus is unknown and rapidly evolving. 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 (or for pre-approval inspections, if required in order for FDA to obtain sufficient assurance or verification of compliance with good manufacturing practice regulations) 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.

***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 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.

***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 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 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.



***The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue, and may present risks of regulatory enforcement and litigation.***

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we do not restrict the marketing of our products only to their approved indications, we may be subject to enforcement action for off-label marketing.

The FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirement that promotional labeling be truthful and not misleading. Any claim of effectiveness made in prescription drug promotion, including comparative effectiveness, must be supported by substantial evidence or substantial clinical experience.

In addition, making comparative claims may draw concerns from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor (or that the competitor's product is inferior), this creates a risk of a lawsuit by the competitor under federal and state false advertising or unfair and deceptive trade practices law, and possibly also state libel law. Such a suit may seek injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by law.

We, and any potential collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or our collaborators obtain marketing approval. Thus, if either of our current product candidates receive marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, such as ensuring that quality control and manufacturing procedures conform to cGMP applicable to drug manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our future collaborators, licensees and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

***Our drug products may be subject to recalls, withdrawals, seizures or other enforcement actions by the FDA or comparable regulatory authorities in other countries if we fail to comply with regulatory requirements or previously unknown problems with our drug products are discovered after they reach the market.***

The FDA or comparable regulatory authorities in other countries may withdraw approval of our drug products if we fail to maintain compliance with regulatory requirements or if problems occur after our drug products reach the market. The discovery of previously unknown problems with a drug product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes or failure to comply with regulatory requirements, including the requirement to promote a drug product only for its approved indications and in accordance with the provisions of its approved label, may result in, among others:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs or comparable regulatory authorities refusing to approve any pending marketing applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of the product; or
- injunctions or the imposition of civil or criminal penalties.



In the event that our drug products are subject to recalls, withdrawals, seizures or other enforcement actions by the FDA or comparable regulatory authorities, our reputation and demand for our drug products could be materially and adversely affected. In addition, we may incur significant and unexpected expenditures and management attention may be diverted in connection with any such recall, withdrawal, seizure or other enforcement action or any corrective action required to be taken, which could have a material and adverse impact on our business and financial condition.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

**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.

***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, as the holder of such patents, asserted a patent challenge directed to the Orange Book listed patents 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, 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 it is 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. If any of our patents are narrowed or invalidated, our business and prospects may be materially and adversely affected. 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 The University of North Carolina at Chapel Hill, or UNC, under the UNC Amended and Restated License Agreement, dated as of December 15, 2008, as amended, or 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 be subject to claims that our employees or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.***

As is common in our industry, a number of our employees, including our Chief Executive Officer and a number of our executive officers, were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors, among others, and may have entered into proprietary rights, non-disclosure and non-competition agreements or similar agreements, in connection with such previous employment. Moreover, we engage the services of scientific advisers and consultants to assist us in the development of our products, many of whom were previously employed at or may have previously been or are currently providing consulting or advisory services to, other biotechnology or pharmaceutical companies, and who may have also entered into proprietary rights, non-disclosure and non-competition (or similar) agreements with such other companies.

While we require that our employees, scientific advisers and consultants do not use the proprietary information or know-how of others in their work for us, we cannot assure you that we will not be subject to claims that we or these employees, scientific advisers or consultants have inadvertently or otherwise used or disclosed the trade secrets or proprietary information of their former employers or former or present clients in their work for us, especially where such former employers or former or present clients are our competitors or potential competitors. Claims brought against us could cause us to incur unexpected and substantial costs, as well as divert our management’s attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities. Consequently, our business may be materially and adversely affected.

***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 U.S. Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or 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.



***If we fail to comply with various procedural, document submission, fee payment or other requirements imposed by the USPTO or comparable patent agencies in other countries, our patent protection could be reduced or eliminated.***

We are required, over the lifetime of an issued patent, to pay periodic maintenance fees to the USPTO and comparable patent agencies in other countries. We are also required by such patent agencies to comply with a number of procedural, documentary, fee payment and other conditions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in the partial or complete loss of patent rights in the relevant jurisdiction. Such situations include, but are not limited to:

- a failure to respond to official actions within the prescribed time limits;
- the non-payment of fees; and
- a failure to properly legalize and submit formal documents.

