# 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 quarterly period ended June 30, 2019**

**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) |

**(919) 328-4400**

(Registrant's Telephone Number, Including Area Code)

(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 | LQDA | Nasdaq Capital Market |

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 and post 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 Exchange Act). ☐ Yes ☒ No

As of August 7, 2019, there were 18,643,442 shares of the issuer's common stock outstanding.

## TABLE OF CONTENTS



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

## CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

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

- 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 the initial public offering and follow-on offering 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 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. 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.

**Liquidia Technologies, Inc.**
**Balance Sheets (Unaudited)**

| | June 30, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 52,120,735 | $ 39,534,985 |
| Accounts receivable | 604,026 | 272,557 |
| Prepaid expenses and other current assets | 323,405 | 219,057 |
| Total current assets | 53,048,166 | 40,026,599 |
| Property, plant and equipment, net | 8,040,739 | 8,130,708 |
| Operating lease right-of-use assets, net | 3,244,195 | — |
| Prepaid expenses and other assets | 378,042 | 1,260,951 |
| Total assets | $ 64,711,142 | $ 49,418,258 |
| **Liabilities and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,099,841 | $ 3,235,949 |
| Accrued expenses | 2,115,913 | 1,459,182 |
| Accrued compensation | 1,720,202 | 2,515,519 |
| Deferred rent | — | 268,599 |
| Current portion of operating lease liabilities | 521,378 | — |
| Current portion of finance lease liabilities | 1,000,578 | 452,703 |
| Current portion of long-term debt | 2,835,583 | 316,906 |
| Total current liabilities | 12,293,495 | 8,248,858 |
| Long-term operating lease liabilities | 5,964,280 | — |
| Long-term finance lease liabilities | 1,355,586 | 376,082 |
| Long-term deferred rent | — | 2,406,084 |
| Long-term deferred revenue | — | 8,071,920 |
| Long-term debt | 13,004,581 | 11,627,643 |
| Total liabilities | 32,617,942 | 30,730,587 |
| Commitments and contingencies (Note 8) | | |
| Stockholders' equity: | | |
| Common stock — $0.001 par value, 40,000,000 shares authorized as of June 30, 2019 and December 31, 2018, 18,643,442 and 15,519,469 issued and outstanding as of June 30, 2019 and December 31, 2018, respectively | 18,643 | 15,520 |
| Additional paid-in capital | 219,398,506 | 185,726,048 |
| Accumulated deficit | (187,323,949) | (167,053,897) |
| Total stockholders' equity | 32,093,200 | 18,687,671 |
| Total liabilities and stockholders' equity | $ 64,711,142 | $ 49,418,258 |

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Revenues | $ 8,072,120 | $ 1,042,879 | $ 8,072,120 | $ 1,968,849 |
| Costs and expenses: | | | | |
| Cost of sales | 807,192 | 94,342 | 807,192 | 121,391 |
| Research and development | 10,723,591 | 5,917,702 | 21,387,894 | 13,544,404 |
| General and administrative | 2,408,651 | 1,991,231 | 5,430,233 | 4,140,956 |
| Total costs and expenses | 13,939,434 | 8,003,275 | 27,625,319 | 17,806,751 |
| Loss from operations | (5,867,314) | (6,960,396) | (19,553,199) | (15,837,902) |
| Other income (expense): | | | | |
| Interest income | 219,869 | 11,846 | 357,654 | 11,846 |
| Interest expense | (253,720) | (245,711) | (472,410) | (18,122,505) |
| Derivative and warrant fair value adjustments | — | 925,337 | — | 171,450 |
| Total other income (expense), net | (33,851) | 691,472 | (114,756) | (17,939,209) |
| Net loss | (5,901,165) | (6,268,924) | (19,667,955) | (33,777,111) |
| Other comprehensive loss | — | — | — | — |
| Comprehensive loss | $ (5,901,165) | $ (6,268,924) | $ (19,667,955) | $ (33,777,111) |
| Net loss per common share: | | | | |
| Basic | $ (0.31) | $ (9.86) | $ (1.13) | $ (53.79) |
| Diluted | (0.32) | (9.86) | (1.14) | (53.79) |
| Weighted average common shares outstanding: | | | | |
| Basic | 18,749,239 | 636,063 | 17,408,667 | 627,938 |
| Diluted | 18,642,965 | 636,063 | 17,283,064 | 627,938 |

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

**Liquidia Technologies, Inc.**
**Statement of Stockholders' Equity (Deficit)**
**For the Three and Six Months Ended June 30, 2019**
**(Unaudited)**

| | Preferred Stock | | | | | | | | | | | | Common Stock | | | | Additional | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Series A | | Series A-1 | | Series B | | Series C | | Series C-1 | | Series D | | Voting | | Class B Nonvoting | | Paid-In | Accumulated | Stockholders' |
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Deficit | 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 | — | — | — | — | — | — | — | — | — | — | — | — | 3,000,000 | 3,000 | — | — | 32,427,000 | — | 32,430,000 |
| Public offering financing costs | — | — | — | — | — | — | — | — | — | — | — | — | | — | — | — | (382,424) | — | (382,424) |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | (13,766,789) | (13,766,789) |
| **Balance as of March 31, 2019** | — | $ — | — | $ — | — | $ — | — | $ — | — | $ — | — | $ — | **18,637,012** | **$18,637** | — | $ — | **$218,721,394** | **$(181,422,784)** | **$ 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** | — | $ — | **$219,398,506** | **$(187,323,949)** | **$ 32,093,200** |

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

**Liquidia Technologies, Inc.**
**Statement of Stockholders' Equity (Deficit)**
**For the Three and Six Months Ended June 30, 2018**
**(Unaudited)**

| | Preferred Stock | | | | | | | | | | | | Common Stock | | | | Additional | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Series A | | Series A-1 | | Series B | | Series C | | Series C-1 | | Series D | | Voting | | Class B Nonvoting | | Paid-In | Accumulated | Stockholders' Equity |
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Deficit | (Deficit) |
| **Balance as of December 31, 2017** | **1,974,430** | **$ 1,974** | **1,834,862** | **$ 1,835** | **4,496,908** | **$ 4,497** | **17,102,578** | **$17,103** | **17,556,178** | **$17,556** | **—** | **$ —** | **549,952** | **$ 550** | **19,645** | **$ 20** | **$ 79,677,540** | **$ (113,413,311)** | **$ (33,692,236)** |
| Cumulative adjustment - adoption of ASC 606 | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | (504,727) | (504,727) |
| Exercise of common stock options | — | — | — | — | — | — | — | — | — | — | — | — | 51,543 | 52 | — | — | 152,352 | — | 152,404 |
| Stock-based compensation | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | 341,314 | — | 341,314 |
| Issuance of Series D preferred stock, net | — | — | — | — | — | — | — | — | — | — | 91,147,482 | 91,147 | — | — | — | — | 53,893,361 | — | 53,984,508 |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | (27,508,187) | (27,508,187) |
| **Balance as of March 31, 2018** | **1,974,430** | **$ 1,974** | **1,834,862** | **$ 1,835** | **4,496,908** | **$ 4,497** | **17,102,578** | **$17,103** | **17,556,178** | **$17,556** | **91,147,482** | **$91,147** | **601,495** | **$ 602** | **19,645** | **$ 20** | **$134,064,567** | **$(141,426,225)** | **$ (7,226,924)** |
| Exercise of common stock options | — | — | — | — | — | — | — | — | — | — | — | — | 26,635 | 26 | — | — | 62,378 | — | 62,404 |
| Stock-based compensation | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | 519,835 | — | 519,835 |
| Net loss | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | — | (6,268,924) | (6,268,924) |
| **Balance as of June 30, 2018** | **1,974,430** | **$ 1,974** | **1,834,862** | **$ 1,835** | **4,496,908** | **$ 4,497** | **17,102,578** | **$17,103** | **17,556,178** | **$17,556** | **91,147,482** | **$91,147** | **628,130** | **$ 628** | **19,645** | **$ 20** | **$134,646,780** | **$(147,695,149)** | **$ (12,913,609)** |

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2019** | **2018** |
| **Operating activities** | | |
| Net loss | $ (19,667,955) | $ (33,777,111) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 1,708,792 | 861,149 |
| Depreciation and amortization | 1,227,265 | 725,934 |
| Amortization of discount on long-term debt and convertible notes | — | 17,550,541 |
| Non-cash interest expense | 28,595 | 269,938 |
| Warrant fair value adjustment | — | (171,450) |
| Non-cash rent (income) expense | — | (102,930) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 261,117 | 1,548,288 |
| Prepaid expenses and other current assets | (104,348) | (75,805) |
| Other non-current assets | 1,437,416 | 93,913 |
| Accounts payable | 1,014,353 | (1,281,510) |
| Accrued expenses | 692,129 | (1,326,639) |
| Accrued compensation | (795,317) | (345,589) |
| Deferred revenue | (8,071,920) | (1,190,444) |
| Net cash used in operating activities | (22,269,873) | (17,221,715) |
| **Investing activities** | | |
| Purchases of property, plant and equipment | (1,080,236) | (629,979) |
| Net cash used in investing activities | (1,080,236) | (629,979) |
| **Financing activities** | | |
| Principal payments on finance leases | (476,423) | (328,109) |
| Proceeds from issuance of long-term debt | 5,000,000 | — |
| Refund of principal payments on long-term debt | — | 588,889 |
| Principal payments on long-term debt | — | (1,000,196) |
| Payments for debt issuance costs | — | (392,000) |
| Proceeds from issuance of Series D preferred stock, net of issuance costs | — | 25,107,009 |
| Proceeds from public offering of common stock, net of underwriting fees and commissions | 31,872,808 | — |
| Payments for offering costs | (554,507) | (525,859) |
| Proceeds from exercise of stock options and warrants | 93,981 | 215,050 |
| Net cash provided by financing activities | 35,935,859 | 23,664,784 |
| Net increase (decrease) in cash | 12,585,750 | 5,813,090 |
| Cash, beginning of period | 39,534,985 | 3,418,979 |
| Cash, end of period | $ 52,120,735 | $ 9,232,069 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 443,816 | $ 302,027 |
| Purchase of equipment with leases | $ — | $ 413,237 |
| Changes in purchases of equipment in accounts payable | $ 150,461 | $ 99,197 |
| Purchase of build-to-suit asset with deferred financing obligation | $ — | $ 272,656 |
| Reclassification of deferred financing obligation to long-term debt | $ — | $ 1,614,466 |
| Reclassification of financing costs on deferred financing obligation to discount on long-term debt | $ — | $ 277,009 |
| Accrued tenant improvements and receivable from landlord | $ 592,586 | $ — |
| Conversion of accrued interest to long-term debt | $ — | $ 106,558 |
| Conversion of convertible notes and accrued interest into Series D preferred stock | $ — | $ 28,877,498 |
| Deferred offering costs incurred but not paid | $ — | $ 849,740 |
| Exercise of stock options through exchange of vested stock options | $ — | $ 128,529 |

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

**Liquidia Technologies, Inc.**
**Notes to Financial Statements (Unaudited)**

## 1. Organization and Description of the Business

Liquidia Technologies, Inc. ("Liquidia" or the "Company") is a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using 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 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.

## 2. Significant Accounting Policies

### Basis of Presentation

The unaudited interim financial statements as of June 30, 2019 and for the three and six months ended June 30, 2019 and 2018 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting. These 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 balance sheets, operating results and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Operating results for the three and six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019. 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 financial statements and related notes should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2018, which are included in the Company's Form 10-K (File No. 001-38601).

With the exception of accounting for leases, there have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2019, as compared to the significant accounting policies disclosed in Note 2 of the financial statements for the years ended December 31, 2018 and 2017.

### Variable Interest Entities

The Company identifies entities (i) that do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (ii) in which the equity investors lack an essential characteristic of a controlling financial interest as variable interest entities ("VIE" or "VIEs"). The Company performs an initial and ongoing evaluation of the entities with which the Company has variable interests to determine if any of these entities are VIEs. If an entity is identified as a VIE, the Company performs an assessment to determine whether the Company has both (i) the power to direct activities that most significantly impact the VIE's economic performance and (ii) the obligation to absorb losses from or the right to receive benefits of the VIE that could potentially be significant to the VIE. If both of these criteria are satisfied, the Company is identified as the primary beneficiary of the VIE and the entity must be consolidated. As of June 30, 2019 and December 31, 2018, the Company determined that Envisia Therapeutics Inc. ("Envisia") was a VIE, although the Company does not consolidate it as the Company is not the primary beneficiary for Envisia. Envisia is accounted for under the equity method. There have been no activities between Envisia and the Company in the six months ended June 30, 2019 or during the year ended December 31, 2018.

**Going Concern**

The Company's 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 closed its initial public offering ("IPO") in July and August 2018 resulting in total net proceeds of $47.3 million, after underwriting discounts and other offering expenses. The Company also closed a follow-on public offering in March 2019 resulting in total net proceeds of $31.9 million, after underwriting discounts and other offering expenses.

