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 September 30, 2018

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 **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)

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 and posted 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 October 30, 2018, there were 15,478,286 shares of the issuer's common stock outstanding.

TABLE OF CONTENTS

		Page
Part I	**Financial Information**	
Item 1.	Financial Statements (unaudited)	1
	Balance Sheets as of September 30, 2018 and December 31, 2017	1
	Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017	2
	Statement of Stockholders' Equity (Deficit) for the Nine Months Ended September 30, 2018 and 2017	3
	Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017	5
	Notes to Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	29
Item 3	Quantitative and Qualitative Disclosures About Market Risk	43
Item 4	Controls and Procedures	43
Part II	**Other Information**	45
Item 1.	Legal Proceedings	45
Item 1A.	Risk Factors	45
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	86
Item 3.	Defaults Upon Senior Securities	86
Item 4.	Mine Safety Disclosures	86
Item 5.	Other Information	86
Item 6.	Exhibits	87
	Signatures	88

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 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)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash	$ 47,515,790	$ 3,418,979
Accounts receivable, less allowance of $0 and $48,108, respectively	81,926	1,622,179
Prepaid expenses and other current assets	240,883	443,460
Total current assets	47,838,599	5,484,618
Property, plant and equipment, net	8,230,945	8,243,012
Prepaid expenses and other assets	1,160,839	1,115,972
Total assets	$ 57,230,383	$ 14,843,602
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,907,757	$ 4,424,948
Accrued expenses	1,439,602	2,785,618
Accrued compensation	1,866,872	1,952,505
Accrued interest	59,505	1,408,869
Deferred rent	268,599	268,628
Current portion of capital lease obligations	471,981	469,798
Current portion of deferred revenue	326,700	3,605,199
Current portion of long-term debt	293,274	15,608,349
Total current liabilities	7,634,290	30,523,914
Long-term capital lease obligations	484,017	510,625
Long-term deferred rent	2,458,186	2,612,552
Long-term deferred revenue	8,071,921	5,527,296
Long-term debt	10,726,433	5,556,782
Deferred financing obligation	—	1,341,810
Warrant liabilities	—	2,462,859
Total liabilities	29,374,847	48,535,838
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock — Series A, $0.001 par value, 0 and 1,974,430 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	1,974
Preferred stock — Series A-1, $0.001 par value, 0 and 1,834,862 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	1,835
Preferred stock — Series B, $0.001 par value, 0 and 4,620,123 shares authorized as of September 30, 2018 and December 31, 2017, respectively, 0 and 4,496,908 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	4,497
Preferred stock — Series C, $0.001 par value, 0 and 17,102,578 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	17,103
Preferred stock — Series C-1, $0.001 par value, 0 and 91,000,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively, 0 and 17,556,178 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	17,556
Preferred stock — Series D, $0.001 par value, 0 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	—
Common stock — Class B (non-voting), $0.001 par value, 0 and 330,664 shares authorized as of September 30, 2018 and December 31, 2017, respectively, 0 and 19,645 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	—	20
Common stock — $0.001 par value, 40,000,000 and 175,000,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively, 15,478,286 and 549,952 issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	15,478	550
Additional paid-in capital	185,208,219	79,677,540
Accumulated deficit	(157,368,161)	(113,413,311)
Total stockholders' equity (deficit)	27,855,536	(33,692,236)
Total liabilities and stockholders' equity (deficit)	$ 57,230,383	$ 14,843,602

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues	$ 169,730	$ 1,820,848	$ 2,138,579	$ 5,442,020
Costs and expenses:				
Cost of sales	—	79,940	121,391	239,819
Research and development	7,156,618	6,532,940	20,701,022	17,966,244
General and administrative	2,283,936	3,004,612	6,424,892	8,079,304
Total costs and expenses	9,440,554	9,617,492	27,247,305	26,285,367
Loss from operations	(9,270,824)	(7,796,644)	(25,108,726)	(20,843,347)
Other income (expense):				
Interest income	128,120	—	139,965	268
Interest expense	(636,573)	(4,155,714)	(18,759,078)	(8,323,924)
Derivative and warrant fair value adjustments	106,265	(7,284,256)	277,715	(8,197,356)
Total other income (expense), net	(402,188)	(11,439,970)	(18,341,398)	(16,521,012)
Net loss	(9,673,012)	(19,236,614)	(43,450,124)	(37,364,359)
Other comprehensive loss	—	—	—	—
Comprehensive loss	$ (9,673,012)	$ (19,236,614)	$ (43,450,124)	$ (37,364,359)
Net loss per common share:				
Basic	$ (0.83)	$ (34.91)	$ (10.16)	$ (68.54)
Diluted	(0.84)	(34.91)	(10.27)	(68.54)
Weighted average common shares outstanding:				
Basic	11,606,489	551,097	4,277,554	545,132
Diluted	11,464,459	551,097	4,229,691	545,132

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

Liquidia Technologies, Inc.
Statement of Stockholders' Equity (Deficit)
For the Nine Months Ended September 30, 2018 and 2017
(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)**	**$ (33,692,23**
Cumulative adjustment - adoption of ASC 606	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(504,727)	(504,72
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	51,543	52	—	—	152,352	—	152,40
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	341,314	—	341,31
Issuance of Series D preferred stock, net	—	—	—	—	—	—	—	—	—	—	91,147,482	91,147	—	—	—	—	53,893,361	—	53,984,50
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(27,508,187)	(27,508,18
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)**	**$ (7,226,92**
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	26,635	26	—	—	62,378	—	62,40
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	519,835	—	519,83
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(6,268,924)	(6,268,92
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)**	**$ (12,913,60**
Initial public offering	—	—	—	—	—	—	—	—	—	—	—	—	4,833,099	4,833	—	—	53,159,256	—	53,164,08
Automatic conversion preferred stock and Class B common stock	(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)	9,967,852	9,968	(19,645)	(20)	124,164	—	—
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	28,314	28	—	—	71,810	—	71,83
Exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	20,891	21	—	—	331	—	35
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	864,352	—	864,35
Reclassification of warrant liabilities	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,185,144	—	2,185,14
IPO financing costs	—	—	—	—	—	—	—	—	—	—	—	—		—	—	—	(5,843,618)	—	(5,843,61
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(9,673,012)	(9,673,01
Balance as of September 30, 2018	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**15,478,286**	**$15,478**	**—**	**$ —**	**$185,208,219**	**$(157,368,161)**	**$ 27,855,53**

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

Liquidia Technologies, Inc.
Statement of Stockholders' Equity (Deficit)
For the Nine Months Ended September 30, 2018 and 2017
(Unaudited)

	Preferred Stock												Common Stock				Additional	Related Party Note Receivable		
	Series A		Series A-1		Series B		Series C		Series C-1		Series D		Voting		Class B Nonvoting		Paid-In	from	Accumulated	Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Shareholder	Deficit	(Deficit)
Balance as of December 31, 2016	**1,974,430**	**$ 1,974**	**1,834,862**	**$ 1,835**	**4,496,908**	**$ 4,497**	**17,102,578**	**$17,103**	**17,556,178**	**$17,556**	**—**	**$ —**	**533,593**	**$ 534**	**19,645**	**$ 20**	**$66,025,349**	**$ (55,000)**	**$ (84,259,071)**	**$ (18,245,203)**
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	1,190	1	—	—	5,432	—	—	5,433
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	127,199	—	—	127,199
Beneficial conversion feature on Convertible Notes	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,956,166	—	—	2,956,166
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(9,836,746)	(9,836,746)
Balance as of March 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**	**$17,556**	**—**	**$ —**	**534,783**	**$ 535**	**19,645**	**$ 20**	**$69,114,146**	**$ (55,000)**	**$ (94,095,817)**	**$ (24,993,151)**
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	11,261	11	—	—	72,641	—	—	72,652
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	86,153	—	—	86,153
Repayment of note to related party shareholder	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	55,000	—	55,000
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,290,999)	(8,290,999)
Balance as of June 30, 2017	**1,974,430**	**$ 1,974**	**1,834,862**	**$ 1,835**	**4,496,908**	**$ 4,497**	**17,102,578**	**$17,103**	**17,556,178**	**$17,556**	**—**	**$ —**	**546,044**	**$ 546**	**19,645**	**$ 20**	**$69,272,940**	**$ —**	**$(102,386,816)**	**$ (33,070,345)**
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	—	—	320	1	—	—	1,509	—	—	1,510
Exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	1,188	1	—	—	9,999	—	—	10,000
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	218,661	—	—	218,661
Beneficial conversion feature on Convertible Notes	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	4,935,246	—	—	4,935,246
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(19,236,614)	(19,236,614)
Balance as of September 30, 2017	**1,974,430**	**$ 1,974**	**1,834,862**	**$ 1,835**	**4,496,908**	**$ 4,497**	**17,102,578**	**$17,103**	**17,556,178**	**$17,556**	**—**	**$ —**	**547,552**	**$ 548**	**19,645**	**$ 20**	**$74,438,355**	**$ —**	**$(121,623,430)**	**$ (47,141,542)**