If we or our licensors, which control the prosecution and maintenance of patents which we license, fail to maintain the patents or patent applications covering our product candidates or technology, such rights would be reduced or eliminated and, consequently, our competitive position, business and prospects may be materially and adversely affected.

***Changes in patent laws or interpretations of patent laws in the United States or elsewhere may diminish the value of our intellectual property or narrow the scope of protection of our patents.***

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, and many of the substantive changes became effective in March 2013. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including changing the United States patent system from a “first to invent” system to a “first inventor to file” system, expanding the definition of prior art and developing a post-grant review system. The provisions under the Leahy-Smith Act changed the way patent applications are prosecuted and may also affect patent litigation. It may have also weakened our ability to obtain patent protection in the United States for applications filed after March 16, 2013.

Further, the post-grant review and *inter partes* review proceedings established under the Leahy-Smith Act have been used by certain parties to cause a cancellation of selected or all claims in relation to the issued patents of their competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than that used in civil actions in the U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in litigation in a U.S. federal court. We cannot assure you that we, our licensors or our collaborators will be successful in defending any challenge by a third party in a USPTO proceeding, or, conversely, that we, our licensors or our collaborators will be successful in challenging a third party in such a proceeding.

In addition, recent court rulings in the United States have narrowed the scope of patent protection available and weakened the rights of patent owners, particularly in the pharmaceutical industry. In 2012, the Supreme Court of the United States, or the Supreme Court, issued a decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc. invalidating patent claims directed to a process of measuring a metabolic product in a patient to optimize a drug dosage for the patient. In 2013, the Supreme Court issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc. invalidating patent claims directed to the breast cancer susceptibility genes BRCA1 and BRCA2. In 2017, the Supreme Court issued its decision in TC Heartland v. Kraft Food Group Brands, holding that patentees can only sue alleged infringers in their state of incorporation. These rulings deviated from precedents and, accordingly, have created uncertainty with regard to our ability to obtain patents in the future as well as the value of such patents, once obtained. Depending on future actions by Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would affect our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.



***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 goodwill.***

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 goodwill 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 result, we could lose all the goodwill 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 the subject of FDA manufacturing inspections, 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 and LIQ865. To our knowledge, no regulatory authority has granted approval to market or commercialize drugs made using our PRINT technology. Further, manufacturing facilities and processes utilizing our PRINT technology have not been the subject of FDA manufacturing inspections. We may never receive approval to market and commercialize any product candidate that uses our PRINT technology.

***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 current good manufacturing practices, or 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 inspection 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.

***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.***

All 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.

***We may not be able to engage third-party contract manufacturing organizations, or CMOs, to manufacture our drug products, if and when approved, on a commercial scale to meet commercial demand for our drug products.***

We may, in the future, need to rely on third-party CMOs or enter into contractual arrangements with third parties to manufacture our drug products, if and when approved, on a commercial scale. However, we cannot assure you that we will be able to contract with such third parties on acceptable terms, if at all, or that such third parties will satisfy our quality standards or meet our supply requirements in a timely manner, if at all. In addition, only a limited number of manufacturers are capable of supplying pharmaceutical products. The manufacturing process for our drug products will be highly regulated, and we will

need to contract with manufacturers that can meet the relevant regulatory requirements on an ongoing basis. If the third-party manufacturers with whom we contract fail to perform their obligations, we may not be able to meet commercial demand for our drug products, which would have a material and adverse impact on our business.

***System failures may disrupt our business operations and delay our product development programs and commercialization activities.***

Our systems, including computer systems, and those of our collaborators, contractors and consultants are vulnerable to, among others, unauthorized access, equipment failure and damage from computer viruses as well as cyber hackers. In the event of a material system failure or security breach of, or significant damage to, our systems, our business operations may be disrupted, and our product development programs and commercialization activities may be delayed. For example, failure of, or damage to, equipment leading to a loss of our clinical trial data could result in delays to the process of obtaining marketing approval for our product candidates, as well as significant and unexpected expenditure to recover or reproduce the lost data. To the extent that any disruption or damage to, or security breach of, the systems of our collaborators, contractors or consultants results in a loss of our data or applications, or the disclosure of our confidential information, our business may be adversely affected.