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 maturing within twelve months. 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 circumstances raise substantial doubt about the Company's ability to continue as a going concern. Management's plans with regard to this matter include continuing attempts to obtain additional financing to sustain its operations. However, there is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company, and the failure of the Company to obtain sufficient funds on acceptable terms, when needed, could have a material adverse effect on the Company's business, results of operations and financial condition. If sufficient financings are not obtained, this may necessitate other actions by the Company. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**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 revenues and expenses during the reporting period. Actual amounts could differ from those estimates.

**Cash**

The Company considers all highly liquid investments with a maturity of three months or less, when purchased, to be cash equivalents. The Company had no cash equivalents as of June 30, 2019 and December 31, 2018.

**Accounts Receivable**

Accounts receivable are stated at historical cost less an allowance for doubtful accounts as of each Balance Sheet date. The Company does not accrue interest on trade receivables. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write offs and the current status of all receivables. The Company writes off customer receivables when it becomes apparent, based upon customer facts and circumstances, that such amounts will not be collected.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and accounts receivable. 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 Balance Sheet. With regards to cash, 100% of the Company's cash is held on deposit with Pacific Western Bank. With regards to revenues and accounts receivable, GlaxoSmithKline plc ("GSK" and "GSK Inhaled") accounted for 100% and 0% of the Company's revenues for the three months ended June 30, 2019 and 2018, respectively, and 100% and 22% of the Company's revenues for the six months ended June 30, 2019 and 2018, respectively, and $0 and $0 of the Company's accounts receivable as of June 30, 2019 and December 31, 2018, respectively.

**Leases**

In February 2016, the FASB issued ASU 2016-02, *Leases*, as amended *(Topic 842)* ("ASU 2016-02"). The provisions of ASU 2016-02 set out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. The Company has elected to account for leases with a term of 12 months or less in a similar manner as under existing guidance for operating leases. ASU 2016-02 supersedes the previous lease standard, Topic 840, *Leases*. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2018. The Company adopted Topic 842, as amended, as of January 1, 2019, using the modified retrospective approach. The modified retrospective approach provides a method for recording existing leases at adoption that approximates the results of a full retrospective approach in the year of adoption. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification. Adoption of the new standard resulted in the recording of net lease assets and lease liabilities of approximately $6.4 million and $9.1 million respectively, as of January 1, 2019. The standard had no impact on cash flows. For operating leases, the asset and liability will be expensed over the lease term on a straight-line basis, with all cash flows classified as an operating activity in the Statement of Cash Flows. For finance leases, interest on the lease liability will be recognized separately from the amortization of the right-of-use asset in the Statement of Operations and the repayment of the principal portion of the lease liability will be classified as a financing activity, while the interest component will be classified as an operating activity in the Statement of Cash Flows.

The net impact of applying Topic 842 was recorded as an adjustment to accumulated deficit of $0.6 million as follows:

| | Balance at December 31, 2018 | Adjustments Due to Topic 842 | Balance at January 1, 2019 |
|---|---|---|---|
| **Balance Sheet:** | | | |
| **Assets** | | | |
| Property, plant and equipment, net | $ 8,130,708 | $ (107,734) | $ 8,022,974 |
| Operating lease right-of-use assets, net | — | 3,985,071 | 3,985,071 |
| | | | |
| **Liabilities** | | | |
| Deferred rent | 2,674,683 | (2,674,683) | — |
| Operating lease liabilities | — | 6,659,725 | 6,659,725 |
| Finance lease liabilities | 828,785 | 1,636,185 | 2,464,970 |
| Long-term debt | 11,944,549 | (1,141,792) | 10,802,757 |
| | | | |
| **Stockholders' equity (deficit)** | | | |
| Accumulated deficit | (167,053,897) | (602,098) | (167,655,995) |

**Revenue Recognition**

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASC 606" or "Topic 606"). The FASB issued Topic 606 to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP. The standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. Topic 606 also includes Subtopic 340-40, *Other Assets and Deferred Costs – Contracts with Customers*, which requires the deferral of incremental costs of obtaining a contract with a customer and certain contract fulfillment costs. The Company adopted this standard and all the related amendments ("new revenue standard") on January 1, 2018, applying the modified retrospective method. The modified retrospective transition method is applied on

a prospective basis from the adoption date and does not recast historical financial statement periods. Any contracts with customers that were not complete as of the adoption date are reviewed and the Company recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of accumulated deficit as of January 1, 2018.

This adoption primarily affected the recognition of non-refundable up-front fees and milestone payments. The Company previously recognized non-refundable up-front fees as deferred revenue which was recognized into revenue on a straight-line basis over the estimated period of the Company's substantive performance obligations, as a component of a multiple element arrangement. Milestone payments were previously accounted for under Accounting Standards Codification ("ASC") 605-28-50-2(e), which had required recognition of a milestone payment when the applicable event was considered to be both substantive and achieved. The adoption of the new revenue standard generally requires licenses that are not considered distinct performance obligations from other goods or services within a contract to be bundled with those goods or services as a combined performance obligation. Revenue associated with the combined performance obligation is recognized over time as those goods or services are delivered.

The adoption of the new revenue standard also impacted the deferral of sublicense payments related to the milestone payments, which were previously expensed when the milestone payments were recognized, and the timing of recognition of deferred sublicense payments related to up-front license payments. Under the new revenue standard, the incremental sublicense payments related to milestone payments will be deferred as contract fulfillment costs and amortized over time, consistent with the method of recognition for the related revenues.

**Segment Data**

In accordance with ASC 280-10-50, *Segment Reporting*, operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company operates in one reportable segment.

Segment information by asset is not disclosed as it is not reviewed by the Chief Operating Decision Maker or used to allocate resources or to assess the Company's operating results and financial performance. All long-lived assets are domiciled within the United States and all revenues were earned within the United States.

**Research and Development Expense**

Research and development costs are expensed as incurred and include direct costs incurred to third parties related to the salaries of, and stock-based compensation for, personnel involved in research and development activities, contractor fees, grant expenses, administrative expenses and allocations of research-related overhead costs. Administrative expenses and research-related overhead costs included in research and development expense consist of allocations of facility and equipment lease charges, depreciation and amortization of assets and insurance directly related to research and development activities.

**Patent Maintenance**

The Company is responsible for all patent costs, past and future, associated with the preparation, filing, prosecution, issuance, maintenance, enforcement and defense of United States patent applications. Such costs are recorded as general and administrative expenses as incurred. To the extent that the Company's licensees share these costs, such benefit is recorded as a reduction of the related expenses.

**Stock-Based Compensation**

The Company accounts for stock-based compensation under the provisions of ASC 718, *Compensation — Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors, including employee stock options, based on estimated fair values. ASC 718 requires companies to estimate the fair value of share-based awards on the grant date using an option-

pricing model. The value of the portion of the award that is ultimately expected to vest is recorded as expense over the requisite service periods in the Company's Statements of Operations and Comprehensive Loss.

The Company accounts for equity instruments issued to nonemployees in accordance with the provisions of ASC 505 50, *Equity-Based Payments to Non-Employees*, under which the stock-based compensation expense is recognized in the financial statements based on their grant date fair values. The Company values equity instruments, stock options and warrants for common stock granted to lenders and consultants using the Black-Scholes option-pricing model. The measurement of non-employee stock-based compensation is recognized as an expense over the term of the related financing or the period over which services are received.

On May 8, 2019, the Company's stockholders approved the Liquidia Technologies, Inc. 2019 Employee Stock Purchase Plan (the "ESPP"). A total of 300,000 shares of the Company's common stock have been 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 commencing on September 1, 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.

**Net Loss Per Share**

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period.

Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares adjusted for the dilutive effect of common equivalent shares outstanding during the period. Common stock equivalents consist of preferred stock, stock options and stock warrants. Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's convertible preferred stock contains participating rights in any dividend paid by the Company and are deemed to be participating securities. Net loss attributable to common stockholders and participating preferred shares are allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in the losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss. Common equivalent shares are excluded from the computation in periods in which they have an anti-dilutive effect on net loss per share.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Due to their anti-dilutive effect, the calculation of diluted net loss per share for the three and six months ended June 30, 2019 and 2018 does not include the following common stock equivalent shares:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Preferred Stock | — | 9,948,207 | — | 9,948,207 |
| Stock Options | 1,994,137 | 1,377,278 | 1,994,137 | 1,377,278 |
| Warrants | 106,274 | 219,761 | 106,274 | 219,761 |
| Total | 2,100,411 | 11,545,246 | 2,100,411 | 11,545,246 |

For the three and six months ended June 30, 2019 the only reconciling item between basic and diluted net loss per share is the impact of the common stock warrants that are included in the calculation of basic net loss per share since their exercise price is de minimis, but excluded from the calculation of diluted net loss per share since the impact of such

warrants is antidilutive. For all periods presented, there were no other reconciling items between basic and diluted net loss per share.

**Fair Value of Financial Instruments**

The carrying values of cash, accounts receivable, and accounts payable at June 30, 2019 and December 31, 2018 approximated 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 June 30, 2019 and December 31, 2018:

| June 30, 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 | $ — | $ 15,757,500 | $ — | $ 15,840,164 |

| December 31, 2018 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Carrying Value |
|---|---|---|---|---|
| Pacific Western Bank Tranche I note - A&R LSA | $ — | $ 10,412,650 | $ — | $ 10,802,355 |
| CSC build-to-suit equipment financing | — | 1,311,135 | — | 1,142,194 |
| Total | $ — | $ 11,723,785 | $ — | $ 11,944,549 |

The fair value of debt was measured as the present value of the respective future cash outflows discounted at a current interest rate as of the end of the reporting period, taking into account the remaining term of liabilities.

**Deferred Offering Costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such equity financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. As of June 30, 2019 and December 31, 2018, the Company recorded deferred offering costs relating to its financing activities of $0 and $110,365, respectively, which is included in Prepaid Expenses and Other Assets in the accompanying Balance Sheets.

**Income Taxes**

The Company did not record a federal or state income tax benefit for the three and six months ended June 30, 2019 and 2018, as a result of the establishment of a full valuation allowance being required against the Company's net deferred tax assets.

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was enacted into law. This new law 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 revenues 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.

**Recent Accounting Pronouncements**

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10) — Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). The provisions of ASU 2016-01 make targeted improvements to enhance the reporting model for financial instruments to provide users of financial statements with more useful information, including certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The guidance was effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2017, and will be effective for the Company for the year ended December 31, 2018. The Company adopted this standard effective January 1, 2018 and the adoption of this standard did not have a material impact on the Company's financial statements.

In June 2016, the FASB issued new accounting guidance that significantly changes how companies will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. The guidance is effective for annual and interim periods beginning after December 15, 2019. Early adoption is permitted for annual reporting periods beginning after December 15, 2018 and must be adopted using a cumulative effect adjustment to accumulated deficit. The adoption of this new accounting guidance is not expected to have a material effect on the Company's financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) — Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). The provisions of ASU 2016-15 address eight specific cash flow issues and how those certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, *Statement of Cash Flows*, and other Topics. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018 and the adoption of this standard did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation* (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018 and the adoption of this standard did not have a material impact on the Company's financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share* (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this update addresses the complexity of accounting for certain financial instruments with "down round" features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and

complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, *Distinguishing Liabilities from Equity*, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company adopted this standard effective January 1, 2019 and the adoption of this standard did not have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)* ("ASU 2018-13"). The provisions of ASU 2018-13 set out modifications to the disclosure requirements regarding fair value measurements. The modifications removed certain disclosure requirements regarding transfers between levels of the fair value hierarchy and valuation processes for Level 3 fair value measurements. In addition, the modifications added requirements to disclose changes in unrealized gains and losses for recurring Level 3 fair value measurements and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The guidance is effective for public companies with annual periods and interim periods within those annual periods beginning after December 15, 2019, and will be effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's financial statements.

In October 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 ("ASU 2018-17"). 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, and is effective for the Company for the year ending December 31, 2020. The Company is currently evaluating the impact that the implementation of this standard will have on the Company's financial statements.

**3. Common and Preferred Stock**

**Authorized Capital**

As of June 30, 2019, the authorized capital of the Company consists of 50,000,000 shares of capital stock, $0.001 par value per share, of which 40,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock.

As of June 30, 2019, the Company had reserved a total of 409,268 shares of common stock for issuance under the Liquidia Technologies, Inc. Stock Option Plan, as amended (the "2004 Plan"), 786,097 shares of common stock for issuance under the Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended (the "2016 Plan"), and 2,220,779 shares of common stock for issuance under the Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan (the "2018 Plan"). On January 1, 2019, the number of shares of common stock available for issuance under the 2018 Plan automatically increased from 1,600,000 to 2,220,778 pursuant to the evergreen provision contained in the 2018 Plan.

During 2017, the Company issued an aggregate of $27.4 million in principal of convertible promissory notes (see Note 9). The convertible notes had an original maturity date of December 31, 2018, as amended, and bore interest at eight percent (8%) per annum. Interest was earned daily and computed on the actual number of days elapsed until all the amounts under the notes have been paid in full. The convertible notes carried multiple conversion scenarios into equity with various discounts.