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

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

	Nine Months Ended September 30, 2018	2017
Operating activities		
Net loss	$ (43,450,124)	$ (37,364,359)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,725,501	432,013
Depreciation	1,135,550	674,243
Amortization of discount on long-term debt and convertible notes	17,550,541	6,232,841
Non-cash interest expense	339,504	1,832,323
Derivative fair value adjustment	—	6,613,369
Warrant fair value adjustment	(277,715)	1,583,987
Non-cash rent (income) expense	(154,395)	673,578
Lease incentive	—	1,094,358
Changes in operating assets and liabilities:		
Accounts receivable	1,540,253	(233,518)
Prepaid expenses and other current assets	(88,979)	(10,336)
Other non-current assets	2,270,929	1,176,134
Accounts payable	(1,711,787)	(46,647)
Accrued expenses	(1,000,939)	558,461
Accrued compensation	(85,633)	(517,448)
Deferred revenue	(1,294,682)	(2,327,427)
Net cash used in operating activities	(23,501,976)	(19,628,428)
Investing activities		
Purchases of property, plant and equipment	(769,870)	(1,249,952)
Net cash used in investing activities	(769,870)	(1,249,952)
Financing activities		
Principal payments on capital lease obligations	(480,940)	(274,617)
Proceeds from issuance of convertible notes	—	21,796,168
Proceeds from issuance of long-term debt	—	4,000,000
Refund of principal payments on long-term debt	588,889	—
Principal payments on long-term debt	(2,433,680)	(200,000)
Payments for debt issuance costs	(392,000)	(460,892)
Proceeds from issuance of Series D preferred stock, net of issuance costs	25,106,896	—
Proceeds from initial public offering, net of underwriting fees and commissions	47,320,584	—
Payments for deferred offering costs	(1,628,090)	(76,129)
Proceeds from exercise of stock options and warrants	286,998	144,595
Net cash provided by financing activities	68,368,657	24,929,125
Net increase in cash	44,096,811	4,050,745
Cash, beginning of period	3,418,979	1,438,712
Cash, end of period	$ 47,515,790	$ 5,489,457
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 869,033	$ 183,761
Purchase of equipment with capital leases	$ 456,517	$ 182,151
Changes in purchases of equipment in accounts payable	$ 145,473	$ 999,796
Purchase of build-to-suit asset with deferred financing obligation	$ 272,656	$ 973,585
Reclassification of deferred financing obligation to long-term debt	$ 277,009	$ —
Reclassification of financing costs on deferred financing obligation to discount on long-term debt	$ 1,614,466	$ —
Conversion of accrued interest to long-term debt	$ 106,558	$ 92,504
Recording of warrant liabilities with corresponding discount on convertible notes	$ —	$ 4,474,122
Recording of derivative liabilities with corresponding discount on convertible notes	$ —	$ 9,872,990
Conversion of convertible notes and accrued interest into Series D preferred stock	$ 28,877,498	$ —
Recording of discount on convertible notes as paid-in capital for beneficial conversion feature	$ —	$ 7,891,412
Debt issuance costs incurred but not paid	$ —	$ 75,000
Deferred offering costs incurred but not paid	$ 340,069	$ 1,090,384
Exercise of stock options through exchange of vested stock options	$ 162,156	$ —
Issuance of convertible note for debt issuance costs	$ —	$ 442,356

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 September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 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 nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2018. 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, 2017, which are included in the Company's Registration Statement on Form S-1, as amended (File No. 333-225960).

The Company adopted the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU 2014-09"), *Revenue from Contracts with Customers* ("Topic 606") on January 1, 2018. There have been no other material changes to the Company's significant accounting policies during the nine months ended September 30, 2018, as compared to the significant accounting policies disclosed in Note 2 of the financial statements for the years ended December 31, 2017 and 2016.

Reverse Stock Split

On July 12, 2018 and July 19, 2018, the Company's Board of Directors and stockholders, respectively, approved an amendment to the Company's amended and restated certificate of incorporation effecting a 1-for-16.8273325471348 reverse stock split of the Company's issued and outstanding shares of common stock and convertible preferred stock. The reverse stock split was effective on July 19, 2018. The par value of the common and redeemable convertible preferred stock was not adjusted as a result of the reverse stock split. All issued and outstanding share and per share amounts included in the accompanying financial statements have been adjusted to reflect this reverse stock split for all periods presented.

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 September 30, 2018 and December 31, 2017, the Company determined that Envisia Therapeutics Inc. (“Envisia”) was a variable interest entity (“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 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 $49.4 million, after underwriting discounts but prior to payment of 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.

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 0% and 84% of the Company’s revenues for the three months ended September 30, 2018 and 2017, respectively, 20% and 81% of the Company’s revenues for the nine months ended September 30, 2018 and 2017, respectively, and $0 or 0% and $1.1 million or 69% of the Company’s accounts receivable as of September 30, 2018 and December 31, 2017, respectively.

Revenue Recognition

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("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. Financial information in comparative periods have not been restated and continue to be reported under the accounting methods in effect for that period.

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.

The cumulative effect of the changes made to the January 1, 2018 balance of accumulated deficit on the Balance Sheet for the adoption of Topic 606 was $0.5 million as follows:

	Balance at December 31, 2017	Adjustments Due to Topic 606	Balance at January 1, 2018
Balance Sheet:			
Assets			
Prepaid expenses and other current assets	$ 443,460	$ 10,551	$ 454,011
Prepaid expenses and other assets	1,115,972	45,529	1,161,501
Liabilities			
Current portion of deferred revenue	3,605,199	105,512	3,710,711
Long-term deferred revenue	5,527,296	455,295	5,982,591
Stockholders' equity (deficit)			
Accumulated deficit	(113,413,311)	(504,727)	(113,918,038)

In accordance with the new revenue standard requirements, the impact of adoption on the Statement of Operations and Comprehensive Loss and Balance Sheet was as follows:

	For the Three Months Ended September 30, 2018		
	As Reported	**Balances Without Adoption of Topic 606**	**Effect of Change** Higher/(Lower)
Statement of Operations and Comprehensive Loss:			
Revenues	$ 169,730	$ 919,730	$ (750,000)
Costs and expenses			
Cost of sales	—	75,000	(75,000)
Net loss	(9,673,012)	(8,998,012)	675,000

	For the Nine Months Ended September 30, 2018		
	As Reported	**Balances Without Adoption of Topic 606**	**Effect of Change** Higher/(Lower)
Statement of Operations and Comprehensive Loss:			
Revenues	$ 2,138,579	$ 4,118,228	$ (1,979,649)
Costs and expenses			
Cost of sales	121,391	319,356	(197,965)
Net loss	(43,450,124)	(41,668,440)	1,781,684

	September 30, 2018		
	As Reported	**Balances Without Adoption of Topic 606**	**Effect of Change** Higher/(Lower)
Balance Sheet:			
Assets			
Prepaid expenses and other current assets	$ 240,883	$ 540,883	$ (300,000)
Prepaid expenses and other assets	1,160,839	631,980	528,859
Liabilities			
Current portion of deferred revenue	326,700	3,326,700	(3,000,000)
Long-term deferred revenue	8,071,921	2,783,334	5,288,587
Stockholders' equity (deficit)			
Accumulated deficit	(157,368,161)	(155,308,433)	2,059,728

Segment Data

The Company manages, reports and evaluates its business in the following two segments: Pharmaceutical Products and Partnering and Licensing. The Company's reportable operating segments have been determined in accordance with the

Company's internal management structure, which is organized based on operating activities, the manner in which the Company organizes segments for making operating decisions and assessing performance and the availability of separate financial results. Unallocated operations and corporate expenses, such as depreciation, facilities costs, corporate management costs and interest expense, are represented within Corporate / Operations.

In the fourth quarter of 2018, the Company determined that it will change the way it manages and operates the reporting entity and is in the process of modifying the Company's information system to produce financial information to support the new structure. The changes will require the Company to revise its segment reporting. It is anticipated that the modification to the system will be completed in the fourth quarter of 2018, at which point management will reorganize its operations and reporting structure and begin to manage its operations under its new segment structure.

The segment data is reflected below for three and nine months ended September 30, 2018 and 2017, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Pharmaceutical Products	$ —	$ —	$ —	$ —
Partnering and Licensing	169,730	1,820,848	2,138,579	5,442,020
Total	169,730	1,820,848	2,138,579	5,442,020
Operating (loss) income:				
Pharmaceutical Products	(5,481,289)	(3,832,268)	(14,427,982)	(10,058,345)
Partnering and Licensing	57,399	564,841	1,342,359	1,637,588
Corporate / Operations	(3,846,934)	(4,529,217)	(12,023,103)	(12,422,590)
Total	(9,270,824)	(7,796,644)	(25,108,726)	(20,843,347)
Interest income	128,120	—	139,965	268
Interest expense	(636,573)	(4,155,714)	(18,759,078)	(8,323,924)
Derivative and warrant fair value adjustments	106,265	(7,284,256)	277,715	(8,197,356)
Net loss	$ (9,673,012)	$ (19,236,614)	$ (43,450,124)	$ (37,364,359)

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.