**Risks Related to Healthcare Regulation**

***We are subject to various laws and regulations, such as healthcare fraud and abuse laws, false claim laws and health information privacy and security laws, among others, and failure to comply with these laws and regulations 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. 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 and distribute our drug products for which we obtain marketing approval.



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:

- the federal Anti-Kickback Statute, which 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, order or recommendation of 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. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. The term “remuneration” expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including, for example, gifts, discounts, waivers of payment, ownership interest and providing anything at less than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The U.S. Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, amended the False Claims Act to provide that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which 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. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the federal government, directly or indirectly. Although we do not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or, as noted above, paying a kickback that results in a claim for items or services. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. Penalties under the False Claims Act include treble damages and per claim penalty amounts ranging from $11,665 to $23,331. The ACA further codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a per se false or fraudulent claim for purposes of the federal False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party

payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, 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;



- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose, among other things, obligations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. Following enactment of the HITECH Act, HIPAA's privacy and security standards now directly apply to business associates of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. We are not a covered entity under HIPAA but in certain situations, we may be considered a business associate. HITECH also created four new tiers of civil monetary penalties, gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. The U.S. Department of Health and Human Services Office for Civil Rights, or the OCR, has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement;

- even when HIPAA does not apply, according to the U.S. Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA. 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. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. The FTC's authority under Section 5 is concurrent with HIPAA's jurisdiction and with any action taken under state law;

- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the ACA which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Federal legislation enacted in 2018 has extended the scope of reporting requirements to apply to payments and transfers of value to not only physicians, but also physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021);

- 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, and state laws governing the privacy and security of health information and the use of prescriber-identifiable data in certain circumstances. 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 (for example, California recently enacted legislation — the CCPA, which went into effect on January 1, 2020 and among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of the sale of their information, and creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach; although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context, and final regulations are expected to be issued by the California Attorney General in 2020, and it remains unclear what language the final regulations will contain and how the legislation and regulations will be interpreted); and

- price reporting laws that require us to calculate and report 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.

Further, we are subject to a number of environmental and health and safety laws and regulations, including those governing laboratory processes and the handling, use, storage, treatment and disposal of hazardous materials and waste.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that certain business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between pharmaceutical companies and providers and patients, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that 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, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid or other government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government and the curtailment or restructuring of our operations as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

***Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.***

European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the European Union, which was formerly governed by the provisions of the European Union Data Protection Directive, was replaced with the European Union General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

***Legislative or regulatory reform of the healthcare system in our target markets may affect our operations and profitability.***

In recent years, there have been numerous initiatives on the federal and state levels in the United States for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Current and future U.S. legislative healthcare reforms may result in price controls and other restrictions for any approved products, if covered, and could seriously harm our business. Given that drug pricing controls is a key legislative and administration priority, it is likely that additional pricing controls will be enacted and could harm our business, financial condition and results of operations.

The ACA, which was signed into law in the United States in March 2010, contained several provisions affecting the pharmaceutical industry:

- the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of HHS, as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients;

- the expansion of eligibility criteria for Medicaid programs which potentially increases both the volume of sales and manufacturers' Medicaid rebate liability;

- in order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B Drug Pricing Program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer;



- the ACA imposed a requirement on manufacturers of branded drugs to provide a 70% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., the donut hole);

- the ACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- the ACA implemented the Physician Payments Sunshine Act;

- the ACA requires annual reporting of drug samples that manufacturers and distributors provide to physicians;

- the ACA expanded healthcare fraud and abuse laws in the United States, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;

- the ACA established a licensing framework for follow-on biologics; and

- the ACA established the new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with the funding for such research.

The Trump Administration and the Congressional Republicans have proposed several efforts to repeal and replace the ACA. President Trump has also signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Additionally, the ACA remains subject to pending legal and constitutional challenges in the United States Supreme Court. See California, et al v. Texas, et al, Cause No. 19-840. The Supreme Court is scheduled to hear a challenge in *California et. al. v. Texas et. al.* on November 10, 2020. This ongoing litigation challenges the ACA's minimum essential coverage provision (known as the individual mandate) and raises questions about the entire law's survival.