In February 2018, the Company received proceeds of $25.6 million in exchange for the corresponding sale of Series D and related rights offering to new and existing investors. The applicable issue price per share for the Series D was $0.59808, subject to adjustment as provided in the certificate of incorporation. In addition, all outstanding convertible notes, plus accrued interest, totaling $28.9 million were converted into Series D at the same price per share without a discount. Outstanding warrants to purchase shares of Series C-1 preferred stock, $0.001 par value per share ("Series C-

1"), were converted to warrants to purchase the equivalent number of shares of Series D. All references herein to these warrants refer to them as warrants to purchase Series D. In total, 91,147,482 shares of Series D were issued. Each share of Series D was convertible at any time into a share of common stock with such conversion ratio subject to future adjustment. Conversion was automatic upon a qualified financing, as defined in the certificate of incorporation. The Series D was senior to all other series of preferred stock.

In the third quarter of 2018, the Company closed the IPO of 4,833,099 shares of common stock, including the underwriters' partial exercise of their over-allotment option in connection therewith, which resulted in aggregate net proceeds of $47.3 million, after underwriting discounts and the payment of other offering expenses. In conjunction with the Company's IPO, all outstanding shares of convertible preferred stock were converted into an aggregate of 9,948,207 shares of common stock.

On March 25, 2019, the Company closed an underwritten follow-on 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 $31.9 million, after deducting underwriting discounts and commissions and other offering expenses.

**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.

The Class B non-voting common stock, $0.001 par value per share, was converted into shares of voting common stock in conjunction with the Company's IPO in the third quarter of 2018.

**Warrants**

Pursuant to the terms of the warrants, upon the conversion of the preferred stock underlying the warrant into common stock, the warrants automatically become exercisable for common stock based upon the conversion ratio of the underlying preferred stock.

Upon closing of the Series D financing, the Company had warrants outstanding to purchase 3,698,128 shares of Series D. In conjunction with the IPO in the third quarter of 2018, these warrants were automatically converted into warrants to purchase 219,761 shares of common stock. During the three months ended March 31, 2019, 64,629 shares of common stock underlying warrants were exercised. As of June 30, 2019 an aggregate of 106,274 shares of common stock underlying warrants were exercisable, each with an exercise price of $0.0168 per share.

**4. Stock Options**

In November 2004, the Board of Directors adopted, and the stockholders approved, the 2004 Plan to create an additional incentive for employees, directors, consultants and advisors. The 2004 Plan authorized the issuance of stock options to be granted as incentive stock options along with nonqualified stock options, restricted stock and other stock-based awards. The Board of Directors determines the exercise price of all options granted. The options vest based on terms provided for in the individual stock option agreements issued pursuant to the 2004 Plan. Options generally vest on a monthly basis over a period of up to 4 years and have a contractual life of ten years. The 2016 Plan is the successor to the 2004 Plan. The terms of the 2016 Plan are similar to the 2004 Plan. The 2016 Plan provides for accelerated vesting under certain change of control transactions.

On July 19, 2018, in conjunction with the Company's IPO, the stockholders approved the 2018 Plan. A total of 1,600,000 shares of the Company's common stock was initially authorized and reserved for issuance under the 2018 Plan. On January 1, 2019, the number of shares of common stock available for issuance under the 2018 Plan automatically increased from 1,600,000 to 2,220,778 pursuant to the evergreen provision contained in 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. 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. The 2018 Plan provides for accelerated vesting under certain change of control transactions.

Determining the appropriate fair value model and the related assumptions requires judgment. The fair value of each option grant is estimated using a Black-Scholes option pricing model. The following table summarizes the assumptions used for estimating the fair value of stock options granted during:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Expected dividend yield | — % | — % | — % | — % |
| Risk-free interest rate | 1.85% - 2.41 % | 2.67% - 2.86 % | 1.85% - 2.54 % | 2.67% - 2.86 % |
| Volatility | 83% - 84 % | 78% - 79 % | 83% - 84 % | 78% - 79 % |
| Expected life | 6.07 years | 6.25 years | 6.08 years | 6.25 years |
| Weighted-average fair value per share | $ 7.04 | $ 7.56 | $ 9.07 | $ 7.56 |

The following table summarizes stock option activity under the 2004 Plan, the 2016 Plan, and the 2018 Plan:

| | Shares Available for Issuance | Options Outstanding | Weighted Average Exercise Price |
|---|---|---|---|
| **Outstanding at December 31, 2018** | 1,193,329 | 1,658,112 | $ 8.76 |
| Shares reserved for future issuance for 2018 Plan | 620,779 | — | |
| Options granted | (580,658) | 580,658 | $ 12.89 |
| Exercised | — | (22,125) | $ 4.22 |
| Cancelled/expired from 2004 Plan | — | — | $ — |
| Cancelled/expired from 2016 Plan | — | (129,234) | $ 9.30 |
| Cancelled/expired from 2018 Plan | 140,228 | (93,274) | $ 14.01 |
| **Outstanding at June 30, 2019** | 1,373,678 | 1,994,137 | $ 9.73 |

The following summarizes certain information about stock options vested and expected to vest as of June 30, 2019:

| | Number of Options | Weighted Average Remaining Contractual Life (In Years) | Weighted Average Exercise Price |
|---|---|---|---|
| Outstanding and expected to vest | 1,739,510 | 8.04 | $ 9.45 |
| Vested and exercisable | 675,734 | 6.30 | $ 6.51 |

The weighted-average grant date price per share was $12.89 and $9.41 per share for the shares issued during the six months ended June 30, 2019 and 2018, respectively.

During the three months ended March 31, 2019, 15,695 stock options were exercised for the purchase of common stock for total cash proceeds of $63,152. The intrinsic value for the options exercised was $223,989.

During the three months ended June 30, 2019, 6,430 stock options were exercised for the purchase of common stock for total cash proceeds of $30,117. The intrinsic value for the options exercised was $23,923.

As of June 30, 2019, the intrinsic value of options outstanding and exercisable was $1,613,522. The weighted average remaining contractual term of options outstanding and exercisable is 8.20 years as of June 30, 2019.

During the six months ended June 30, 2019 and 2018, stock-based compensation expense for employee stock option awards totaled $1,708,792 and $861,149, respectively. As of June 30, 2019, there was $9,646,071 of total unrecognized compensation cost related to non-vested stock option grants, which is expected to be recognized over a weighted average period of 3.04 years.

In March 2018, the Board of Directors approved a grant of 127,576 non-performance based restricted stock units ("RSUs") under the 2016 Plan. The weighted average fair value of such RSUs was $9.31 per share for the six months ended June 30, 2019. RSUs represent the right to receive shares of common stock of the Company at the end of a specified time period. The RSUs were to vest over a four-year period similar to stock options. RSUs can only be settled in shares of the Company's common stock. RSUs are valued at the date of grant and recognized in compensation expense over the vesting period.

**Stock Option Modifications**

In March 2019 certain stock options and RSUs were modified pursuant to a consulting agreement with the Company's former President and CFO in addition to a retention agreement with the Interim CFO. A total of 127,576 stock options had their vesting period extended to include the one-month term of the post-separation consulting agreement through March 31, 2019. Additionally, 2,658 additional RSUs held by the Company's former President and CFO vested in March 2019. Furthermore, a total of 30,545 shares of common stock underlying options were modified for possible acceleration of vesting during the following six months as compared to the remaining vesting period of approximately 12 months. The combined result of these modifications was additional stock option expense of $30,566 for the six months ended June 30, 2019.

**5. License Agreements**

The Company performs research under a license agreement with The University of North Carolina at Chapel Hill ("UNC") as amended (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 derives revenues primarily from licensing its proprietary PRINT technology and from performing research and development services. Revenues are 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 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 June 30, 2019. 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 revenues, 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.

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.

On July 20, 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 revenues during the six months ended June 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.

In June 2016, the Company entered into a development and license agreement with G&W Laboratories ("G&W") to develop multiple products for topical delivery in dermatology using the Company's PRINT technology (the "G&W Agreement"). The first non-refundable up-front fee of $1.0 million was received in June 2016. Research and development services commenced in July 2016 on the first program pursuant to this agreement. In April 2018, the Company and G&W mutually agreed to terminate the G&W Agreement. As a result, during the second quarter of 2018, the remaining unamortized balances in the related deferred revenue and deferred sublicense payments of $0.9 million and $0.1 million, respectively, were fully recorded as Revenues and Cost of Sales, respectively, in the accompanying Statement of Operations and Comprehensive Loss for the year ended December 31, 2018.

The following tables represent a disaggregation of revenue by each significant research, development and licensing agreement and payment type for the three and six months ended June 30, 2019 and 2018:

| | Revenue for the Three Months Ended June 30, 2019 From | | | |
|---|---|---|---|---|
| | Non-Refundable Payments | | Research and Development | |
| | Milestones | Up-front Payments | Services | Total |
| 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 |

| | Revenue for the Three Months Ended June 30, 2018 From | | | |
|---|---|---|---|---|
| | Non-Refundable Payments | | Research and Development | |
| | Milestones | Up-front Payments | Services | Total |
| GSK Inhaled | $ — | $ — | $ — | $ — |
| Other | — | 943,419 | 99,460 | 1,042,879 |
| **Total** | $ — | $ 943,419 | $ 99,460 | $ 1,042,879 |

| | Revenue for the Six Months Ended June 30, 2019 From | | | |
|---|---|---|---|---|
| | Non-Refundable Payments | | Research and Development | |
| | Milestones | Up-front Payments | Services | Total |
| 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 |

| | Revenue for the Six Months Ended June 30, 2018 From | | | |
|---|---|---|---|---|
| | Non-Refundable Payments | | Research and Development | |
| | Milestones | Up-front Payments | Services | Total |
| GSK Inhaled | $ 45,058 | $ 225,293 | $ 168,000 | $ 438,351 |
| Other | — | 943,419 | 587,079 | 1,530,498 |
| **Total** | $ 45,058 | $1,168,712 | $ 755,079 | $1,968,849 |

**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 Sales in the same period. As of June 30, 2019, the balances of these unamortized payments included in current and long-term prepaid expenses and other assets was $0 and $0, respectively. As of December 31, 2018, the balances of these unamortized payments included in current and long-term prepaid expenses and other assets was $0 and $807,192, respectively.

**7. Property, Plant and Equipment**

Property, plant and equipment consisted of the following:

| | June 30, 2019 | December 31, 2018 |
|---|---|---|
| Lab and build-to-suit equipment | $ 5,674,477 | $ 6,123,194 |
| Grant equipment | 1,123,833 | 1,143,701 |
| Office equipment | 128,669 | 130,460 |
| Furniture and fixtures | 237,951 | 205,051 |
| Computer equipment | 796,867 | 799,515 |
| Leasehold improvements | 8,516,396 | 8,878,361 |
| Construction-in-progress | 940,788 | 155,148 |
| Total property, plant and equipment | 17,418,981 | 17,435,430 |
| Accumulated depreciation | (9,378,242) | (9,304,722) |
| Property, plant and equipment, net | $ 8,040,739 | $ 8,130,708 |

The Company recorded depreciation and amortization expense of $618,230 and $401,080 for the three months ended June 30, 2019 and 2018, respectively, and $1,227,265 and $725,934 for the six months ended June 30, 2019 and 2018, respectively.

In December 2016, the Company executed an agreement with a commercial manufacturer to build a PRINT particle fabrication line for the production in support of LIQ861. The ultimate cost was approximately $1.6 million. The Company financed this transaction with a third-party vendor, CSC Leasing Company ("CSC"). CSC made payments to the manufacturer per the payment schedule in the agreement as the asset was fabricated. CSC charged the Company a monthly lease rate on the scheduled payments made to the manufacturer as interim financing costs until the asset was completed and placed in service. Upon completion of fabrication, the lease commenced on March 1, 2018 ("CSC Financing").

In accordance with ASC 840, *Leases*, for build-to-suit arrangements where the Company is involved in the fabrication of an asset prior to the commencement of the ultimate financing or takes some level of construction risk, the Company is considered the accounting owner of the assets during the fabrication period. Accordingly, during the fabrication phase, the Company recorded a construction-in-progress asset within Property, Plant and Equipment and a corresponding deferred financing obligation liability for contributions by CSC toward fabrication. Upon completion of the fabrication in March 2018, since the Company maintained substantially all of the risk and rewards of ownership of the asset, the Company recorded the transaction as a financing, continuing to record the asset and reclassifying the deferred financing obligation to debt. In accordance with Topic 842, the CSC Financing was recharacterized as a finance lease in the first quarter of 2019 and accounted for accordingly (see Note 8).

**8. Commitments and Contingencies**

**Leases**

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

The Company conducts its operations from leased facilities in Morrisville, North Carolina, the leases for which expire in 2026. The leases are for general office, laboratory, research and development and light manufacturing space. The lease agreements require the Company to pay property taxes, insurance, common area expenses and maintenance costs. In November 2014 and November 2015, the Company executed the first and second extension period clauses, respectively, resulting in additional months to the lease for the related premises extending until October 2022. As part of these extensions, the Company received tenant allowances of $228,973 and $392,020, respectively, for expansion of laboratory and office space. In January 2017, the Company signed a second extension to the lease of its primary building for an additional 48 months and expiring October 31, 2026. A tenant allowance of approximately $2,000,000 was also made available for use to help fund the expansion and build out of the primary building. This allowance was fully utilized as of June 30, 2019. In November 2018, the Company amended the lease of its primary building to expand by 8,264 additional square footage expiring October 31, 2026 in exchange for terminating the Company's other lease with the same landlord for 4,400 noncontiguous square feet. A tenant allowance of approximately $1.0 million was also made available for use to help fund the build out related to the expansion of the primary building lease. The incremental rent over the terminated lease for the first 12 months of this lease expansion amounts to $0.1 million, subject to lease escalation in subsequent periods. In June 2019, the Company signed a commitment to incur construction costs of up to $3.1 million related to the leasehold improvements for this lease expansion, against which the tenant allowance will be applied.