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. Diluted net loss per share is equivalent to basic net loss per share for all years presented herein because common stock equivalent shares from unexercised stock options, outstanding warrants, preferred stock and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive. Due to their dilutive effect, the calculation of diluted net loss per share for the three and nine months ended September 30, 2018 and 2017 does not include the following common stock equivalent shares:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Preferred Stock	—	4,172,437	—	4,172,437
Stock Options	1,642,004	673,684	1,642,004	673,684
Warrants	198,870	235,805	198,870	235,805
Total	1,840,874	5,081,926	1,840,874	5,081,926

For the three and nine months ended September 30, 2018 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 other periods presented, there were no 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 September 30, 2018 and December 31, 2017 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 September 30, 2018 and December 31, 2017:

September 30, 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	$ —	$ 2,136,320	$ —	$ 2,126,422
Pacific Western Bank Tranche II note	—	2,536,270	—	2,538,047
Pacific Western Bank Tranche III note	—	3,381,693	—	3,384,063
CSC build-to-suit equipment financing	—	1,406,093	—	1,206,932
UNC Promissory Note	—	1,764,243	—	1,764,243
Total	$ —	$ 11,224,619	$ —	$ 11,019,707

December 31, 2017	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	$ —	$ 2,512,301	$ —	$ 2,488,572
Pacific Western Bank Tranche II note	—	2,845,194	—	2,820,382
Pacific Western Bank Tranche III note	—	3,793,644	—	3,760,509
UNC Promissory Note	—	2,257,684	—	2,257,684
Convertible notes	—	—	28,702,268	9,837,984
Warrant liabilities	—	—	2,462,859	2,462,859
Total	$ —	$ 11,408,823	$ 31,165,127	$ 23,627,990

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 year-end date, taking into account the remaining term of liabilities.

Warrant Liabilities

The Company has classified warrants to purchase shares of preferred stock as a liability on its Balance Sheets as these warrants were free-standing financial instruments that will require the Company to issue convertible securities upon exercise. The warrants were initially recorded at fair value on date of grant, and were subsequently remeasured to fair value at each reporting period. Changes in fair value of the warrants are recognized as a component of other income (expense) in the Statements of Operations and Comprehensive Loss. In conjunction with the Company's IPO, the warrants were converted to warrants for common stock. Following that conversion, these warrants no longer meet the criteria to be presented as a liability and have been reclassified to additional paid-in capital. The Company will no longer include the warrants as liabilities or recognize changes in their fair value on the Statements of Operations and Comprehensive Loss.

The Company used the Black Scholes option pricing model, which incorporates assumptions and estimates, to value the preferred stock warrants. The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Estimates and assumptions impacting the fair value measurement included the fair value per share of the underlying preferred stock, the remaining contractual term of the warrant, the risk-free interest rate, the expected dividend yield and the expected volatility of the price of the underlying preferred stock. The Company determined the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third party valuations and additional factors that were deemed relevant. The Company estimated its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. Expected dividend yield was based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Embedded Derivatives

Embedded derivatives that are required to be bifurcated from the underlying instrument are accounted for and valued as a separate financial instrument. In conjunction with the Company's convertible notes (see Note 10), embedded derivatives exist associated with the future consummation of a qualified financing event, as defined in the notes, and a subsequent discounted conversion of the instrument to capital stock. The embedded derivatives were bifurcated and classified as derivative liabilities on the Balance Sheets and separately adjusted to their fair values at the end of each reporting period. Changes in fair values of the derivative liabilities are recognized as a component of other income (expense) in the Statements of Operations and Comprehensive Loss. These embedded derivatives were eliminated upon conversion of the underlying convertible notes into Series D preferred stock, $0.001 par value per share ("Series D") (see Note 3).

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 were recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. As of December 31, 2017, the Company recorded deferred offering costs relating to its IPO of $125,000, 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 nine months ended September 30, 2018 and 2017, 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 tax system to a territorial tax system. 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 for five years. The Company has calculated its best estimate of the impact of the TCJA in its income tax provision in accordance with its understanding of the TCJA and guidance available. Using the guidance issued by the SEC staff in Staff Accounting Bulletin No. 118, the Company completed the accounting for the TCJA with the filing of the 2017 U.S. federal income tax return, which had no material impact. The legislative changes effective for the tax year 2018 did not have a material impact on the Company's financial statements.

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 ending 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 February 2016, the FASB issued ASU 2016-02, *Leases (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. Leases with a term of 12 months or less will be accounted for 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, and will be effective for the Company for the year ending December 31, 2019. The Company is currently evaluating the impact that the implementation of this standard will have 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 is evaluating the effect that ASU 2017-11 will have on its financial statements and related disclosures.

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.

3. Common and Preferred Stock

Authorized Capital

As of September 30, 2018, in conjunction with the IPO and the reverse stock split, the authorized capital of the Company was decreased to consist 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 September 30, 2018 the Company had reserved a total of 1,004,297 shares of common stock for issuance under the Liquidia Technologies, Inc. Stock Option Plan, as amended (the "2004 Plan"), 1,355,610 shares of common stock for issuance under the Liquidia Technologies, Inc. 2016 Equity Incentive Plan, as amended (the "2016 Plan"), and 1,600,000 shares of common stock for issuance under the Liquidia Technologies, Inc. 2018 Long-Term Incentive Plan (the "2018 Plan").

During 2017, the Company issued an aggregate of $27.4 million in principal of convertible promissory notes (see Note 10). 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 voting and 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. Each series of preferred stock had anti-dilution protection in the event of a dilutive issuance, as defined in the certificate of incorporation. The Series D bore an 8% per annum noncumulative dividend ($0.0478 per share of Series D) when and if declared. The Series D had a liquidation preference equal to the aggregate of the proceeds and the note conversions, or $54.5 million plus accrued but unpaid dividends, after which holders of Series D participate with all other stockholders in the remainder of liquidation proceeds on an as converted basis. The Series D was senior to all other series of preferred stock.

On July 30, 2018, the Company closed its IPO in which it issued 4,545,455 shares of common stock for net proceeds of $46.5 million, after underwriting discounts but prior to payment of other offering expenses. On August 14, 2018, the underwriters partially exercised the over-allotment option in connection with the IPO, and, as a result, the Company issued an additional 287,644 shares for net proceeds of $2.9 million, after underwriting discounts but prior to 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.

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.

Warrants

In connection with historical private placement offerings, the Company issued warrants to purchase its preferred stock with an exercise term of ten years from the date of issuance. 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, these warrants were automatically converted into warrants to purchase 219,761 shares of common stock. During the three months ended September 30, 2018, 20,891 warrants were exercised resulting in 198,870 warrants outstanding as of September 30, 2018. The exercise price of these warrants is $0.0168 per share.

As of December 31, 2017, there were outstanding warrants for 123,215 shares of Series B that were convertible into warrants for 14,663 shares of common stock at the same time as all outstanding shares of Series B were converted to common stock. These Series B warrants had an exercise price of $3.56 per share and expired on March 28, 2018.

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. This reserve will automatically increase on January 1, 2019 and each subsequent anniversary 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected dividend yield	— %	— %	— %	— %
Risk-free interest rate	2.91% - 3.01 %	1.81 %	2.67% - 3.01 %	1.34% - 1.92 %
Volatility	79 %	78 %	78% - 79 %	77% - 78 %
Expected life	6.25 years	6.25 years	6.25 years	6.25 years
Weighted-average fair value per share	$ 8.33	$ 4.53	$ 8.33	$ 4.53

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
Balance at December 31, 2017	31,192	667,592	$ 4.56
Shares reserved for future issuance	2,579,446	—	
Options granted	(1,196,023)	1,196,023	$ 9.82
RSU's granted	(185,768)	—	$ 10.19
Exercised	—	(106,155)	$ 4.30
Cancelled/expired from 2004 Plan	—	(70,477)	$ 7.37
Cancelled/expired from 2016 Plan	—	(44,979)	$ 9.26
Balance at September 30, 2018	1,228,847	1,642,004	$ 8.33

The following summarizes certain information about stock options vested and expected to vest as of September 30, 2018:

	Number of Options	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price
Outstanding and expected to vest	1,461,885	9.02	$ 8.28
Vested and exercisable	394,713	6.37	$ 4.41

The weighted-average grant date price per share was $9.82 and $20.36 per share for the shares issued during the nine months ended September 30, 2018 and 2017, respectively.

During the nine months ended September 30, 2018, 106,155 stock options were exercised for the purchase of common stock for total cash proceeds of $286,646. The intrinsic value for the options exercised was $1,156,152.

As of September 30, 2018, the intrinsic value of options outstanding and exercisable was $31,178,309. The weighted average remaining contractual term of options outstanding and exercisable is 9.02 years as of September 30, 2018.

During the nine months ended September 30, 2018 and 2017, stock based compensation expense for employee stock option awards totaled $1,725,501 and $432,013, respectively. As of September 30, 2018, there was $7,567,560 of total unrecognized compensation cost related to non-vested stock option grants, which is expected to be recognized over a weighted average period of 2.0 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 nine months ended September 30, 2018. RSUs represent the right to receive shares of common stock of the Company at the end of a specified time period. The RSUs vest over a four-year period similar to stock options. 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.

In connection with the IPO, on July 25, 2018, the Compensation Committee of the Board of Directors approved, under the 2018 Plan, the grants of an aggregate of 310,432 stock options with an exercise price of $11.00 per share and 41,084 RSUs.