There is no assurance that any future replacement, modification or repeal of the ACA – were that to occur – would not adversely affect our business and financial results. The full effects of the ACA may be unknown until all outstanding legal issues are resolved, the statutory provisions are fully implemented,

and CMS, the FDA, and other federal and state agencies issue final applicable regulations or guidance. These developments could potentially alter coverage and marketing requirements, thereby affecting our pricing and market share if individuals lose coverage for certain benefits.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, federal budget proposals have included measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. The U.S. Congress and the Trump Administration have indicated that they will continue to seek new legislative and administrative measures to control drug costs, including by addressing the role of PBMs in the supply chain. Drug pricing is and will remain a key bipartisan issue in the coming year.

Additionally, for example, on July 24,2020, President Trump signed Executive Orders directing the Department of Health and Human Services (HHS) to take several steps to lower costs on prescription drugs. The Executive Orders cover a range of policies, including but not limited to (i) tying the prices paid by the U.S. government (e.g., Medicare) for drugs and biological products to prices paid in other countries; (ii) ensuring that rebates that drug makers pay to pharmacy benefit managers and insurers in the Medicare Part D program are passed directly to patients when they purchase a medication, so long as the change is not projected to increase Federal spending, Medicare beneficiary premiums or patients' total out-of-pocket costs; and (iii) allowing states, wholesalers and pharmacies to import FDA-approved drugs from Canada and other countries and sell them in the United States if the FDA deems them safe. The impact and timing of these Executive Orders, and other drug pricing initiatives released on September 24, 2020, is uncertain, as the directives contained therein would require agency rulemaking and implementation. These policy proposals, if implemented, could significantly impact the pharmaceutical industry in the United States and adversely affect our ability to generate revenues or commercialize our product candidates in the United States. Policies to be pursued in the future relative to drug pricing may be more aggressive, regardless of which party controls the White House.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The boom in state laws targeting drug pricing is unprecedented and the requirements are not uniform from state to state, creating additional compliance and commercialization challenges for manufacturers.

We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including drugs and biologics. The fate of the ACA and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.



***Healthcare laws and regulations may affect the pricing of our drug products and may affect our profitability.***

In certain countries, the government may provide healthcare at a subsidized cost to consumers and regulate prices, patient eligibility or third-party payor reimbursement policies to control the cost of drug products. Such a system may lead to inconsistent pricing of our drug products from one country to another. The availability of our drug products at lower prices in certain countries may undermine our sales in other countries where our drug products are more expensive. In addition, certain countries may set prices by reference to the prices of our drug products in other countries. Our inability to secure adequate prices in a particular country may adversely affect our ability to obtain an acceptable price for our drug products in existing and potential markets. If we are unable to obtain a price for our drug products that provides an appropriate return on our investment, our profitability may be materially and adversely affected.

**Risks 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 and clinical 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. If we are unable to attract and retain skilled personnel, including in particular Neal F. Fowler, our Chief Executive Officer, our business and prospects may be materially and adversely affected.

***Our employees and our independent contractors, principal investigators, CROs, CMOs, consultants or commercial collaborators, as well as their respective subcontractors, if any, may engage in misconduct or fail to comply with certain regulatory standards and requirements, which could expose us to liability and adversely affect our reputation.***

Our employees and our independent contractors, principal investigators, CROs, CMOs, consultants or commercial collaborators, as well as their respective subcontractors, if any, may engage in fraudulent conduct or other illegal activity, which may include intentional, reckless or negligent conduct that violates, among others, (a) FDA laws and regulations, or those of comparable regulatory authorities in other countries, including those laws that require the reporting of true, complete and accurate information to the FDA, (b) manufacturing standards, (c) healthcare fraud and abuse laws or (d) laws that require the true, complete and accurate reporting of financial information or data. For example, such persons may improperly use or misrepresent information obtained in the course of our clinical trials, create fraudulent data in our preclinical studies or clinical trials or misappropriate our drug products, which could result in regulatory sanctions being imposed on us and cause serious harm to our reputation. It is not always possible for us to identify or deter misconduct by our employees and third parties, and any precautions we may take to detect or prevent such misconduct may not be effective. Any misconduct or failure by our employees and our independent contractors, principal investigators, CROs, CMOs, consultants or commercial collaborators, as well as their respective subcontractors, if any, to comply with the applicable laws or regulations may subject us to enforcement action or otherwise expose us to liability or compliance costs, which, depending on the nature of the violation, may include but not necessarily be limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid or other