The Company also leases copier equipment under an operating lease, which expires in 2023.

The Company leases specialized lab equipment under finance leases. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset. The interest rates related to these lease obligations range from 0.2% to 12.2%. The CSC Financing (see Note 7) has a term of three years with equal monthly payments that by themselves imply an interest rate equal to approximately 5.4% per annum. The effective interest rate is 14.9%. The CSC Financing is secured by a lien on the related build-to-suit equipment and includes an option to purchase the build-to-suit equipment at maturity at an amount equal to the lesser of fair market value or 23% of the initial financed amount. The right-of-use assets related to finance leases net of amortization is $2,192,153 as of June 30, 2019 and is included in lab equipment, build-to-suit equipment, computer equipment and leasehold improvements within property, plant and equipment in the accompanying Balance Sheet (see Note 7).

The Company's lease cost is reflected in the accompanying Statements of Operations and Comprehensive Loss as follows:

| | Classification | Three Months Ended June 30, 2019 |
|---|---|---|
| Operating lease cost | General and administrative | $ 238,922 |
| Finance lease cost | | |
| Amortization of lease assets | General and administrative | 313,800 |
| Interest on lease liabilities | Interest expense | 48,267 |
| Lease cost | | $ 600,989 |

The weighted average remaining lease term and discount rates as of January 1, 2019 were as follows:

| | |
|---|---|
| Weighted average remaining lease term (years) | |
| Operating leases | 3.9 |
| Finance leases | 1.3 |
| Weighted average discount rate | |
| Operating leases | 10.3 % |
| Finance leases | 3.03 % |

The discount rate for operating leases was estimated based upon market rates of collateralized loan obligations of comparable companies on comparable terms. The discount rate for finance leases are estimated based upon the underlying lease terms. The future minimum lease payments as of June 30, 2019 were as follows:

| Year ending December 31: | Operating Leases | Finance Leases | Total |
|---|---|---|---|
| 2019 (remaining six months) | $ 572,212 | $ 587,093 | $ 1,159,305 |
| 2020 | 1,172,759 | 1,221,405 | 2,394,164 |
| 2021 | 1,207,708 | 669,739 | 1,877,447 |
| 2022 | 1,243,934 | 82,743 | 1,326,677 |
| 2023 | 1,283,253 | — | 1,283,253 |
| Thereafter | 3,830,425 | — | 3,830,425 |
| Total minimum lease payments | 9,310,291 | 2,560,980 | 11,871,271 |
| Less: Interest | (2,824,633) | (204,815) | (3,029,448) |
| Present value of lease liabilities | $ 6,485,658 | $ 2,356,165 | $ 8,841,823 |

As previously reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and under legacy lease accounting (ASC 840), future minimum lease payments under non-cancellable leases as of December 31, 2018 are as follows:

| | Operating Leases | Finance Leases |
|---|---|---|
| 2019 | $ 1,077,532 | $ 464,797 |
| 2020 | 1,168,710 | 354,739 |
| 2021 | 1,203,658 | 33,774 |
| 2022 | 1,239,885 | — |
| 2023 | 1,276,356 | — |
| Thereafter | 3,818,795 | — |
| Total minimum lease payments | $ 9,784,936 | 853,310 |
| Less: Interest | | (24,525) |
| Present value of lease liabilities | | $ 828,785 |

**Other**

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. As future contingent consideration under the agreement, the Company agreed to pay $400,000 related to the timing of the Company's first Phase 3 clinical trial which commenced site initiation in December 2017. The consideration of $400,000 is comprised of initial consideration of $20,000 paid in 2017, $80,000 paid upon first dosing of the first patient in the Phase 3 clinical trial which occurred in 2018, and $300,000 due no later than December 31, 2018, which was paid

in 2018. In addition, the Company also agreed to pay future contingent royalties on net sales totaling no more than $1,500,000. As of June 30, 2019 and December 31, 2018, $0 and $0 was recorded as Current Liabilities in the accompanying Balance Sheets, respectively.

In December 2017, GSK Inhaled made the Company aware of its modified plans under the GSK Inhaled Collaboration and Option Agreement, and the reduced requirement and budget for support, commensurate with its research and development plans related to PRINT effective March 31, 2018. As a result, in December 2017, the Company committed to a plan to reduce its workforce which was communicated to the workforce and completed the plan in January 2018. The total employee severance expense resulting from this plan was $404,407, which was recorded in March 2018 to Research and Development Expense in the accompanying Statements of Operations and Comprehensive Loss for the six months ended June 30, 2018. No further employee severance expense is planned related to this matter.

**9. Long-Term Debt**

Long-term debt consisted of the following as of:

| | Maturity Date | June 30, 2019 | December 31, 2018 |
|---|---|---|---|
| Pacific Western Bank note | October 25, 2022 | $ 15,840,164 | $ 10,802,355 |
| CSC build-to-suit equipment financing, net of discount | February 28, 2021 | — | 1,142,194 |
| Less current portion | | (2,835,583) | (316,906) |
| Long-term debt, less current portion | | $ 13,004,581 | $ 11,627,643 |

**Pacific Western Bank**

In January 2016 and October 2016, the Company entered into a Loan and Security Agreement ("LSA") and an amendment, respectively, with Pacific Western Bank ("Pacific Western"). The LSA provided that the Company may borrow up to $10.0 million three tranches of a term loan ("Term Loan") to supplement working capital and finance facility expansion and capital equipment purchases. The Term Loan was collateralized by a lien on all assets of the Company that are not otherwise encumbered, including a negative pledge on intellectual property prohibiting its sale without Pacific Western's consent. Amounts borrowed under the Term Loan could be repaid at any time without penalty or premium. The Term Loan was interest-only through July 6, 2017, followed by an amortization period of 30 months of equal monthly payments of principal plus interest, beginning on August 6, 2017 and continuing on the same day of each month thereafter until paid in full. Any amounts borrowed under the Term Loan bore interest at 3.75% during the initial 18-month interest-only period. Following the interest-only period, the interest rate increased to 5.00%, which was to be fixed for the duration of the Term Loan. Subsequent to the Company closing its IPO, on August 6, 2018 the Company paid Pacific Western a liquidity event success fee of $400,000, which was recorded as Interest Expense in the accompanying Statement of Operations and Comprehensive Loss.

In early 2017, the Company breached a covenant in the LSA with Pacific Western Bank by failing to set mutually agreeable financial or milestone covenants on or before January 30, 2017. On March 30, 2017, pursuant to a Fourth Amendment to the LSA entered into between the Company and Pacific Western, Pacific Western waived the breach of this covenant and the covenant remains in effect.

In October 2017, the Company breached a covenant in its LSA with Pacific Western by failing to maintain minimum levels of cash. On November 30, 2017, pursuant to the Eighth Amendment to the LSA, Pacific Western waived the breach of this covenant and amended the LSA to require the Company to maintain a cash balance of at least $2.5 million monitored daily, from November 30, 2017 until the Company receives at least $12.0 million from the issuance of equity instruments by December 31, 2017. The Company was in breach of this covenant as of December 31, 2017. In February 2018, Pacific Western waived the breach of this covenant as a result of the Company receiving equity financing in excess of the requirement.

On March 29, 2018, the Company and Pacific Western executed the Ninth Amendment to the LSA (the "Ninth Amendment"). With the Ninth Amendment, new covenants were enacted requiring the Company to (1) at all times maintain a balance of cash at Pacific Western of at least $8.0 million, an increase of $5.5 million from its prior cash balance covenant, and (2) not observe any materially adverse data from its LIQ861 Phase 3 study on or before December 31, 2018. Pursuant to this Ninth Amendment, the interest-only period for the Tranche I loan was amended to include the period from January 7, 2018 to July 6, 2018, and the interest-only period for the Tranche II and Tranche III loans was amended to include the period from January 13, 2018 to July 12, 2018. Prior to executing the amendment, the Company had made principal payments of $0.6 million inside of the defined interest-only period, which were subsequently refunded on the same day. All amendments to the Pacific Western LSA were accounted for as a modification.

On October 26, 2018, the Company and Pacific Western entered into an Amended and Restated Loan and Security Agreement (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 (as defined below) 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 and maturity. The A&R LSA provides 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 drawn to $16.0 million. Both tranches require payments of interest-only through December 31, 2019, which interest-only period can be extended by six months if the Company closes on at least $40.0 million in new financing from either equity sales or licensing activities by October 31, 2019 (the "Financing Condition").

The A&R LSA carries a one-time success fee tiered by tranche totaling between $187,000 and $375,000 depending upon whether the Financing Condition is met, and a prepayment penalty of 1% to 2% for the first 24 months of the drawn tranche. The minimum cash covenant is $8.5 million, which can be reduced to $6 million in the event the Financing Condition is met. 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 other things, 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 either New Enterprise Associates or 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. On May 21, 2019, the Company and Pacific Western entered a First Amendment to A&R LSA to amend, among other things, the capital expenditure limitations to the Company.

**UNC Promissory Note**

In September 2012, the Company issued an unsecured promissory note with principal amount of $0.6 million as a sublicense fee to UNC, with principal and interest due in full on September 1, 2016, bearing an interest rate equal to the one-year LIBOR plus 2%, compounding annually, or the UNC Promissory Note. In June 2016, the Company (as licensee) negotiated modifications to its license agreement with UNC in exchange for an increase of $1.5 million to the note payable and extension of the maturity to December 31, 2017. As the Company had previously recorded a contingent liability of $1.5 million related to this license, the increase to the note payable was recorded as a reduction to the accrued expense balance at this time. In addition, the initial note of $0.6 million plus accrued interest were extended under the same terms. The combined note payable interest rate was increased by 1%. In December 2017, the Company executed an amendment to the UNC Promissory Note that extended the maturity date of the promissory note from December 31, 2017 to June 30, 2018. All other terms and conditions of the Letter Agreement continued in force through the new maturity date. In June 2018, the Company executed an amendment to the UNC Promissory Note that extended the maturity date of the promissory note from June 30, 2018 to December 31, 2018 with the potential for acceleration depending on the proceeds of the IPO. All other terms and conditions of the Letter Agreement were to continue in force through the new maturity date. All such amendments to the UNC Promissory Note were accounted for as a modification. On August 2, 2018, the Company made a payment of $600,000 to UNC. The Company repaid the entire balance

outstanding plus accrued interest pursuant to the closing of the A&R LSA with Pacific Western on October 26, 2018. The balance of the promissory note at June 30, 2019 and December 31, 2018 was $0 and $0, respectively.

**Convertible Notes**

In January and February 2017, the Company issued an aggregate of $11.8 million in principal of convertible promissory notes (the "January and February Notes"). The January and February Notes were accompanied by warrants to purchase of up to 25% of the aggregate principal amounts of the notes, equal to 3,698,128 shares of Series D. The January and February Notes were scheduled to mature on December 31, 2018, as amended, and bore interest at 8% per annum. Interest was earned daily and computed on the actual number of days elapsed until all the amounts under the notes had been paid in full. All unpaid principal and all accrued, but unpaid interest of each investor's note was due and payable on demand at the request of the investor at any time after December 31, 2018. In addition, upon the consummation of an asset sale, acquisition, or IPO, as defined, the investors may have elected to accelerate the repayment of the note or convert into common stock or Series C-1 based on various scenarios.

In July 2017, the Company entered into a series of unsecured convertible note agreements of $10.4 million in the aggregate (the "July Notes"). The July Notes bore interest at a rate of 8% per annum with a scheduled maturity date of December 31, 2018. In conjunction with this financing, the Company also entered into a commitment with an advisor in the form of a convertible note amounting to $0.4 million with terms similar to the related transaction. The July Notes were not accompanied by warrants. Principal plus accrued interest were convertible into either preferred or common stock at the time of a qualified financing, as defined in the July Notes, at a discount to the share price, depending on the type of financing similar to the January and February Notes.

In November 2017, the Company issued a series of unsecured subordinated convertible notes with an aggregate principal amount of $5.2 million to new and existing investors (the "November Notes"). The November Notes bore interest at a rate of 8% per annum with a scheduled maturity date of December 31, 2018. Principal plus accrued interest were convertible into either preferred or common stock at the time of a qualified financing, as defined in the November Notes, at a discount to the share price, depending on the type of financing. In conjunction with this financing, the Company also incurred fees of $0.4 million. The November Notes were not accompanied by warrants. Conversion discounts on these convertible notes were largely similar to the July Notes except that there was no discount upon mandatory conversion into a private financing round.

*Accounting for Convertible Notes*

The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from allocation of proceeds to interest expense using the straight-line method over the expected term of the notes pursuant to ASC 835, *Interest* (ASC 835).