5. License Agreements

Liquidia 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, Liquidia 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, Liquidia is obligated to pay UNC royalties equal to a low single-digit percentage of all net sales of Liquidia drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC Letter Agreement. Liquidia 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 we expect to be entitled to in exchange for those services and technology.

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 Liquidia 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. 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. The result of this change will likely be a delay in resumption of research services from when previously estimated. Therefore, there was no impact on the financial statements for the nine months ended September 30, 2018.

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 nine months ended September 30, 2018.

The Company's research, development and licensing agreements provide for multiple promised goods and services to be satisfied by the Company and include a license to the Company's technology in a particular field of study, participation in collaboration committees, performance of certain research and development services and obligations for certain manufacturing services. The transaction price for these contracts includes non-refundable fees and fees for research and development services. Non-refundable up-front fees which may include, for example, an initial payment upon effectiveness of the contractual relationship or payment to secure a right for a future license, are recorded as deferred revenue and recognized into revenue over time as the Company provides the research services under the contract required to advance the products to the point where the Company is able to transfer control of the licensed technology to the customer (''Technology Transfer''). The contract consideration may also include additional non-refundable payments due to the Company based on the achievement of research, development, regulatory or commercialization milestone events. In agreements involving multiple goods or services promised to be transferred to customers, the Company must assess, at the inception of the contract, whether each promise represents a separate performance obligation (i.e., is "distinct"), or whether such promises should be combined as a single performance obligation. As these goods and services are considered to be highly interrelated, they were considered to represent a single, combined performance obligation. The Company includes an estimate of the probable amount of milestone payments to which it will be entitled in the transaction price. The estimate requires evaluation of factors which are outside of the Company's control and significantly limit the Company's ability to achieve the remaining milestone payments. Therefore, the Company has not included any future milestone payments in the transaction price allocated to research, development and licensing agreements as of September 30, 2018. 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 prior to 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 until Technology Transfer is expected to occur.

The estimate of the research services to be provided prior to 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 required to achieve Technology Transfer. 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 expected to be received for research and development services, which are primarily billed quarterly in arrears on a time and materials basis, as the services are performed and collection is reasonably assured.

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.

The following tables represent a disaggregation of revenue by each significant research, development and licensing agreement and payment type for the three and nine months ended September 30, 2018 and 2017:

	Revenue for the Three Months Ended September 30, 2018 From			
	Non-Refundable Payments		Research and Development	
Under Topic 606	Milestones	Up-front Payments	Services	Total
GSK Inhaled	$ —	$ —	$ —	$ —
Other	—	—	169,730	169,730
Total	$ —	$ —	$ 169,730	$ 169,730

	Revenue for the Three Months Ended September 30, 2017 From			
	Non-Refundable Payments		Research and Development	
Under Topic 605	Milestones	Up-front Payments	Services	Total
GSK Inhaled	$ —	$ 750,000	$ 775,618	$ 1,525,618
Gates Foundation	—	36,408	—	36,408
Other	—	49,396	209,426	258,822
Total	$ —	$ 835,804	$ 985,044	$ 1,820,848

Under Topic 606	Revenue for the Nine Months Ended September 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	756,809	1,700,228
Total	$ 45,058	$ 1,168,712	$ 924,809	$ 2,138,579

Under Topic 605	Revenue for the Nine Months Ended September 30, 2017 From			
	Non-Refundable Payments		Research and Development	
	Milestones	Up-front Payments	Services	Total
GSK Inhaled	$ —	$ 2,250,000	$ 2,160,577	$ 4,410,577
Gates Foundation	—	109,223	—	109,223
Other	—	148,203	774,017	922,220
Total	$ —	$ 2,507,426	$ 2,934,594	$ 5,442,020

Transaction Price Allocated to the Remaining Performance Obligations

In December 2017, the Company was made aware of delays and reduced requirements and budget for support for its GSK and G&W Laboratories collaborators and revised its estimate of the remaining estimated period of the performance obligations. As a result, approximately $3.0 million of deferred revenue previously considered current was reclassified to long-term deferred revenue as it was not expected to be recognized within 12 months. As of September 30, 2018, approximately $8.0 million of revenue is expected to be recognized from remaining performance obligations for non-refundable payments. The Company expects to recognize revenue on approximately 0%, 3% and 11% of these remaining performance obligations in 2019, 2020 and 2021 respectively, with the balance recognized thereafter. Revenue from remaining performance obligations for research and development services as of September 30, 2018 was not material.

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. As of September 30, 2018, the balances of these unamortized payments included in current and long-term prepaid expenses and other assets was $0 and $807,192, respectively. As of December 31, 2017, the balances of these unamortized payments under ASC 605 included in current and long-term prepaid expenses and other assets was $319,758 and $552,730, respectively.

7. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

	September 30, 2018	December 31, 2017
Lab and build-to-suit equipment	$ 6,103,074	$ 3,847,546
Grant equipment	1,143,701	1,143,701
Office equipment	123,655	123,655
Furniture and fixtures	205,051	205,051
Computer equipment	709,266	677,569
Leasehold improvements	8,757,291	7,218,687
Construction-in-progress	128,061	2,830,407
Total property, plant and equipment	17,170,099	16,046,616
Accumulated depreciation	(8,939,154)	(7,803,604)
Property, plant and equipment, net	$ 8,230,945	$ 8,243,012

The Company recorded depreciation expense of $409,617 and $226,647 for the three months ended September 30, 2018 and 2017, respectively, and $1,135,550 and $674,243 for the nine months ended September 30, 2018 and 2017, 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 Pharmaceutical Products. 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.

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. As of September 30, 2018, the net book value of the build-to-suit asset was $1,479,927 and $1,206,932 was also recorded as long-term debt (see Note 10). As of December 31, 2017, $1,341,810 was recorded in construction-in-progress with an equal deferred financing obligation.

8. Related-Party Transactions

Envisia

For shared services provided by Liquidia to Envisia, Liquidia recorded $0 and $2,080, respectively, for sharing of patent costs as a reduction of Research and Development Expenses in the accompanying Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2018 and 2017, respectively.

CEO Loan

In September 2016, the Company's Chief Executive Officer entered into a loan agreement with the Company to finance the exercise of stock options to purchase 29,713 shares of common stock for $94,271. Interest accrued at 1.00% per annum. This loan receivable was recorded in the Company's 2016 Balance Sheet at that date as a $55,000 offset to stockholders' equity (deficit). The note receivable was repaid in full in 2017.

9. Commitments and Contingencies

Operating Leases

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 September 30, 2018.

These allowance amounts were recorded as a long-term deferred rent liability and amortized as a reduction in rent expense over the remaining term of the lease. The balance of all unamortized deferred rent and allowances totaled $2,726,785 and $2,881,180 as of September 30, 2018 and December 31, 2017, respectively.

In October 2018, the Company signed a non-binding letter of intent to expand the lease of its primary building 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.

The Company also leases copier equipment under an operating lease, which expires in 2019.

Capital Leases

The Company leases specialized lab equipment under leases classified as capital leases. The related capitalized assets are amortized on a straight-line basis over the estimated useful life of the asset. The interest rates related to these lease obligations range from 0.2% to 12.2%.

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 to be paid upon first dosing of the first patient in the Phase 3 clinical trial, and $300,000 due no later than December 31, 2018. In addition, the Company also agreed to pay future contingent royalties on net sales totaling no more than $1,500,000. As of September 30, 2018 and December 31, 2017, $300,000 and $380,000 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 Liquidia 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 is $404,407, which was recorded in March to Research and Development Expense in the accompanying Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2018. No further employee severance expense is planned related to this matter.

10. Long-Term Debt

Long-term debt consisted of the following as of:

	Maturity Date	September 30, 2018	December 31, 2017
Pacific Western Bank Tranche I note	December 8, 2019	$ 2,126,422	$ 2,488,572
Pacific Western Bank Tranche II note	October 10, 2020	2,538,047	2,820,382
Pacific Western Bank Tranche III note	October 10, 2020	3,384,063	3,760,509
UNC Promissory Note	December 31, 2018	1,764,243	2,257,684
Convertible notes, net of discounts	December 31, 2018	—	9,837,984
CSC build-to-suit equipment financing, net of discount	February 28, 2021	1,206,932	—
Less current portion		(293,274)	(15,608,349)
Long-term debt, less current portion		$ 10,726,433	$ 5,556,782

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 upon the full enrollment of the LIQ861 Phase 3 clinical trial, provided that we have not observed 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 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”). As the existing current debt was refinanced with long-term debt subsequent to the balance sheet date but prior to the issuance of this report on Form 10-Q, the Company moved the current portion of the existing long-term debt to long-term debt.

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 and the Company has publicly disclosed its safety data analysis for LIQ861 with no materially adverse data observed. 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.

CSC Build-To-Suit Equipment Financing

See Note 7 for further discussion of the background of the equipment financing (“CSC Financing”). The CSC Financing 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.

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%. The balance of the promissory note at September 30, 2018 and December 31, 2017 was $1,764,243 and $2,257,684, respectively. 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 continue 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.