government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government and the curtailment or restructuring of our operations as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. If any action is instituted against us as a result of the alleged misconduct of our employees or other third parties, regardless of the final outcome, our reputation may be adversely affected and our business may suffer as a result. If we are unsuccessful in defending against any such action, we may also be liable to significant fines or other sanctions, which could have a material and adverse effect on us.

**Risks Related to our Common Stock**

***An active trading market for our common stock may not be sustainable. If an active trading market is not sustained, our ability to raise capital in the future may be impaired.***

We completed our initial public offering in July 2018. Prior to this time, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Capital Market, an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell shares of our common stock without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.



***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.

As of October 31, 2020, 37,752,882 shares of our common stock were outstanding, of which 33,145,870 shares of common stock, or 87.8% of our outstanding shares as of October 31, 2020, 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, or Rule 144. The resale of the remaining 4,607,012 shares held by our stockholders as of October 31, 2020 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 31, 2020, the holders of approximately 1.9 million shares, or 5.0%, of our outstanding shares as of October 31, 2020, 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 are party to an Open Market Sale Agreement℠ with Jefferies LLC, as sales agent and/or principal, pursuant to which we may offer shares of our common stock from time to time through "at-the-market" offerings. We are not obligated to make or continue to make any sale of shares of our common stock under the "at-the-market" offerings. Although any sale of securities pursuant to the "at-the-market" offerings will result in a concomitant increase in cash for each share sold, it may result in stockholder dilution and may cause our share price to fall.

***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 clinical trials of LIQ861, LIQ865 or any product candidate we may develop, or those of our competitors;
- 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 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.

***Future sales and issuances of equity securities, convertible securities or other securities could result in additional dilution of the percentage ownership of holders of our common stock.***

Our stockholders may experience dilution upon future equity issuances, including any other convertible debt or equity securities we may issue in the future, the exercise of stock options to purchase common stock granted to our employees, consultants and directors, including options to purchase common stock granted under our stock option and equity incentive plans, the issuance of common stock in settlement of previously issued awards under our stock option and equity incentive plans that may vest in the future or the issuance of common stock pursuant to our employee stock purchase plan.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell equity securities, convertible securities or other securities in one or more transactions at prices and in a manner we determine from time to time. If we sell equity securities, convertible securities or other securities, current investors may be materially diluted by such subsequent sales. We may also need our stockholders to authorize the issuance of additional shares of common stock under our amended and restated certificate of incorporation, as amended, if we do not have sufficient authorized shares to raise such additional capital or issue future awards under our incentive plan. New investors could also gain rights, preferences and privileges senior to those of holders of our existing equity securities.

***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 21.5% of our capital stock as of October 31, 2020, of which 2.9% are beneficially owned by our executive officers and directors. 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.

***If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.***

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases research coverage of us, fails to regularly publish reports on us or issues an adverse opinion about our business, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***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 2019 assessment of the effectiveness of internal control over financial reporting, or ICFR, indicate that we have multiple material weaknesses.***

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, or 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 for the fiscal year ended December 31, 2019. In connection with the assessment of the effectiveness of our ICFR, our management identified the following material weaknesses that existed as of December 31, 2019:

During 2019, 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 ICFR 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 consolidated 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 financial statements that would not be prevented or detected.

Additionally, we could be subject to regulatory scrutiny, a loss of public and investor confidence, and to litigation from investors and stockholders, all of which could have a material adverse effect on our business and the trading price of our shares. Subsequent to our December 31, 2019 year end, we began taking a number of actions, including designing and implementing new controls and revising existing controls, in order to remediate the material weaknesses described above. See Part I, Item 4. Controls and Procedures in this Quarterly Report on Form 10-Q. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could result in charges by the SEC with violating the books and records and internal control provisions of the federal securities laws which may result in penalties and fines to our company, directors and officers, and also could restrict our future access to the capital markets.