In connection with the issuance of the convertible notes and warrants, the Company recorded discounts equal to the full amount of each series of notes based on an allocation of proceeds to the warrants, an allocation to bifurcated derivatives which consist of a contingent put option upon a change of control or acceleration upon event of default and a contingent call option upon a change of control included in the notes, and a beneficial conversion feature, before issuance costs, based on the difference between the fair value of the underlying common stock at the commitment date of each note transaction and the effective conversion price of the notes, as limited by the proceeds allocated to the notes. Since the initial carrying value of all three series of convertible notes was $0, the combined debt issuance costs of $1,397,624 were charged to Interest Expense. See Note 2 for discussion of the Company's policies for accounting for convertible instruments with detachable liability-classified warrants.

In February 2018, the Company received proceeds of $25.6 million in exchange for the corresponding sale of shares of Series D at a price per share of $0.59808. In addition, all outstanding convertible notes, plus accrued interest, totaling $28.9 million, were converted into Series D at the same price per share. The unamortized balances of the discounts on convertible notes of $17.6 million were then amortized to interest expense. Therefore, the balances of these notes at June 30, 2019 was $0.  No gain or loss was recorded upon the conversion of the convertible notes.

*Accounting for the Warrant Liabilities*

The Company's liability-classified warrants were recorded as liabilities at their estimated fair value at the date of issuance, with the subsequent changes in estimated fair value recorded in derivative and warrant fair value adjustments in the Company's Statements of Operations and Comprehensive Loss. The warrants, with a fair value of $4,474,122 at inception, were initially recorded as warrant liabilities on the Balance Sheets with a corresponding discount to the notes. The change in the estimated fair value of the warrant liabilities resulted in a fair value adjustment and is included in derivative and warrant fair value adjustments in the Statements of Operations and Comprehensive Loss. In conjunction with the IPO, the warrants automatically converted to warrants to purchase common stock. Therefore, upon IPO, the warrant liabilities were marked to fair market value and transferred to additional paid-in capital. Changes in the values of the warrant liabilities for the six months ended June 30, 2019 and 2018 are summarized below:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| Fair value, beginning of period | $ — | $ 2,462,859 |
| Issuance of warrants | — | — |
| Change in fair value | — | (171,450) |
| Transfer to additional paid-in capital | — | — |
| Fair value, end of period | $ — | $ 2,291,409 |

*Assumptions Used in Determining Fair Value of Liability Classified Warrants*

To estimate the fair value of the warrants, the Company used a combination of the Current Value Method, Option Pricing Method ("OPM") and Black-Scholes Option Pricing Model, in a Probability-Weighted Expected Return Method ("PWERM") context, or the Hybrid Method ("Hybrid Method"). The Company estimated the fair value of the most senior series of preferred stock and estimated the fair value of common stock in the various conversion scenarios. The Company used a Black-Scholes option pricing model to estimate the fair value of the warrants using the life of the warrants, assuming a sale of the Company does not occur, and the fair value of underlying equity values from the first step. The Company probability-weighted each scenario to arrive at an estimated fair value of the warrants.

Depending upon the scenario, warrants could be exercised to purchase either common stock or the most senior series of preferred stock. To value the warrants in each scenario, the Company used either an OPM or the Black-Scholes option pricing model. The hybrid method is a useful alternative to explicitly modeling all PWERM scenarios in situations when the Company has transparency into one or more near-term exits but is unsure about what will occur if the current plans fall through.

Key assumptions in the hybrid method include:

- OPM-various conversion scenarios
- Probability
- Timing (Each financing scenario)
- Enterprise value
- Type of Security
- Estimated security value
- Methodology of valuing warrant OPM

Scheduled annual maturities of long-term debt as of June 30, 2019 are as follows:

| **Year ending December 31:** | |
|---|---|
| 2019 - (six months remaining) | $ — |
| 2020 | 5,818,182 |
| 2021 | 5,818,182 |
| 2022 | 4,363,636 |
| Total | 16,000,000 |
| Less: Unamortized discount | (124,874) |
| Less: Unamortized debt issuance costs | (34,962) |
| Less: Current portion of long-term debt | (2,835,583) |
| | $ 13,004,581 |

**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 financial statements and related notes appearing in this quarterly report. 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**

Liquidia Technologies, Inc. ("Liquidia", "we", "us" or "our") is a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using 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.

**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 pulmonary arterial hypertension, or 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:

| Product | Indication | Formulation & Route | Phase 1 | Phase 2 | Phase 3 | Next Key Milestone | Worldwide Commercial Rights |
|---|---|---|---|---|---|---|---|
| LIQ861[1] | PAH | Dry powder inhalation | | | | Submit NDA late-2019 | Liquidia |
| LIQ865 | Local, post-operative pain | Sustained-release injectable | | | | Phase 2 ready end of 2019 | Liquidia |

1. After consultation with the FDA, we advanced from a Phase 1 trial directly to a pivotal Phase 3 trial and will seek approval under the 505(b)(2) pathway.

**LIQ861**

Our lead product candidate, LIQ861, is being evaluated in an open-label Phase 3 clinical trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, as a potential treatment for patients with PAH. LIQ861 is an inhaled dry powder formulation of treprostinil that is administered using a convenient, disposable dry powder inhaler, or DPI. 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.

The primary objective of the INSPIRE study is to evaluate the long-term safety and tolerability of LIQ861. The study is designed to evaluate patients who have either been under stable treatment with Tyvaso (nebulizer-delivered treprostinil) for at least three months and are transitioned to LIQ861 under the protocol or who have been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol.

As reported on March 11, 2019, we completed enrollment and met the primary endpoint in our INSPIRE trial. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two months of treatment. During the two-month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events. Moreover, dosing has exceeded the 150 mcg capsule strength in some centers and we have not yet determined a maximum tolerated dose of LIQ861. We also completed enrollment in our one-directional crossover sub-study comparing bioavailability and pharmacokinetics, or PK, of treprostinil as sub-study patients transitioned from Tyvaso to LIQ861.

On April 3, 2019, we reported further data from our INSPIRE trial on exploratory endpoints at two months of treatment that demonstrated generally favorable results with respect to six-minute walk distance (6MWD) and quality of life as indicated by the Minnesota Living with Heart Failure Questionnaire (MLWHFQ). On May 14, 2019, we reported further presentation of this data at the American Thoracic Society (ATS) International Conference 2019.

On June 5, 2019, we reported results from the INSPIRE study indicating that the 75 mcg capsule strength of LIQ861 correlates with the 54 mcg dose of Tyvaso, the maximum recommended label dose of Tyvaso. Analysis of the data from the PK sub-study in patients showed variability in systemic plasma levels of both LIQ861 and Tyvaso, which is believed to be attributed to variation in severity of disease and has been seen in prior studies of treprostinil in patients. To more accurately characterize the PK of LIQ861, we conducted an additional PK study in healthy volunteers in which we observed unexpected variability in PK levels. Post-hoc analysis showed that plasma levels of treprostinil were tightly correlated to the LIQ861 dose delivered. We continue working to supplement the PK data set of LIQ861 and to further assess and minimize the variability in dosing and PK levels. Based upon additional non-clinical and clinical work completed to date, we now believe the unexpected variability seen in the healthy volunteer study was due to an administration technique unique to the conduct of the study in the phase 1 setting. We therefore plan to complete our PK work in the third quarter of 2019, with results expected during the fourth quarter of 2019.

In August 2019, we had a report that one clinical investigator reassessed a serious adverse event, preliminarily identified as hypersensitivity pneumonitis, as being possibly related to LIQ861, whereas the investigator had previously, in May and June 2019, characterized the event as not related to LIQ861. Based on our work to date, 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 current assessment. However, we are reporting the event to the FDA, as required, and we will continue to monitor and assess this event for any change. We expect to conclude the INSPIRE study during the third quarter of 2019. Following completion of this study, we plan to provide patients the opportunity to continue receiving LIQ861 by conducting an open label extension study as a follow-on to the INSPIRE study. We are also considering conducting additional clinical trials to generate additional data on LIQ861, including a hemodynamic study and a pediatric study, among others. We are targeting a New Drug Application, or NDA, submission to the U.S. Food and Drug Administration, or FDA, for LIQ861 in late 2019.

**LIQ865**

We have completed two Phase 1 clinical trials of our second product candidate, LIQ865, for the treatment of local post-operative pain. LIQ865 is our proprietary injectable, sustained-release formulation of bupivacaine, a non-opioid pain medication. We have designed LIQ865 to be administered as a single treatment for the management of local post-operative pain for three to five days after a procedure. If approved, we believe that LIQ865 has the potential to provide significantly longer post-operative pain relief compared to currently marketed formulations of bupivacaine. We initiated Phase 2-enabling toxicology studies in the first quarter of 2019. We expect to complete these studies by the end of 2019 and to commence initial Phase 2 proof-of-concept clinical trials in 2020.

**Other**

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.

**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 $170.0 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 $19.7 million and $33.8 million for the six months ended June 30, 2019 and 2018, respectively, and $53.1 million and $29.2 million for the years ended December 31, 2018 and 2017. As of June 30, 2019, we had an accumulated deficit of $187.3 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 candidate. 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 June 30, 2019, we had $52.1 million of cash. We believe that our existing cash will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. See “Liquidity and Capital Resources.”

**Our Collaborations**

Our only revenue, which has been derived from collaborating with, and licensing our proprietary PRINT technology to, pharmaceutical companies, amounted to $8.1 and $2.0 million for the six months ended June 30, 2019 and 2018, respectively. GlaxoSmithKline plc, or GSK, accounted for $8.1 and $0.4 million for the six months ended June 30, 2019 and 2018, respectively, or 100% and 22% respectively, of our total revenue during these periods. We have received up-front fees for technology access, milestone payments, and fees to develop drug products through research and development services, such as particle formulation and manufacturing.

***GSK***

In June 2012, we entered into an Inhaled Collaboration and Option Agreement with GSK, or the GSK ICO Agreement, under which we granted GSK exclusive options and licenses to further develop and commercialize inhaled therapies using our PRINT technology. 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, conducting preclinical studies of inhaled therapeutics developed, manufactured or otherwise produced using our PRINT technology. In consideration for GSK’s exercise of this option, we received a non-refundable up-front payment of $15.0 million,

which amount was being amortized into revenue over a period of time based on the estimated remaining development period and on a similar basis as research and development services were expected to be performed.

Under the terms of the GSK ICO Agreement, we are also entitled to certain milestone payments aggregating up to $158 million upon the achievement of specified milestone 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. We also entered into other engagements with GSK under the GSK ICO Agreement, primarily for platform research services.

In December 2017, GSK informed us of its modified plans under the GSK ICO Agreement that reduced its requirements and budget for our research and development support in 2018. As a result, in January 2018, we reduced our research and development workforce accordingly, and we incurred approximately $400,000 in expense relating to the workforce reduction.

In June 2018, GSK notified us of its intention to review continuation of development of an inhaled antiviral for viral exacerbations in chronic obstructive pulmonary disease, or COPD, part of the GSK ICO Agreement, after completion of its related Phase 1 clinical trial. On July 20, 2018, GSK confirmed that it will not continue the COPD program. We do not expect to incur additional revenues or expenses directly associated with the COPD program.

In June 2019, we and GSK executed a third amendment to the collaboration agreement providing us rights to develop and commercialize certain additional inhaled programs at our sole cost and development. This amendment granted us the right to develop three additional molecular entities for application in inhaled programs using our PRINT technology and a mechanism to acquire rights to develop further molecular entities for inhaled applications. New inhaled programs developed under this amendment carry milestone and royalty payments due to GSK upon initiation of Phase 3 studies and subsequent commercialization, respectively. Additionally, prior to us licensing these new inhaled programs to a third party, GSK has a right of first negotiation for these programs.

The third amendment, among other factors, including the lack of continued performance anticipated by us and GSK under the original agreement, led us 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 unamortized balances in the related deferred revenue and deferred sublicense payments of $8.1 million and $0.8 million, respectively, were fully recorded as Revenues and Cost of sales, respectively, during the six months ended June 30, 2019. Any potential milestone or royalty payments from us to GSK associated with this amendment will be recorded as operating expenses.

**G&W Laboratories**

In June 2016, we entered into a development and license agreement, or the G&W Labs Agreement, with G&W Laboratories, Inc., or G&W Labs, to develop multiple products for topical delivery in dermatology using our PRINT technology. We received the first non-refundable up-front fee of $1.0 million under this agreement in June 2016, which amount was being amortized into revenue over a period of time based upon the estimated remaining development period and on a similar basis as research and development services were expected to be performed. We began performing research and development services under this agreement in July 2016. In April 2018, we and G&W Labs mutually agreed to terminate the G&W Labs Agreement. As a result, during the year ended December 31, 2018, the remaining unamortized balances in the related deferred revenue and deferred sublicense payments of $0.9 million and $0.1 million, respectively, were fully recorded as Revenues and Cost of sales, respectively, in the accompanying Statement of Operations and Comprehensive Loss.