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 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 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 September 30, 2018 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 nine months ended September 30, 2018 and 2017 are summarized below:

	Nine Months Ended September 30,	
	2018	2017
Fair value, beginning of period	$ 2,462,859	$ —
Issuance of warrants	—	4,474,122
Change in fair value	(277,715)	1,583,987
Transfer to additional paid-in capital	(2,185,144)	—
Fair value, end of period	$ —	$ 6,058,109

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

Accounting for the Derivative Liabilities

Management determined that the various conversion features discussed above represent, in substance, a put option (redemption feature) designed to provide the investor with a fixed monetary amount, settled in shares. Management determined that this put option and the contingent interest should be separated from the notes and accounted for as a compound derivative liability primarily because the notes were issued at a substantial discount because the warrants, put option, and the contingent interest meet the net settlement criterion. The compound derivative liabilities were initially recorded as derivative liabilities on the Balance Sheets and a corresponding discount to the notes. As the estimated fair value of the derivative liabilities was $0 at December 31, 2017 and did not change in value as of September 30, 2018, no fair value adjustment was recorded for the nine months ended September 30, 2018. The change in the estimated fair value of the derivative liabilities for the nine months ended September 30, 2017 resulted in a fair value adjustment and is included in Derivative and Warrant Fair Value Adjustments in the Statements of Operations and Comprehensive Loss.

Changes in the values of the derivative liabilities for the nine months ended September 30, 2018 and 2017 are summarized below:

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Fair value, beginning of period	$ —	$ —
Issuance of derivatives	—	9,872,990
Change in fair value	—	6,613,368
Fair value, end of period	$ —	$ 16,486,358

Assumptions Used in Determining Fair Value of Compound Bifurcated Derivative

The Company assessed the accounting for the convertible notes and determined that there were several embedded derivatives that required bifurcation from the host debt instrument at fair value in accordance with ASC 815, *Derivatives and Hedging.* These embedded derivatives are more like equity instruments, and thus not "clearly and closely related" to the economic characteristics of the convertible notes. Further, they were determined not to meet the definition of being indexed to the Company's own stock due to the variable number of shares to be converted under different scenarios. When a host instrument has multiple embedded derivative features that require bifurcation, ASC 815 requires that they be bundled as one and accounted for separately from the convertible notes at fair value.

To determine the fair value of such derivatives, the Company compared (1) the expected payout from the different conversion scenarios upon their expected date of occurrence, discounted to present value at a risk-free rate, to (2) the fair value of the convertible notes if it were paid in cash or converted into Series C-1 on December 31, 2017. The difference between these two results represents the fair value of the bundled derivative.

First, the Company estimated the expected payout under the various conversion scenarios. The principal and accrued interest on the convertible notes were calculated through the expected payout date, and divided by the stated conversion price discount to determine the amount that would be paid upon occurrence of the event. The payoff from each scenario was then discounted to present value at the risk-free rate and the Company probability-weighted each scenario to arrive at the expected payout value for purposes of the valuation. Next, it was assumed that if conversion under the certain financing scenarios did not occur by December 31, 2017, it would be most advantageous for the investors to convert the convertible notes into Series C-1 or request payment of principal and interest in cash. The value of the convertible notes under these scenarios was modeled using the OPM. The difference between the payout value under the various conversion scenarios and the value of the convertible notes under the OPM, assuming the convertible notes are not converted or paid until December 31, 2017, results in the fair value of the bundled derivative.

Accounting for the Beneficial Conversion Feature

The Company did not separate from the notes the conversion feature in which the holders may convert the principal and interest on the notes into shares of the Company's Series C-1 at $0.59808 per share if a qualified financing, as defined in the notes, had not occurred prior to December 31, 2017. The Company concluded that this conversion feature is a beneficial conversion feature that should be recognized separately and measured initially at its intrinsic value. Since the intrinsic value of this beneficial conversion feature is greater than the proceeds allocated to the notes, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the proceeds allocated to the notes. The Company recorded the beneficial conversion feature of $2,956,166, $4,935,246, and $5,150,000 as additional paid in capital upon issuance of the respective convertible notes and a corresponding discount to the notes on the Balance Sheet for the January and February Notes, July Notes and November Notes, respectively.

Scheduled annual maturities of long-term debt as of September 30, 2018 are as follows:

Year ending December 31:		
2018 - (three months remaining)	$	2,972,164
2019		4,868,840
2020		2,993,363
2021		410,660
Total		11,245,027
Less: Unamortized discount		(199,161)
Less: Unamortized debt issuance costs		(26,159)
Less: Current portion of long-term debt		(293,274)
	$	10,726,433

The schedule by year reflects maturities prior to the refinancing on October 26, 2018 that is discussed above.

11. Subsequent Events

In October 2018, the Company signed a non-binding letter of intent to expand the lease of its primary building by 8,264 additional square footage expiring October 31, 2026 in exchange for terminating another lease the Company has with the same landlord for 4,400 noncontiguous square feet (see Note 9).

On October 26, 2018, the Company and Pacific Western entered into the A&R LSA in which the Company received an initial tranche of $11.0 million to extinguish its current debt under the LSA, repay in full the outstanding indebtedness under the UNC Promissory Note and for general corporate purposes (see Note 10).

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				2-week safety data 1Q:19	Liquidia
LIQ865	Local, post-operative pain	Sustained-release injectable				Ph2-enabling studies commencing 4Q:18	Liquidia

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

LIQ861

Our lead product candidate, LIQ861, is being evaluated in a single, 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 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, 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.

As of October 24, 2018, 109 patients have enrolled in our INSPIRE trial and we have completed enrollment for the safety portion of the trial. We are currently focusing our efforts on completing patient enrollment in our one-directional crossover sub-study to compare bioavailability and pharmacokinetics of treprostinil as the patients transition from Tyvaso to LIQ861. The primary objective of the INSPIRE study is to evaluate the long-term safety and tolerability of LIQ861. The INSPIRE study is designed to evaluate patients who have either been under stable treatment with 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. Our first patient was enrolled in the INSPIRE trial on March 15, 2018. Of the total enrolled patient population, as of October 24, 2018, 104 patients have received at least two weeks of LIQ861. We expect to report 2-week safety data in the first quarter of 2019 followed by pharmacokinetics results for the sub-study anticipated in the second quarter of 2019. 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.

We intend to conduct an additional clinical trial that explores the hemodynamic effects of LIQ861 in PAH patients. Although the FDA has not requested that we undertake this clinical trial, the data may help assess the effects of LIQ861 on acute and chronic hemodynamic measurements and right heart function. Data from this clinical trial would also add to our understanding of safety, tolerability and pharmacokinetics of LIQ861. We expect to enroll our first patient in this additional clinical trial in the first quarter of 2019.

We intend to conduct additional clinical work in support of our marketing and commercial activities in advance of our U.S. launch for LIQ861.

LIQ865

Our second product candidate, LIQ865, for which we have completed a Phase 1b clinical trial, is being evaluated as a potential treatment for local post-operative pain. LIQ865 is our proprietary injectable, sustained-release formulation of bupivacaine, a non-opioid pain medicine. 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, which we believe, if approved, has the potential to provide significantly longer post-operative pain relief compared to currently marketed formulations of bupivacaine. We completed a Phase 1a clinical trial in Denmark in March 2017 and a Phase 1b clinical trial in the United States in April 2018, both of which supported continued development of LIQ865. We expect to initiate Phase 2-enabling toxicology studies for LIQ865 in the fourth quarter of 2018.

In addition to developing our two current product candidates, we license our PRINT technology to leading pharmaceutical companies seeking to develop their own potential drug and biologic therapies. 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 manufacture them using in-house capabilities. Where appropriate, we will rely on third-party contract manufacturing organizations, or CMOs, to produce, package and distribute our approved drug products on a commercial scale.

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, convertible promissory notes, $10.0 million in term loans from a bank and a $2.1 million loan from The University of North Carolina at Chapel Hill, or UNC. We do not expect to generate significant product revenue unless and until we obtain marketing approval for and commercialize LIQ861, LIQ865 or one of our other future product candidates.

Since our inception, we have incurred significant operating losses. Our net loss was $43.5 million and $37.4 million for the nine months ended September 30, 2018 and 2017, respectively, and $29.2 million and $15.9 million for the years ended December 31, 2017 and 2016, respectively, and as of September 30, 2018, we had an accumulated deficit of $157.4 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, and 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.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

As of September 30, 2018, we had cash of $47.5 million. We believe that our existing cash together with funds available under the A&R LSA (as defined below), will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter 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. See “Liquidity and Capital Resources.”

Our Collaborations

Our only revenue, which has been derived from collaborating and licensing our proprietary PRINT technology to pharmaceutical companies, amounted to $2.1 million and $5.4 million for the nine months ended September 30, 2018 and 2017, respectively. GlaxoSmithKline plc, or GSK, accounted for $0.4 million and $4.4 million for the nine months ended September 30, 2018 and 2017, respectively, or 20% and 81%, respectively, of our total revenue. Our collaborators make up-front fees or technology access payments, pay us to achieve clinical milestones, pay us fees to develop their drug products through research and development services like particle formulation and manufacturing and will pay us royalties upon ultimate commercial sales of the related products.