For as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to an additional four years. An independent assessment of the effectiveness of our internal controls could detect additional problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur additional remediation expenses.

***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.



***We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, we have incurred costs associated with recently adopted corporate governance requirements, including requirements of the U.S. Securities and Exchange Commission and the Nasdaq Stock Market LLC, or Nasdaq. These rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly. These rules and regulations also make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage that we received as a private company. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Board or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

When we cease to be an "emerging growth company" and when our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 of the Sarbanes-Oxley Act will correspondingly increase. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

***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 amended and restated certificate of incorporation and amended and restated 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, or the 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 amended and restated certificate of incorporation, as amended, 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 amended and restated certificate of incorporation, as amended 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 amended and restated certificate of incorporation, as amended, or our amended and restated 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 amended and restated 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 A&R LSA with PWB 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.



**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 |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated as of June 29, 2020, by and among Liquidia Technologies, Inc., RareGen, LLC, Liquidia Corporation, Gemini Merger Sub I, Inc., Gemini Merger Sub II, LLC and PBM RG Holdings, LLC (incorporated herein by reference to Exhibit 2.1 to Liquidia Corporation's Registration Statement on Form S-4, filed with the SEC on August 5, 2020). |
| 2.2 | Limited Waiver and Modification to Agreement and Plan of Merger, dated as of August 3, 2020, by and among Liquidia Technologies, Inc., RareGen, LLC, Liquidia Corporation, Gemini Merger Sub I, Inc., Gemini Merger Sub II, LLC and PBM RG Holdings, LLC (incorporated herein by reference to Exhibit 2.2 to Liquidia Corporation's Registration Statement on Form S-4, filed with the SEC on August 5, 2020). |
| 10.1 | Joinder and Second Amendment to Amended and Restated Loan and Security Agreement, effective as of July 3, 2020, by and among Liquidia Corporation, Gemini Merger Sub I, Inc., Gemini Merger Sub II, LLC, Liquidia Technologies, Inc. and Pacific Western Bank (incorporated herein by reference to Exhibit 10.17 to Liquidia Corporation's Registration Statement on Form S-4, filed with the SEC on August 5, 2020). |
| 10.2 | Consulting Agreement, dated as of August 20, 2020, by and between Liquidia Technologies, Inc. and Arktoros, LLC (incorporated herein by reference to Exhibit 10.1 to Liquidia Technologies, Inc.'s Current Report on Form 8-K, filed with the SEC on August 20, 2020). |
| 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 Technologies, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in Inline eXtensible Business Reporting Language (iXBRL) filed electronically herewith: (i) Consolidated Balance Sheets as of September 30, 2020 (unaudited) and December 31, 2019, (ii) Consolidated Statements of Operations and Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2020 and 2019, (iii) Consolidated Statements of Stockholders' Equity (unaudited) for the three and nine months ended September 30, 2020 and 2019, (iv) Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2020 and 2019 and (v) Notes to 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 6, 2020

**LIQUIDIA TECHNOLOGIES, INC.**
By: /s/ Neal F. Fowler
Neal F. Fowler
Chief Executive Officer

DATE: November 6, 2020

**LIQUIDIA TECHNOLOGIES, INC.**
By: /s/ Steven Bariahtaris
Steven Bariahtaris
Interim Chief Financial Officer

**Exhibit 31.1**

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

I, Neal F. Fowler, certify that:

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

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 15(d)-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 6, 2020

By: /s/ Neal F. Fowler
Name: Neal F. Fowler
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, Steven Bariahtaris, certify that:

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

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 15(d)-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 6, 2020

By: /s/ Steven Bariahtaris
Name: Steven Bariahtaris
Title: Interim 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 Technologies, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the three months ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neal F. Fowler, 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 6, 2020

By: /s/ Neal F. Fowler
Name: Neal F. Fowler
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 Technologies, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the three months ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven Bariahtaris, Interim 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 6, 2020

By: /s/ Steven Bariahtaris
Name: Steven Bariahtaris
Title: Interim Chief Financial Officer
(Principal Financial Officer)