**Components of Statements of Operations**

***Revenue***

Our revenue has primarily been derived from collaborating and licensing our proprietary PRINT technology to pharmaceutical companies. In the future, we also expect to derive our revenue from our own pharmaceutical products. Up until the fourth quarter of 2018, we managed, reported and evaluated our business in the following two segments: Pharmaceutical Products and Partnering and Licensing. These reportable operating segments were determined in accordance with our internal management structure, which was organized based on operating activities, the manner in which we organized segments for making operating decisions and assessing performance and the availability of separate financial results.

In the fourth quarter of 2018, due to significantly diminished activities pursuant to collaborations, we changed the way we manage and operate the reporting entity and modified our information system to produce financial information for the chief operating decision maker, or CODM, to support the new structure. The changes required us to revise our segment reporting. Management reorganized our operations and reporting structure and began to manage our operations under our new segment structure, resulting in a single reportable segment. The financial statements were adjusted to reflect this change in segment reporting for all periods presented.

All long-lived assets are domiciled within the United States and all revenues were earned within the United States.

***Cost of Sales***

Cost of sales consists of the amortization of license fees owed to UNC upon our receipt of licensing revenues. The amortization is recorded in the same period and in the same manner in which the related revenue is recognized.

***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, or CROs, 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 Phase 3 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 as well as prepare for potential commercial readiness for LIQ861, our lead product candidate.

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 facility-related costs, patent filing and prosecution costs and professional fees for marketing, legal, auditing and tax services and insurance costs.

We anticipate that our annual general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher accounting, legal, consulting and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, investor relations costs, and director and officer insurance premiums associated with being a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

***Other Income (Expense)***

Other income (expense) is comprised primarily of interest income and expense and derivative and warrant fair value adjustments. Interest income consists of interest earned on our cash deposits. Interest expense consists of interest charges on capital leases and debt. These charges include monthly recurring interest on such obligations in addition to non-cash

charges. Non-cash charges include the accrual of interest expense at the end of each reporting period in addition to the expensing of debt issuance costs and amortization of discounts on long-term debt to interest expense. Derivative and warrant fair value adjustments consist of the unrealized gains and losses as a result of marking these financial instruments to fair market value at the end of each reporting period.

**Critical Accounting Policies and Estimates**

For a description of our significant accounting policies, see Notes to Financial Statements (Unaudited) – Note 2 – *Significant Accounting Policies*. Of these policies, the following are considered critical to an understanding of our financial statements as they require the application of the most difficult, subjective and complex judgments; (i) revenue recognition, (ii) stock-based compensation, and (iii) research and development costs.

**Results of Operations**

***Three Months Ended June 30, 2019 Compared to Three Months Ended June 30, 2018***

The following table summarizes our results of operations:

| | Three Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| Revenues | $ 8,072 | $ 1,043 |
| Costs and expenses: | | |
| Cost of sales | 807 | 94 |
| Research and development | 10,723 | 5,918 |
| General and administrative | 2,409 | 1,991 |
| Total costs and expenses | 13,939 | 8,003 |
| Loss from operations | (5,867) | (6,960) |
| Other income (expense): | | |
| Interest income | 220 | 12 |
| Interest expense | (254) | (246) |
| Derivative and warrant fair value adjustments | — | 925 |
| Total other income (expense) | (34) | 691 |
| Net loss | $ (5,901) | $ (6,269) |

*Revenues*

Revenues were $8.1 million for the three months ended June 30, 2019, compared to $1.0 million for the three months ended June 30, 2018. The increase of $7.1 million, or 710.0%, was due to the recognition of $8.1 million of deferred revenue from the GSK ICO Agreement resulting from the Third Amendment that was entered into in June 2019.

*Cost of Sales*

Cost of sales was $0.8 million for the three months ended June 30, 2019, compared to $0.1 million for the three months ended June 30, 2018. The increase of $0.7 million, or 700.0%, was due to the increase in revenues. Cost of sales 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 $10.7 million for the three months ended June 30, 2019, compared to $5.9 million for the three months ended June 30, 2018. The increase of $4.8 million, or 81.4%, was primarily due to the

ongoing clinical development of LIQ861 which commenced in late December 2017. Research and development expenses during the three months ended June 30, 2019 consisted of $7.4 million and $1.6 million attributable to our ongoing development of LIQ861 and LIQ865, respectively, and $1.7 million from general research and development that was not directly related to a particular product.

*General and Administrative Expenses*

General and administrative expenses were $2.4 million for the three months ended June 30, 2019, compared to $2.0 million for the three months ended June 30, 2018. The increase of $0.4 million, or 20.0%, was primarily due to an increase in employee-related expenditures and stock-based compensation totaling $0.3 million. General and administrative expenses are mainly the result of personnel expenses, including stock-based compensation, as well as legal and consulting fees and tax expense.

*Loss from Operations*

We recorded a loss from operations of $5.9 million for the three months ended June 30, 2019, compared to $7.0 million for the three months ended June 30, 2018. The decrease of $1.1 million, or 15.7%, was due to an increase in revenues, partially offset by an increase in cost of sales, an increase in research and development expenses and an increase in general and administrative expenses, during the three months ended June 30, 2019 as compared to the three months ended June 30, 2018.

*Other Income (Expense)*

Interest income was $0.2 million for the three months ended June 30, 2019, compared to $12,000 for the three months ended June 30, 2018. The increase of $0.2 million was primarily due to our access to interest-bearing accounts in 2019.

Interest expense was $0.3 million for the three months ended June 30, 2019, compared to $0.2 million for the three months ended June 30, 2018. The increase in interest expense was primarily due to higher levels of debt during the three months ended June 30, 2019 as compared to the three months ended June 30, 2018.

Derivative and warrant fair value adjustments resulted in income of $0 for the three months ended June 30, 2019, compared to income of $0.9 million for the three months ended June 30, 2018. The decrease of $0.9 million was primarily due to the conversion of the warrants for convertible preferred stock to warrants for common stock at the time of the initial public offering.

***Six Months Ended June 30, 2019 Compared to Six Months Ended June 30, 2018***

The following table summarizes our results of operations:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| Revenues | $ 8,072 | $ 1,969 |
| Costs and expenses: | | |
| Cost of sales | 807 | 121 |
| Research and development | 21,388 | 13,545 |
| General and administrative | 5,430 | 4,141 |
| Total costs and expenses | 27,625 | 17,807 |
| Loss from operations | (19,553) | (15,838) |
| Other income (expense): | | |
| Interest income | 358 | 12 |
| Interest expense | (473) | (18,122) |
| Derivative and warrant fair value adjustments | — | 171 |
| Total other income (expense) | (115) | (17,939) |
| Net loss | $ (19,668) | $ (33,777) |

*Revenues*

Revenues were $8.1 million for the six months ended June 30, 2019, compared to $2.0 million for the six months ended June 30, 2018. The increase of $6.1 million, or 305.0%, was due to the recognition of $8.1 million of deferred revenue from the GSK ICO Agreement resulting from the Third Amendment that was entered into in June 2019.

*Cost of Sales*

Cost of sales was $0.8 million for the six months ended June 30, 2019, compared to $0.1 million for the six months ended June 30, 2018. The increase of $0.7 million, or 700.0%, was due to the increase in revenues. Cost of sales 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 $21.4 million for the six months ended June 30, 2019, compared to $13.5 million for the six months ended June 30, 2018. The increase of $7.9 million, or 58.5%, was primarily due to the ongoing clinical development of LIQ861 which commenced in late December 2017. Research and development expenses for the six months ended June 30, 2019 consisted of $15.8 million and $2.3 million attributable to our ongoing development of LIQ861 and LIQ865, respectively, and $3.3 million from general research and development that was not directly related to a particular product.

*General and Administrative Expenses*

General and administrative expenses were $5.4 million for the six months ended June 30, 2019, compared to $4.1 million for the six months ended June 30, 2018. The increase of $1.3 million, or 31.7%, was primarily due to an increase in employee-related expenditures of $0.6 million, an increase in stock-based compensation of $0.6 million and an increase in professional fees of $0.1 million. General and administrative expenses are mainly the result of personnel expenses, including stock-based compensation, as well as legal and consulting fees and tax expense.

*Loss from Operations*

We recorded a loss from operations of $19.6 million for the six months ended June 30, 2019, compared to $15.8 million for the six months ended June 30, 2018. The increase of $3.8 million, or 24.1%, was due to an increase in cost of sales, an increase in research and development expenses and an increase in general and administrative expenses, partially offset by an increase in revenues, during the six months ended June 30, 2019 as compared to the six months ended June 30, 2018.

*Other Income (Expense)*

Interest income was $0.4 million for the six months ended June 30, 2019, compared to $12,000 for the six months ended June 30, 2018. The increase of $0.4 million was primarily due to our access to interest-bearing accounts in 2019.

Interest expense was $0.5 million for the six months ended June 30, 2019, compared to $18.1 million for the six months ended June 30, 2018. The decrease in interest expense of $17.6 million, or 97.2%, was primarily due to lower levels of debt during the six months ended June 30, 2019 and the conversion of $27.4 million of convertible notes into shares of Series D preferred stock in February 2018.

Derivative and warrant fair value adjustments resulted in income of $0 for the six months ended June 30, 2019, compared to income of $0.2 million for the six months ended June 30, 2018. The decrease of $0.2 million was primarily due to the conversion of the warrants for convertible preferred stock to warrants for common stock at the time of the initial public offering.

**Liquidity and Capital Resources**

***Overview***

We have financed our growth and operations through a combination of funds generated from our licensing revenues, the issuance of convertible preferred stock and common stock, capital 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 June 30, 2019, we had a cash balance of $52.1 million, stockholders' equity of $32.1 million and an accumulated deficit of $187.3 million. As of June 30, 2019, we had a net commitment of $2.2 million for leasehold improvements.

***Sources of Liquidity***

We have financed a portion of our working capital through debt instruments. We maintained a $10.0 million term loan facility with Pacific Western Bank, or PWB, for working capital purposes pursuant to a loan and security agreement, or the LSA. Immediately prior to entry into the A&R LSA (as defined below), we had fully utilized our $10.0 million term loan facility with PWB with a remaining outstanding balance of $8.0 million. The facility was secured by all of our assets other than intellectual property. We could not encumber our intellectual property without the consent of PWB. The outstanding principal amount under the loan facility bore interest at 5.0% per annum. Of the then-current amount outstanding, the loan was to mature with respect to $3.0 million in January 2020, with the remainder being due and payable in October 2020. Beginning in August 2018, the term loan would have required equal monthly payments of principal plus interest each month thereafter until amortized and paid in full. We have, in the past, breached multiple covenants in our LSA related to cash levels and reporting requirements. PWB provided waivers in relation to all such prior breaches.

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 require payments of interest-only through December 31, 2019, which interest-only period can be extended by six months if we close on at least $40.0 million in new financing from either equity sales or licensing activities by October 31, 2019, or the Financing Condition. The A&R LSA carries a one-time success fee of up to $375,000 depending on whether the Financing Condition is met, and a prepayment penalty of 1% to 2% for the first 24 months of the drawn tranche. The minimum cash covenant is $8.5 million, which can be reduced to $6.0 million in the event the Financing Condition is met. In May 2019, we and PWB entered into an amendment to the A&R LSA, to, among other things, 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 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 of Directors, or Board, which results in the failure of at least one partner of either New Enterprise Associates or 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.

During most of the year ended December 31, 2018, we had outstanding a promissory note to UNC, or the UNC Promissory Note. The UNC Promissory Note was unsecured and bore interest at a rate equal to one-year LIBOR plus 3%, compounded annually. The UNC Promissory Note was due and payable in full on December 31, 2018. Following the completion of the initial public offering of our common stock in July 2018, we made a payment to UNC of $600,000 in August 2018. We repaid the entire balance outstanding under the UNC Promissory Note, plus accrued interest pursuant to the closing of the A&R LSA with PWB in October 2018.

In a series of closings from January 2017 through November 2017, we issued and sold an aggregate of $27.4 million of unsecured subordinated convertible promissory notes, each accruing simple interest at a rate of 8.0% per annum.

In February 2018, we issued and sold an aggregate of 91,147,482 shares of Series D preferred stock at a price per share equal to $0.59808. Of the 31 investors that participated in the financing, 10 investors purchased an aggregate of 42,863,825 shares of Series D preferred stock for an aggregate purchase price of $25.6 million and 26 holders of outstanding convertible notes, in the aggregate amount of $28.9 million, converted their notes into an aggregate of 48,283,657 shares of Series D preferred stock.

In July 2018, we closed the initial public offering of 4,833,099 shares of common stock at a public offering price of $11.00 per share, including the underwriters' partial exercise of their over-allotment option in connection therewith, which resulted in aggregate net proceeds of $47.3 million, after underwriting discounts and the payment of other offering expenses.

In March 2019, we closed an underwritten follow-on public offering of 3,000,000 shares of our common stock at a public offering price of $11.50 per share, which resulted in aggregate net proceeds of $31.9 million, after deducting underwriting discounts and commissions and other offering expenses.