GSK

We have actively collaborated with GSK on the use of our PRINT technology in respiratory disease since 2012.

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 is 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 are expected to be performed, a period of 96 months as of September 30, 2018. 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 under the GSK ICO Agreement. Revenues from research and development services under the GSK ICO Agreement amounted to $0.2 million and $2.2 million for the nine months ended September 30, 2018 and 2017, respectively.

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, we expect revenues from research and development services under the GSK ICO Agreement to be less than $250,000 during 2018. In response, in January 2018, we reduced our research and development workforce accordingly, and incurred approximately $400,000 in expense relating to the workforce reduction.

We also entered into other engagements with GSK under the GSK ICO Agreement, primarily for platform research services. GSK has been conducting a Phase 1 clinical trial of an inhaled chronic obstructive pulmonary disease, or COPD, product candidate that is formulated as an inhaled dry powder using the PRINT technology. In June 2018, GSK notified us of its intention to review continuation of development of an inhaled antiviral for viral exacerbations in 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. GSK continues to express an interest in using PRINT technology for new inhaled programs, though no specific assets have been identified at this time. We and GSK are actively negotiating rights for us to develop and commercialize additional inhaled programs.

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 are expected to be performed, a period of 57 months as of September 30, 2018. 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 nine months ended September 30, 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.

Gates Foundation

In 2011, we entered into a collaboration agreement with the Bill & Melinda Gates Foundation, primarily for research services related to developing vaccines targeted at developing markets. We received an up-front fee of $1.0 million under this agreement, which we recognized as revenue through December 2017. We are not performing any services under this collaboration agreement and do not expect to recognize any further revenue under the agreement.

Components of Statements of Operations

Revenue

Our revenue is primarily 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. We report financial information in the following two business segments:

> **Pharmaceutical Products.** We utilize our proprietary PRINT technology to develop novel product candidates, such as LIQ861 and LIQ865. We have not commenced the commercialization of any pharmaceutical products and have not recognized any product revenues to date for this business segment. We intend to commercialize LIQ861 independently in the United States and to evaluate our commercialization and development plans for LIQ865. Outside of the United States, we intend to pursue the regulatory approval and commercialization of LIQ861 and LIQ865 with leading pharmaceutical companies with regional expertise. Revenues from these licensing arrangements would be recognized in this segment. In addition, if LIQ861 or LIQ865 is approved for marketing, we expect to recognize any revenues from sales of that product in this segment.

> **Partnering and Licensing.** We also utilize our proprietary PRINT technology to enable the development of product candidates by other pharmaceutical companies. We perform research and development services for third parties in the areas of particle formulation and manufacturing and charge market billing rates. We typically receive up-front fees or technology access payments, as well as milestone payments for each phase of clinical achievement. If any of these drug products achieve commercialization, we also expect to be eligible to receive royalties from sales of those drug products. For the three and nine months ended September 30, 2018

and 2017, all of our revenue from our license and collaboration agreements described above was part of our Partnering and Licensing segment.

In the fourth quarter of 2018, we determined that we will change the way we manage and operate the reporting entity and we are in the process of modifying our information system to produce financial information to support the new structure. The changes will require us to revise our segment reporting. It is anticipated that the modification to the system will be completed in the fourth quarter of 2018, at which point management will reorganize its operations and reporting structure and begin to manage its operations under its new segment structure.

For the three and nine months ended September 30, 2018 and 2017, a substantial amount of our revenue from collaborating and licensing our proprietary PRINT technology to pharmaceutical companies was derived from the GSK ICO Agreement. This arrangement with GSK accounted for $0.4 million and $4.4 million in revenue for the nine months ended September 30, 2018 and 2017, respectively, representing 20% and 81% of our total revenue for the nine months ended September 30, 2018 and 2017, respectively. This revenue comprised billings for research and development services, milestone payments and amortization of deferred revenue from up-front payments.

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 of LIQ861, continue the development of LIQ865, conduct additional clinical trials, continue manufacturing process development and scale up and prepare for regulatory filings for our product candidates and regulatory inspection of facilities utilizing our PRINT manufacturing process.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

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

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

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include 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 general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and the U.S. Securities and Exchange Commission, or SEC, requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. We anticipate the additional costs for these services will increase our general and administrative expenses by approximately $1.5 million to $2.0 million on an annual basis. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to 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 expense consists of interest charges on capital leases and long-term 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 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 September 30, 2018 Compared to Three Months Ended September 30, 2017

The following table summarizes our results of operations:

	Three Months Ended September 30,	
	2018	2017
	(in thousands)	
Revenues	$ 170	$ 1,821
Costs and expenses:		
Cost of sales	—	80
Research and development	7,157	6,533
General and administrative	2,284	3,005
Total costs and expenses	9,441	9,618
Loss from operations	(9,271)	(7,797)
Other income (expense):		
Interest income	128	—
Interest expense	(636)	(4,156)
Derivative and warrant fair value adjustments	106	(7,284)
Total other income (expense)	(402)	(11,440)
Net loss	$ (9,673)	$ (19,237)

Revenues

Revenues were $0.2 million for the three months ended September 30, 2018, compared to $1.8 million for the three months ended September 30, 2017. The decrease of $1.6 million, or 88.9%, was due to lower research and development services performed, coupled with the adoption of Accounting Standards Codification, or ASC, 606, *Revenue from Contracts with Customers*, or ASC 606. Our revenues attributable to the GSK ICO Agreement were $0 during the three months ended September 30, 2018. Under the GSK ICO Agreement, we received an up-front payment of $15.0 million in 2015, which was being recognized as revenue over a period of approximately seven years. Effective January 1, 2018, we adopted ASC 606. In addition, management revised the estimated performance periods under our collaboration agreements to reflect the current circumstances such that the weighted average time period over which management was recognizing revenue related to up-front and milestone payments was initially increased from approximately 29 months to approximately 96 months. Revenue related to up-front payments is recognized ratably to the extent that research and development services are performed. The combined effect of the adoption of ASC 606 and no revenues for research and development services earned during the period results in a decrease in revenue recognized from non-refundable up-front payments for the three months ended September 30, 2018 by $0.8 million as compared to the three months ended September 30, 2017. In addition, we performed research and development services for other customers resulting in revenues of $0.2 million for such services during the three months ended September 30, 2018 as compared to $1.0 million during the three months ended September 30, 2017.

Cost of Sales

Our cost of sales was $0 for the three months ended September 30, 2018, compared to $79,940 for the three months ended September 30, 2017. 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. This amount was attributable to our Partnering and Licensing segment.

Research and Development Expenses

Our research and development expenses were $7.2 million for the three months ended September 30, 2018, compared to $6.5 million for the three months ended September 30, 2017. The increase of $0.7 million, or 10.8%, was primarily due to the ongoing Phase 3 clinical trial of LIQ861 which commenced in late December 2017. Research and development expenses consisted of $5.4 million from the Pharmaceutical Products segment, of which $5.3 million and $0.1 million were attributable to our ongoing development of LIQ861 and LIQ865, respectively, $0.1 million from the Partnering and Licensing segment, and $1.6 million from general research and development that was not directly related to a particular segment.

General and Administrative Expenses

Our general and administrative expenses were $2.3 million for the three months ended September 30, 2018, compared to $3.0 million for the three months ended September 30, 2017. The decrease of $0.7 million, or 23.3%, was primarily due to costs of an abandoned equity offering being expensed during the three months ended September 30, 2017. General and administrative expense 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 $9.3 million for the three months ended September 30, 2018, compared to $7.8 million for the three months ended September 30, 2017. The increase of $1.5 million, or 19.2%, was primarily due to a decrease in revenues and an increase in research and development expenses, partially offset by a decrease in general and administrative expenses during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017.

Other Income (Expense)

Interest income was $128,119 for the three months ended September 30, 2018, compared to $0 for the three months ended September 30, 2017.

Interest expense was $0.6 million for the three months ended September 30, 2018, compared to $4.2 million for the three months ended September 30, 2017. The decrease in interest expense of $3.6 million, or 85.7% was primarily due to lower levels of debt during the three months ended September 30, 2018 as a result of 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 $0.1 million for the three months ended September 30, 2018, compared to expense of $7.3 million for the three months ended September 30, 2017. The increase of $7.4 million was primarily due to an overall decline in value of the warrant liabilities and the conversion of the warrants to warrants for common stock at the time of the initial public offering.

Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

The following table summarizes our results of operations:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Revenues	$ 2,138	$ 5,442
Costs and expenses:		
Cost of sales	121	240
Research and development	20,701	17,966
General and administrative	6,425	8,079
Total costs and expenses	27,247	26,285
Loss from operations	(25,109)	(20,843)
Other income (expense):		
Interest income	140	—
Interest expense	(18,759)	(8,324)
Derivative and warrant fair value adjustments	278	(8,197)
Total other income (expense)	(18,341)	(16,521)
Net loss	$ (43,450)	$ (37,364)

Revenues

Revenues were $2.1 million for the nine months ended September 30, 2018, compared to $5.4 million for the nine months ended September 30, 2017. The decrease of $3.3 million, or 61.1%, was due to lower research and development services performed, coupled with the adoption of ASC 606. Our revenues attributable to the GSK ICO Agreement were $0.4 million during the nine months ended September 30, 2018. Under the GSK ICO Agreement, we received an up-front payment of $15.0 million in 2015, which was being recognized into revenue over a period of approximately seven years. Effective January 1, 2018 we adopted ASC 606. In addition, management revised the estimated performance periods under our collaboration agreements to reflect the current circumstances such that the weighted average time period over which management was recognizing revenue related to certain up-front and milestone payments was initially increased from approximately 29 months to approximately 96 months. Revenue related to up-front payments is recognized ratably to the extent that research and development services are performed. These changes were partially offset by the full acceleration of revenue recognition of $0.9 million related to the mutual termination of the G&W Labs Agreement in April 2018. The combined effect of adoption of ASC 606 and acceleration of revenue recognition related to the G&W Labs Agreement was a decrease in revenue recognized from non-refundable up-front payments for the nine months ended September 30, 2018 by $1.3 million as compared to the nine months ended September 30, 2017. In addition, we performed research and development services resulting in revenues of $1.0 million for such services during the nine months ended September 30, 2018 as compared to $2.9 million during the nine months ended September 30, 2017.

Cost of Sales

Our cost of sales was $0.1 million for the nine months ended September 30, 2018, compared to $0.2 million for the nine months ended September 30, 2017. 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. This amount was attributable to our Partnering and Licensing segment.

Research and Development Expenses

Our research and development expenses were $20.7 million for the nine months ended September 30, 2018, compared to $18.0 million for the nine months ended September 30, 2017. The increase of $2.7 million, or 15.0%, was due to the commencement of the Phase 3 clinical trial of LIQ861 in late December 2017. Research and development expenses consisted of $14.4 million from the Pharmaceutical Products segment, of which $14.0 million and $0.5 million were attributable to our ongoing development of LIQ861 and LIQ865, respectively, $0.8 million from the Partnering and Licensing segment, and $5.5 million from general research and development that was not directly related to a particular segment.

General and Administrative Expenses

Our general and administrative expenses were $6.4 million for the nine months ended September 30, 2018, compared to $8.1 million for the nine months ended September 30, 2017. The decrease of $1.7 million or 21.0% was primarily due to the deferral of equity offering costs during the nine months ended September 30, 2018 as compared to similar costs being expensed during the nine months ended September 30, 2017 for an abandoned equity offering. General and administrative expense 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 $25.1 million for the nine months ended September 30, 2018, compared to $20.8 million for the nine months ended September 30, 2017. The increase of $4.3 million, or 20.7%, was primarily due to a decrease in revenues and an increase in research and development expenses, partially offset by a decrease in general and administrative expenses during the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017.

Other Income (Expense)

Interest income was $139,965 for the nine months ended September 30, 2018 compared to $268 for the nine months ended September 30, 2017.

Interest expense was $18.8 million for the nine months ended September 30, 2018, compared to $8.3 million for the nine months ended September 30, 2017. The increase in interest expense of $10.5 million, or 126.5%, was primarily due to amortization of discounts on convertible notes of $17.6 million during the nine months ended September 30, 2018 as compared to $6.2 million during the nine months ended September 30, 2017. The unamortized discounts on convertible notes was being amortized through the maturity date of the notes, which was December 31, 2018. The amortization was accelerated by the early conversion of the notes into Series D preferred stock in February 2018.

Derivative and warrant fair value adjustments resulted in income of $0.3 million for the nine months ended September 30, 2018, compared to expense of $8.2 million for the nine months ended September 30, 2017. The increase of $8.5 million, or 103.7% was primarily due to an overall decline in value of the warrant liabilities and the conversion of the warrants 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 September 30, 2018, we have no outstanding material commitments for capital expenditures. We monitor our net operating cash flow and maintain a level of cash deemed adequate by our management for working capital purposes.

As of September 30, 2018, we had stockholders' equity of $27.9 million and an accumulated deficit of $157.4 million. Our cash balance was $47.5 million as of September 30, 2018.

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. As of September 30, 2018, we had fully utilized our 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 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 loan and security agreement related to cash levels and reporting requirements. PWB has provided waivers in relation to all such prior breaches.

On October 26, 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 current debt of $8.0 million under the LSA, repay in full the 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 upon the full enrollment of the LIQ861 Phase 3 clinical trial, provided that we have not observed 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 tiered by tranche totaling between $187,000 and $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 million in the event the Financing Condition is met and we publicly disclose our safety data analysis for LIQ861 with no materially adverse data observed.

The A&R LSA with PWB 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 the nine months ended September 30, 2018, we had outstanding a promissory note to UNC, or the UNC Promissory Note. As of September 30, 2018, the outstanding balance of this note payable was $1.8 million. 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, on August 2, 2018 we made a payment to UNC of $600,000. 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 on October 26, 2018.

In a series of closings from January 9, 2017 to November 29, 2017, we issued and sold an aggregate of $27.4 million underlying a total of 27 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 this offering, 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 which resulted in net proceeds of $46.5 million, after underwriting discounts but prior to payment of other offering expenses. On August 14, 2018, the underwriters partially exercised the over-allotment option in connection with the initial public offering, and, as a result, we issued an additional 287,644 shares for net proceeds of $2.9 million, after underwriting discounts but prior to payment of other offering expenses.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (23,502)	$ (19,628)
Investing activities	(770)	(1,250)
Financing activities	68,369	24,929
Net increase in cash	$ 44,097	$ 4,051

Operating Activities

Net cash used in operating activities increased $3.9 million, from $19.6 million for the nine months ended September 30, 2017 to $23.5 million for the nine months ended September 30, 2018. The increase was mainly due to the increase 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 nine months ended September 30, 2018, the net cash used in operating activities was $23.5 million, which was comprised of operating cash outflows before working capital changes of $23.1 million and net working capital outflows of $0.4 million.

Investing Activities

Net cash used in investing activities decreased $0.4 million from $1.2 million for the nine months ended September 30, 2017 to $0.8 million for the nine months ended September 30, 2018. The decrease was due to decreased purchases of property, plant and equipment.

Financing activities

Net cash provided by financing activities increased $43.5 million from $24.9 million for the nine months ended September 30, 2017 to $68.4 million for the nine months ended September 30, 2018. This increase was primarily due to net proceeds from the sale of Series D preferred stock of $25.1 million, net proceeds from the initial public offering of $47.3 million, a refund of principal payments of $0.6 million and proceeds from the exercise of stock options of $0.2 million. These inflows were partially offset by principal payments on debt of $2.9 million and financing costs.

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, requires 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 existing cash position together with additional funding from the A&R LSA will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2019, including the completion of our ongoing Phase 3 clinical trial for LIQ861 and the initiation of our Phase 2-enabling toxicology studies in 2018 for LIQ865. 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 pharmaceutical drugs, 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 nine months ended September 30, 2018 or in the years ended December 31, 2017, 2016 and 2015.

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 September 30, 2018. 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 September 30, 2018, 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 September 30, 2018 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 $43.5 million for the nine months ended September 30, 2018, and $29.2 million and $15.9 million for the years ended December 31, 2017 and 2016, respectively. We also had negative operating cash flows in the nine months ended September 30, 2018, and for the years ended December 31, 2017 and 2016, in addition to negative working capital at December 31, 2017. As of September 30, 2018 and December 31, 2017, we had an accumulated deficit of $157.4 million and $113.4 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 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 we expect to initiate Phase 2-enabling toxicology studies for LIQ865 in the fourth quarter of 2018. We cannot assure you that our clinical trials, if commenced, will be successful or meet their endpoints.

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 leading pharmaceutical companies, including GSK, to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. We have not obtained marketing approval for any of our product candidates and, accordingly, have not demonstrated an ability to generate revenue from 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 nine months ended September 30, 2018 and the year ended December 31, 2017 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.

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 near-term revenue from GSK.

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, or the GSK VCO Agreement, which lapsed in April 2016. We have historically received a significant portion of our revenue from GSK pursuant to these licensing agreements. For the nine months ended September 30, 2018 and 2017, 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 20% and 81%, respectively, of our total revenue. For the years ended December 31, 2017 and 2016, our revenue attributable to our collaboration and licensing arrangements with GSK accounted for 84% and 90%, respectively, of our total revenue.

GSK has recently informed us of changes to its plans with respect to the GSK ICO Agreement that we expect will materially affect the amounts we will receive from GSK under this agreement for the year ending December 31, 2018. 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 nine months ended September 30, 2018. We do not expect to receive additional revenues from GSK during the remainder of fiscal year 2018 as a result of GSK's modified plans. 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 COPD under 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 expenses directly associated with the COPD program. GSK continues to express an interest in using PRINT technology for new inhaled programs, though no specific assets have been identified at this time.

As a result of these changes, we do not expect to receive any near-term revenue from GSK from our collaboration and licensing arrangements. We do not expect to generate comparable revenue from our other existing or future collaboration and licensing agreements in the near term, and we do not know if GSK will initiate development of a new program that will generate comparable revenue. In the event there are any further modifications to these arrangements, including if GSK exercises its right to terminate the ICO Agreement in its entirety or in respect of a particular product, or if GSK makes further changes to any existing development plans with us, we may not recognize the potential benefits of this collaboration.