***Cash Flows***

The following table summarizes our sources and uses of cash for the periods indicated:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ (22,270) | $ (17,222) |
| Investing activities | (1,080) | (630) |
| Financing activities | 35,936 | 23,665 |
| Net increase in cash | $ 12,586 | $ 5,813 |

***Operating Activities***

Net cash used in operating activities increased $5.1 million, from $17.2 million for the six months ended June 30, 2018 to $22.3 million for the six months ended June 30, 2019. The increase was mainly due to the impact from the decrease in amortization of discounts on long-term debt and convertible notes reflected in the section adjustments to reconcile net cash used in operating activities, partially offset by the decrease in net loss. The primary drivers of operating cash requirements were our research and development and general and administrative activities in each period. For the six months ended June 30, 2019, the net cash used in operating activities was $22.3 million, which was comprised of operating cash outflows before working capital changes of $16.7 million and net working capital outflows of $5.6 million.

***Investing Activities***

Net cash used in investing activities increased $0.5 million from $0.6 million for the six months ended June 30, 2018 to $1.1 million for the six months ended June 30, 2019. The increase was due to increased purchases of property, plant and equipment.

***Financing activities***

Net cash provided by financing activities increased $12.2 million from $23.7 million for the six months ended June 30, 2018 to $35.9 million for the six months ended June 30, 2019. This increase was primarily due to net proceeds from the follow-on offering of common stock of $31.9 million and the $5.0 million draw under the A&R LSA during the six months ended June 30, 2019, as compared to the sale of Series D preferred stock of $25.1 million during the six months ended June 30, 2018.

**Funding Requirements**

We plan to focus in the near-term on the development, regulatory approval and potential commercialization of LIQ861 and LIQ865. 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 continue to invest in discovery efforts to explore additional product candidates, potentially build commercial capabilities and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, 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 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 will incur significant legal, accounting and other expenses that we were not required to incur as a private company. 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 that previously were inapplicable to us as a private company. 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 into the second quarter of 2020, including the completion of our ongoing Phase 3 clinical trial and other development work for LIQ861 and the completion of our Phase 2-enabling toxicology studies for LIQ865, which we anticipate will result in LIQ865 being Phase 2-ready by the end of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to 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 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.

**Effect of Inflation**

Inflation did not have a significant impact on our net sales, revenues or net loss for the six months ended June 30, 2019 or in the years ended December 31, 2018 and 2017.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented in this quarterly report on Form 10-Q, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

**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 intend to rely on certain of these exemptions, including without limitation:

- 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;
- 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 revenues 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.

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

Not applicable.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company 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 SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, or persons

performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, our principal executive officer and our principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.

**Changes in Internal Control Over Financial Reporting**

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II-OTHER INFORMATION

**Item 1. Legal Proceedings.**

We are not currently but may become subject to certain legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, there are currently no claims that would have a material adverse effect on our consolidated 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, including our 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 Our Company and our Financial Condition**

***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 $19.7 million for the six months ended June 30, 2019, and $53.1 million and $29.2 million for the years ended December 31, 2018 and 2017, respectively. We also had negative operating cash flows in the six months ended June 30, 2019, and for the years ended December 31, 2018 and 2017. As of June 30, 2019 and December 31, 2018, we had an accumulated deficit of $187.3 million and $167.1 million, respectively.

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 are primarily dependent on the success of our lead product candidate, LIQ861, and to a lesser degree, LIQ865, which are still in clinical development, and these product candidates may fail to receive marketing approval or may not be commercialized successfully.***

We have no 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, which is intended as an inhaled therapy for 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 product sales for at least the next few years, if ever.

We have completed a Phase 1 clinical trial for LIQ861 and an early Phase 1a clinical trial in Denmark for LIQ865 and a Phase 1b clinical trial for LIQ865 in the United States. We commenced a Phase 3 clinical trial for LIQ861 in the first quarter of 2018 and reported completion of enrollment and achievement of the primary endpoint in the INSPIRE trial in the first quarter of 2019. LIQ861 was observed to be well-tolerated in 109 patients, with 101 patients (93%) completing at least two months of treatment. During the two-month period, LIQ861 was evaluated at doses up to 150 mcg capsule strength with no study-drug related serious adverse events, with some dosing above the 150 mcg capsule strength. Exploratory endpoints of the INSPIRE trial demonstrated favorable functional and patient outcomes. We also completed enrollment in our one-directional crossover sub-study comparing bioavailability and PK of treprostinil as sub-study patients transitioned from Tyvaso to LIQ861. On June 5, 2019, we reported results from the INSPIRE study indicating that the 75 mcg capsule strength of LIQ861 correlates with the 54 mcg dose of Tyvaso, the maximum recommended label dose of Tyvaso. Analysis of the data from the PK sub-study in patients showed variability in systemic plasma levels of both LIQ861 and Tyvaso, which is believed to be attributed to variation in severity of disease and has been seen in prior studies of treprostinil in patients. To more accurately characterize the PK of LIQ861, we conducted an additional PK study in healthy volunteers. Post-hoc analysis showed that plasma levels of treprostinil were tightly correlated to the LIQ861 dose delivered. We are continuing work to supplement the PK data set of LIQ861 and to further assess and minimize the variability in dosing and PK levels. Based upon additional non-clinical and clinical work completed to date, we now believe the unexpected variability was due to an administration technique unique to the conduct of the study in the Phase 1 setting. We therefore plan to complete our PK work in the third quarter of 2019, with results expected during the fourth quarter of 2019. In August 2019, we had a report that one clinical investigator reassessed a serious adverse event, preliminarily identified as hypersensitivity pneumonitis, as being possibly related to LIQ861, whereas the investigator had previously, in May and June 2019, characterized the event as not related to LIQ861. Based on our work to date, 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 current assessment. However, we are reporting the event to the FDA, as required, and we will continue to monitor and assess this event for any change. Furthermore, we commenced preparations for Phase 2-enabling toxicology studies for LIQ865 in the fourth quarter of 2018 and initiated these initial studies in March 2019. We anticipate that, following the initial Phase 2-enabling toxicology studies, which we expect to complete by the end of 2019, we will commence initial Phase 2 proof-of-concept clinical trials for LIQ865 in 2020. We cannot assure you that our toxicology studies or clinical trials, if commenced, will be successful or meet their endpoints or that the endpoints will be sufficient to receive marketing approval.

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. 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.

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.

***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.

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

Our financial statements for the six months ended June 30, 2019 and the year ended December 31, 2018 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. If we are unable to obtain sufficient funding, 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. Our ability to continue as a going concern could also materially limit our ability to raise additional funds through the issuance of new debt or equity securities or generate revenues from licensing and collaboration arrangements. 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 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 an 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.

***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. For the six months ended June 30, 2019 and 2018, 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% and 22%, respectively, of our total revenue. For the years ended December 31, 2018 and 2017, our revenue attributable to our collaboration and licensing arrangements with GSK accounted for 16% and 84%, respectively, of our total revenue.

GSK has informed us of changes to its plans with respect to the GSK ICO Agreement that has materially affected the amounts we received from GSK under this agreement for the year ended December 31, 2018 and which we expect will continue to materially affect the amounts we will receive from GSK under this agreement for the year ending December 31, 2019. In December 2017, GSK informed us of its modified plans under the GSK ICO Agreement that reduced its requirements and budget for our research and development support in 2018. Revenues from research and development services under the GSK ICO Agreement were $0.2 million for the year ended December 31, 2018. In response, in January 2018 we reduced our research and development workforce accordingly, and incurred approximately $400,000 in expense relating to the modification. Further, in June 2018, GSK notified us of its intention to review continuation of development of an inhaled antiviral for viral exacerbations in chronic obstructive pulmonary disease, or COPD, under the GSK ICO Agreement, after completion of its related Phase 1 clinical trial. In July 2018, GSK confirmed that it will not continue the COPD program. We do not expect to incur additional expenses directly associated with the COPD program. In part because GSK is no longer actively advancing any programs under our collaboration, we entered into the Third Amendment to the GSK ICO Agreement, 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.

As a result of these changes, 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 is completed under the proportional performance model. Therefore, the remaining deferred revenue of $8.1 million was recognized as revenues during the six months ended June 30, 2019, and we do not expect to receive any additional revenue from GSK pursuant to our collaboration.

***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 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 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, 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.

***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 that they enter into 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 developing blocking patents to which we do not have a license.

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. In particular, we expect that LIQ861 will face competition from Tyvaso®, and Ventavis®, which are existing drug products indicated for the treatment of PAH, potential new entrants

such as Insmed Inc.'s INS-1009, as well as generic equivalents of Tyvaso following the expiry of Tyvaso's patent in 2018. We are aware that MannKind Corporation, or MannKind, filed an Investigational New Drug application, or IND, and completed a Phase 1 trial evaluating an inhaled dry powder treprostinil product for the treatment of PAH. In October 2018, United Therapeutics Corporation, or United Therapeutics, and MannKind closed their worldwide exclusive licensing and collaboration agreement for the development and commercialization of a dry powder formulation of treprostinil, an investigational product currently being evaluated in clinical trials for the treatment of PAH. Under the agreement, United Therapeutics will be 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. Additionally, we are aware that Arena Pharmaceuticals, Inc., or Arena, has commenced a Phase 3 trial evaluating ralinepag, an oral IP receptor agonist for the treatment of patients suffering from PAH. In January 2019, Arena and United Therapeutics closed on a global license agreement for ralinepag. Under the agreement, United Therapeutics is now responsible for the development, manufacture and commercialization of ralinepag. These new collaborations may accelerate competition for LIQ861.

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. In addition, while EXPAREL is currently the only direct competitor to LIQ865 on the market, Durect Corporation, Innocoll Holdings plc and Heron Therapeutics, Inc., or Heron, each have products in the pipeline that are potential competitors to LIQ865, which are estimated to enter the market in 2019, and generic equivalents of EXPAREL may enter the market following the expiry of EXPAREL's patent in 2018. In October 2018, 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 and a Prescription Drug User Fee Act, or PDUFA, goal date of April 30, 2019. On May 1, 2019, Heron announced that it received a complete response letter for HTX-011 from the FDA. If we are unable to maintain our competitive position, our business and prospects will 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 which 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, in part, depend on 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.

***Inadequate funding for the FDA, the SEC 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 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 the SEC and 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, 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, SEC and other government employees and stop critical activities. If a prolonged government shutdown 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, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

**Risks Related to our Business Operations**

***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 others. 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 in the case of our exclusivity arrangements 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;
- 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 (for example, our development and licensing agreement with G&W Laboratories, Inc., which we mutually terminated in April 2018), and if terminated, may result in our need for additional capital to pursue further drug product development or commercialization;
- 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.

***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, 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. If our supplier is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, or if it ceases its relationship with us, we may not be able to obtain alternative supplies of treprostinil from other suppliers on acceptable terms, in a timely manner, or at all. Furthermore, LIQ861 is administered using RS00 Model 8 DPI, a DPI manufactured by Plastiape S.p.A. 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.

***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.

***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.

***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.

***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 Fowler, our Chief Executive Officer, our business and prospects may be materially and adversely affected.

***Our employees and our independent contractors, principal investigators, CROs, consultants or commercial collaborators, as well as their respective sub-contractors, 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, consultants or commercial collaborators, as well as their respective sub-contractors, 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, consultants or commercial collaborators, as well as their respective sub-contractors, 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.

***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.

***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 the Development and Commercialization of our 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 design, scope or implementation 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 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;
- 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 we may not be able to satisfy the FDA requirements for our processes or facilities;
- 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 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 not approve of our manufacturing processes or facilities or those of our third-party manufacturers, which would be required to be corrected prior to marketing approval;
- 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 they were previously not opposed to. 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 their 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 what we requested approval for, 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.

***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.

***Our preclinical studies and clinical trials may not be successful and delays to 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 the safety and efficacy traits 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. We have not successfully

completed the clinical development of any of our product candidates and, accordingly, 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.

***We are planning to pursue 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.***

Our business model is to develop our own drug products in addition to collaborating with, among others, pharmaceutical companies to develop their drug products or drug products in collaboration. 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, 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. 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 patent infringement lawsuits in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the review or 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 NDA that each such patent is invalid, unenforceable or will not be infringed and the patentholder 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) application. It is not uncommon for a manufacturer of an approved product 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 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.

***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.

***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.

***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; and
- the number and nature of competing therapies and clinical trials.

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. 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.

***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.***

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 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.

***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 intend to conduct an additional clinical trial in Europe that explores the hemodynamic effects of LIQ861 in PAH patients, 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.

***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.

***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, 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 current pipeline product candidates, LIQ861 and LIQ865, require extensive clinical data analysis, regulatory review and additional testing. Clinical trials and data analysis can be very 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.

***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 revenues 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, or conduct additional clinical trials or we may need to recall the product;
- we may be subject to litigation or product liability claims, fines, injunctions or criminal penalties; and
- our reputation may suffer.

***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.

***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.***

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 products may not achieve market acceptance.***

Our business model is to develop our own drug products in addition to collaborating with, among others, pharmaceutical companies to develop their drug products or drug products in collaboration. 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 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 reference listed drug in their formularies or otherwise restrict patient access to a reference listed drug when a less costly generic equivalent or other alternative is available. In particular, given that several therapeutically similar drug products to LIQ861, including 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 it is 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 we may

not be placed on the formularies of key institutions and/or receive favorable reimbursement for LIQ865, if and when it is 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 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 our 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.

***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 are cleared by the FDA for these specific indications, we may only promote or market our product candidates for their specifically cleared or approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the cleared or approved indications for use, known as “off-label uses.” We cannot, however, 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 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.

***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, 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.

***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 natural disasters, such as fires, floods, earthquakes and hurricanes, among others.

***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 labelling 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.

***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 suspension or revocation of product license 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.

***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 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, 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.

**Risks Related to our Intellectual Property**

***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. 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 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 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.

***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, we may be required to include a certification of patent invalidity or non-infringement, or a paragraph IV certification, in an NDA submitted under the 505(b)(2) regulatory pathway, to certify that a patent over a reference listed drug is invalid, unenforceable or will not be infringed by the manufacture, use or sale of our product candidate. The holder of such patent may file a patent infringement lawsuit against us after receiving notice of the paragraph IV certification. Any such patent infringement lawsuit, if filed, will trigger a one-time, automatic, 30-month stay of the FDA's ability to approve our application, unless the patent litigation is resolved in our favor or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of a product candidate only to be subject to significant delay and incur substantial costs in litigation before such product candidate may be commercialized, if at all. Companies that produce reference listed drugs routinely bring claims for patent infringement against applicants under the 505(b)(2) regulatory pathway that are seeking regulatory approval to manufacture and market generic or reformulated forms of their reference listed drugs.

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.

***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 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 U.S. Patent and Trademark Office, or 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.

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 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;

- 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. 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. In addition, federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may also implicate the False Claims Act. Although the False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes;
- 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- 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, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and business associates. Among other things, HITECH made certain aspects of HIPAA's rules (notably the Security Rule) directly applicable to business associates — independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and 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 Department of Health and Human Services Office of 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, with one recent penalty exceeding $16 million;
- 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 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. On October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine Act"), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act, to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments and transfers of value 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 which differ from each other in significant ways and may not have the same effect, and may apply more broadly thus complicating compliance efforts (for example, California recently enacted legislation — the California Consumer Privacy Act, or CCPA — which goes into effect 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 certain disclosures 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; legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations, and 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 it remains unclear what, if any, modifications will be made to this legislation or how it 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 healthcare companies and healthcare providers, 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.

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 revenues 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. For example, the ACA which was signed into law in the United States in March 2010, is one such law that has affected the pharmaceutical industry.

Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- 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 Health and Human Services, or HHS, as a condition of Medicare Part B and Medicaid coverage of the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, establishing new methodologies by which AMP is calculated and rebates owed by manufacturers under the Medicaid Drug Rebate Program are collected for drugs that are inhaled, infused, instilled, implanted or injected, adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended-release formulations) of solid oral dosage forms of branded products, expanding the universe of Medicaid utilization

subject to drug rebates to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, and expanding the population potentially eligible for Medicaid drug benefits;

- the expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the federal poverty level beginning in 2014, thereby potentially increasing 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. Effective in 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Recent proposed guidance from the HHS Health Resources and Services Administration, if adopted in its current form, may affect manufacturers' rights and liabilities in conducting audits and resolving disputes under the 340B program;
- 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;
- 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 research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products by influencing decisions relating to coverage and reimbursement rates; and
- the ACA established the Center for Medicare and Medicaid Innovation within the Centers for Medicare & Medicaid Center, or Innovation Center, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. The Innovation Center has been funded through 2019, and funding will be automatically renewed for each 10 year budget window thereafter.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. President Trump has 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. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or the TCJA, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health

insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The decision has been stayed pending outcome of an appeal to the Fifth Circuit Court of Appeals, so the ruling does not have immediate effect. Recently, on July 9, 2019, the U.S. Court of Appeals for the Fifth Circuit heard arguments on appeal in *Texas v. Azar*. It is unclear how the eventual decision from this appeal, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business. It is also unclear how regulations and sub-regulatory policy, which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2.0% per fiscal year, which went into effect in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. In January 2013, then-President Barack Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among others, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws, and other legislative, regulatory, and judicial developments may result in additional reductions in Medicare and other healthcare funding, which could have a material and adverse effect on our customers and accordingly, our financial operations.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent 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. Recent 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. Additionally, on May 11, 2018, President Trump laid out his administration's "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, as well as additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS is soliciting feedback on some of these measures and has begun attempting to implement others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019; and in May 2019 CMS finalized a rule that was to take effect July 9, 2019 requiring direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. In June 2019, however, several pharmaceutical companies filed suit in the U.S. District Court for the District of Columbia, opposing the implementation of the rule. Although some of these, and other, proposals related to the administration's Blueprint may require additional authorization to become effective may ultimately be withdrawn (as was the case for a proposed rule that would have modified drug rebates), or may face challenges in the courts, 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 pharmacy benefit managers in the supply chain. 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for patients to access certain investigational new drug products that have completed a Phase I clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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. 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 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 July 31, 2019, 18,643,442 shares of our common stock were outstanding, of which approximately 13.1 million shares of common stock, or 70% of our outstanding shares as of July 31, 2019, 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 approximately 5.5 million shares held by our stockholders 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 July 31, 2019, the holders of approximately 10.2 million shares, or 55%, of our outstanding shares as of July 31, 2019, 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.

***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 prior equity offerings to complete our ongoing Phase 3 clinical trial and other development work for LIQ861, advance LIQ865 through our Phase 2-enabling toxicology studies which commenced in March 2019 and into initial Phase 2 proof-of-concept clinical trials expected to commence in 2020, fund operations supporting the development of, and commercial activities for, LIQ861 and LIQ865, and for working capital and general corporate purposes. Our management has broad discretion in the application of such proceeds and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish available 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.

***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. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this quarterly report on Form 10-Q, these factors include:

- the results of our or our competitors’ clinical trials;
- adverse results or delays in the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including without limitation the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products and product candidates, including clinical trial requirements for approvals;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- failure to commercialize our product candidates or failure to achieve the size or growth of the markets we intend to target to meet our expectations;
- departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introductions or announcements of new products offered by us or significant acquisitions, strategic collaborations, joint ventures or capital commitments by us, our collaborators or our competitors and the timing of such introductions or announcements;

- the introduction by our competitors of new products or technologies, or the success of our competitors' products or technologies;
- our ability or inability to effectively manage our growth;
- changes in the structure of healthcare payment systems;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- market conditions in the pharmaceutical and biotechnology sectors or the economy generally;
- our ability or inability to raise additional capital through the issuance of equity or debt or collaboration arrangements and the terms on which we raise it;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- period-to-period fluctuations in our quarterly results of operations or those of our competitors;
- discrepancies between our actual operating results and the estimates or projections of investors or securities analysts;
- fluctuations in the share price and trading volumes of other publicly traded companies engaged in similar business activities as us;
- market conditions in the pharmaceutical industry and in general;
- research and reports published by securities and industry analysts on our company or other companies engaged in similar business activities as us;
- safety concerns in relation to the use of any of our product candidates or approved products; and/or
- our involvement in significant lawsuits, including patent or stockholder litigation.

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 in more than one transaction, current investors may be materially diluted by subsequent sales. 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 30.5% of our capital stock as of July 31, 2019, of which 3.2% are beneficially owned by our executive officers. 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.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

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 financial statements or identify other areas for further attention or improvement.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2019. However, 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 five years. An independent assessment of the effectiveness of our internal controls could detect 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 the expense of remediation.

***We will incur increased costs now that we are a public company.***

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We have also 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.

***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 revenues of $1.07 billion or more, (ii) the last day of 2023, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

Provisions of our 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.

***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 existing or any future debt agreements 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.

***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 March 2019 follow-on equity offering, our initial public offering as well as other past transactions and any ownership changes that we may experience in the future as a result of subsequent shifts in ownership of our shares of common stock, we may trigger an "ownership change" limitation. We have not completed a formal study to determine if any "ownership changes" within the meaning of IRC Section 382 have occurred. If "ownership changes" within the meaning of Section 382 of the Code have occurred, and if we earn net taxable income, our ability to use our net operating loss carryforwards and research and development tax credits generated since inception to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

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

On December 22, 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 revenues 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 fourth 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.

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

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (d) any action asserting a claim against us governed by the internal affairs doctrine. 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.

**Item 2. Unregistered Sales of Equity and Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

**EXHIBIT INDEX**

| Exhibit No. | Document |
|---|---|
| 10.1 | Executive Employment Agreement, dated as of May 22, 2019, by and between Liquidia Technologies, Inc. and Richard D. Katz, M.D. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on May 22, 2019). |
| 10.2* | First Amendment to Amended and Restated Loan and Security Agreement, dated as of May 21, 2019, by and between Liquidia Technologies, Inc. and Pacific Western Bank. |
| 10.3** | Amendment No.3 to the Inhaled Collaboration and Option Agreement, dated June 24, 2019, by and between Liquidia Technologies, Inc. and Glaxo Group Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 28, 2019). |
| 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 June 30, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets as of June 30, 2019 (unaudited) and December 31, 2018, (ii) Statements of Operations and Comprehensive Loss (unaudited) for the three and six months ended June 30, 2019 and 2018, (iii) Statement of Stockholders' Equity (Deficit) (unaudited) for the six months ended June 30, 2019 and 2018, (iv) Statements of Cash Flows (unaudited) for the six months ended June 30, 2019 and 2018 and (v) Notes to Financial Statements (unaudited). |

* Filed herewith.

** Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

*** In accordance with SEC Release 33-8238, Exhibits 32.1 and 32.2 are being furnished and not filed.

**SIGNATURES**

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**LIQUIDIA TECHNOLOGIES, INC.**

DATE: August 14, 2019

By: /s/Neal Fowler
Neal Fowler
Chief Executive Officer

**LIQUIDIA TECHNOLOGIES, INC.**

DATE: August 14, 2019

By: /s/Richard D. Katz, M.D.
Richard D. Katz, M.D.
Chief Financial Officer

# FIRST AMENDMENT
# TO
# AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

This First Amendment to Amended and Restated Loan and Security Agreement (this "***Amendment***") is made and entered into as of May 21, 2019, by and between PACIFIC WESTERN BANK, a California state chartered bank ("***Bank***"), and LIQUIDIA TECHNOLOGIES, INC. ("***Borrower***").

## RECITALS

Borrower and Bank are parties to that certain Amended and Restated Loan and Security Agreement dated as of October 26, 2018 (as amended from time to time, the "***Agreement***"). The parties desire to amend the Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1) Section 7.8 of the Agreement is hereby amended and restated, as follows:

**7.8 Capitalized Expenditures.** Make Capitalized Expenditures in excess of (a) $2,500,000 in the aggregate during Borrower's fiscal year ending December 31, 2019, or (b) $500,000 in the aggregate in any fiscal year of Borrower thereafter; provided that any unused amount of Capitalized Expenditures in any fiscal year (beginning with Borrower's fiscal year ending December 31, 2019) up to $500,000 may be added to the limitations under this subsection (b) and used by Borrower in the subsequent fiscal year.

2) Bank's notice addresses in Section 10 of the Agreement are hereby amended and restated, as follows:

If to Bank: Pacific Western Bank
406 Blackwell Street, Suite 240
Durham, North Carolina 27701
Attn: Loan Operations Manager
FAX: (919) 314-3080
E-Mail: loannotices@pacwest.com

with a copy to: Pacific Western Bank
406 Blackwell Street, Suite 240
Durham, North Carolina 27701
Attn: Scott Hansen
E-Mail: shansen@pacwest.com

3) Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Agreement. The Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or

remedy of Bank under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement.

4) Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct as of the date of this Amendment.

5) This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

6) As a condition to the effectiveness of this Amendment, Bank shall have received, in form and substance satisfactory to Bank, the following:

   a) this Amendment, duly executed by Borrower;

   b) payment of all Bank Expenses incurred in connection with this Amendment, including Bank's expenses for the documentation of this Amendment and any related documents, and any UCC, good standing or intellectual property search or filing fees (provided that Borrower shall be responsible for no more than $2,500 of such Bank Expenses), which may be debited from any of Borrower's accounts; and

   c) such other documents and completion of such other matters, as Bank may reasonably deem necessary or appropriate.

***[Signature Page Follows]***

IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the first date above written.

**LIQUIDIA TECHNOLOGIES, INC.**

By: /s/ Neal F. Fowler
Name: Neal F. Fowler
Title: Chief Executive Officer

PACIFIC WESTERN BANK

By: /s/ Ashley N. Pittman
Name: Ashley N. Pittman
Title: Senior Vice President

***[Signature Page to First Amendment to Amended and Restated Loan and Security Agreement]***

**Exhibit 31.1**

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

I, Neal 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)) 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) 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

    c) 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: August 14, 2019

By: /s/ Neal Fowler
Name: Neal 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, Richard D. Katz, M.D., 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)) 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) 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

    c) 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: August 14, 2019

By: /s/ Richard D. Katz, M.D.
Name: Richard D. Katz, M.D.
Title: Chief Financial Officer
(Principal Financial Officer)

**Exhibit 32.1**

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

In connection with the Quarterly Report of Liquidia Technologies, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neal 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: August 14, 2019

By: /s/ Neal Fowler
Name: Neal 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 quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard D. Katz, M.D., 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: August 14, 2019

By: /s/ Richard D. Katz, M.D.
Name: Richard D. Katz, M.D.
Title: Chief Financial Officer
(Principal Financial Officer)