Our credit facility with 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, or A&R LSA, with PWB, pursuant to which PWB extended a $11.0 million term loan facility to us, 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 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. Our facility with PWB is secured 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 approved products 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, has recently 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. On September 4, 2018 United Therapeutics Corporation, or United Therapeutics, and MannKind announced that they entered into a 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. This new collaboration may accelerate competition for our product candidate 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. each have products in the pipeline that are potential competitors to LIQ865, which are estimated to enter the market in 2018 or 2019, and generic equivalents of EXPAREL may enter the market following the expiry of EXPAREL's patent in 2018. 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.

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 will continue to collaborate, with, among others, pharmaceutical companies such as GSK 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 non-U.S. regulatory authorities, we intend to enter into strategic relationships with international collaborators for the commercialization of such products outside of the United States.

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 approved products, 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, including GSK, may have significant discretion in determining the efforts and resources that they will contribute;
- our collaborators, including GSK, 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);
- 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, the G&W Labs Agreement 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, device, and encapsulation and packaging for 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, LGM Pharma, LLC, or LGM Pharma, for treprostinil, the active pharmaceutical ingredient of LIQ861. If LGM Pharma 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, Xcelience LLC, of 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 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 for 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 those in senior management, including Neal Fowler, our Chief Executive Officer, and Kevin Gordon, our President and Chief Financial 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 expose us to governmental investigations, other regulatory action or lawsuits. 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;
- 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 approved drug products 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 that 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 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 such as GSK to develop drug products. 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. A claim by the applicant that a patent is invalid or will not be infringed is subject to challenge by the patent holder, requirements may give rise to patent litigation and mandatory 30-month delays in approval of a 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 makes 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 PRINT technology and products based on it, including LIQ861 and, to a lesser degree, LIQ865. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize drugs using our novel delivery system. We may never receive approval to market and commercialize any product candidate that uses our PRINT technology.

Manufacturing facilities and processes utilizing our PRINT technology have not been the subject of FDA manufacturing inspections and we cannot assure you that our PRINT technology or any product candidate made using the PRINT technology will satisfy the FDA requirements for approval.

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;
- 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 the Phase 3 clinical trial 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 approval 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 the 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, and may, in the future, conduct the 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 the 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.

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 the 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 such as GSK to develop drug products. 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 approved drug products 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 drugs 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 to 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 any 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 approved drug products, 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 outside of the United States. 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 outside of the United States 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 these 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 and 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 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 approved 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;
- 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 expenditure 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 CMOs to manufacture our approved drug products 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 manufacturing joint ventures with third parties to manufacture our approved drug products 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 be changed.

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 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, or the duration of the patent protection of our drug products and 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 claims. 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, the patent protecting our product candidates may expire before or shortly after such product candidates are commercialized, if at all.

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 strengthen our patent position.

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

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

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

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

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

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

In addition, we license certain patent rights for our PRINT technology from UNC under the UNC 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 may affect the way patent applications will be prosecuted and may also affect patent litigation. It may also weaken our ability to obtain patent protection in the United States for those 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 a 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, 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, or 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 $5 million;
- 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 U.S. Department of Health and Human Services, or HHS, 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”), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act, to physician assistants, nurse practitioners, and other mid-level practitioners. This law will go into effect in 2021, requiring reporting of payments and transfers made in that same calendar year;
- 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;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, 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, thus complicating compliance efforts; 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 and the Health Care and Education Reconciliation Act of 2010, which amends the ACA, collectively, the U.S. Health Reform Laws, were signed into law in the United States in March 2010.

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 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 U.S. Department of Health and Human Services 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 50% (and 70% commencing on January 1, 2019) 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;
- a 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. Since January 2017, President Trump has signed two 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, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the TCJA, includes a provision repealing, 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". Additionally, 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. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. 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 new laws 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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, 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 has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. Although most of these, and other, proposals will require authorization through additional legislation to become effective, the U.S. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, including by addressing the role of pharmacy benefit managers in the supply chain. On October 15, 2018, the Department of Health and Human Services Secretary, Alex Azar, unveiled a proposed rule that could require drug companies to disclose the price of their products in pharmaceutical advertisements. 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.

More recently, 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. The Right to Try Act did not establish any new entitlement or positive right to any party or individual, nor did it create any new mandates, directives, or additional regulations requiring a manufacturer or sponsor of an eligible investigational new drug product to provide expanded access.

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 U.S. Health Reform Laws 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 we have completed our initial public offering and shares of our common stock are listed and trading 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 our stockholders 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.

At the completion of our initial public offering on August 14, 2018, 15,431,950 shares of our common stock were outstanding. All shares of common stock sold in our initial public offering 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 10,598,851 shares, or 68.7% of our outstanding shares after the completion of the initial public offering as of August 14, 2018, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters; however, subject to applicable securities law restrictions these shares will be able to be sold in the public market beginning 181 days after July 25, 2018. 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 stand-off and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act, or Rule 701.

After completion of the initial public offering, the holders of 10,135,200 shares, or 65.7%, of our common stock, 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 also have registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares to be issued under our equity incentive plans, they can be freely sold in the public market upon issuance or resale (as applicable), subject to the lock-up agreements described above.

In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, limitations on declaring dividends and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through collaborations, strategic alliances or licensing arrangements with third parties, and we could be required to do so at an earlier stage than otherwise would be desirable. In connection with any such collaborations, strategic alliances or licensing arrangements, we may be required to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

Our management has broad discretion in using the net proceeds from the initial public offering and may not use them effectively.

We expect to use the net proceeds of the initial public offering to complete our ongoing Phase 3 clinical trial of LIQ861, advance LIQ865 through our planned Phase 2-enabling toxicology studies initiated in 2018, fund operations supporting the development of LIQ861 and LIQ865, continue to broaden out our proprietary PRINT platform and repay outstanding indebtedness in the normal course. Our management will have broad discretion in the application of the balance of the net 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 the net proceeds from the initial public offering 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. 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, 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 if the size and growth of the markets we intend to target fail to meet expectations;
- additions or 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, or 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.

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, our stockholders may be materially diluted by subsequent sales. Such sales would also likely result in material dilution to our existing equity holders, and new investors could 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 49.0% of our capital stock as of September 30, 2018, of which 2.3% are beneficially owned by our executive officers. Accordingly, our executive officers, directors and principal stockholders are substantially able to determine the composition of the Board, substantially retain the voting power to approve 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. We do not currently have, and may never obtain research coverage by securities and industry analysts. If no or few analysts commence research coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, 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 as early as the fiscal year ending December 31, 2018. However, for as long as we are an “emerging growth company” under 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 will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC and Nasdaq. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may 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. 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;
- creating a staggered board of directors such that all members of our Board are not elected at one time;
- allowing for the issuance of authorized but unissued shares of our capital stock without any further vote or action by our stockholders; and
- establishing 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 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. Should this occur, and if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

The recently passed TCJA could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the TCJA which significantly reforms the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits. Federal net operating losses arising in taxable years ending after December 31, 2017 will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax reform legislation may have on our business. 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

On October 26, 2018, we and Pacific Western Bank, or 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 (i) extinguish our current debt of $8.0 million under the Loan and Security Agreement with PWB, dated as of January 6, 2016, as amended, (ii) repay in full the $1.8 million in outstanding indebtedness under an outstanding promissory note issued to The University of North Carolina at Chapel Hill and (iii) 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 upon the full enrollment of the LIQ861 Phase 3 clinical trial, provided that we have not observed 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 tiered by tranche totaling between $187,000 and $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 million in the event the Financing Condition is met and we publicly disclose our safety data analysis for LIQ861 with no materially adverse data observed. 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, we are also obligated to comply with various other customary covenants, including, among other things, restrictions on our ability to dispose of assets, replace or suffer the departure of the Chief Executive Officer or Chief Financial Officer without delivering ten days’ prior written notification to PWB, 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.

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*	Amended and Restated Loan and Security Agreement, dated as of October 26, 2018, by and between Pacific Western Bank and Liquidia Technologies, Inc.
31.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act.
31.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act.
101*	The following materials from Liquidia Technologies, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Balance Sheets as of September 30, 2018 (unaudited) and December 31, 2017, (ii) Statements of Operations and Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2018 and September 30, 2017, (iii) Statement of Stockholders' Equity (Deficit) (unaudited) for the nine months ended September 30, 2018 and 2017, (iv) Statements of Cash Flows (unaudited) for the nine months ended September 30, 2018 and September 30, 2017 and (v) Notes to Financial Statements (unaudited).

* Filed herewith.

** 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: October 31, 2018	By: /s/Neal Fowler
	Neal Fowler
	Chief Executive Officer

	LIQUIDIA TECHNOLOGIES, INC.
DATE: October 31, 2018	By: /s/Kevin Gordon
	Kevin Gordon
	President and Chief Financial Officer

Exhibit 10.1

LIQUIDIA TECHNOLOGIES, INC.

AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

This AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT (the "Agreement") is entered into as of October 26, 2018 by and between PACIFIC WESTERN BANK, a California state-chartered bank ("Bank") and LIQUIDIA TECHNOLOGIES, INC. ("Borrower").

RECITALS

A. Bank and Borrower have entered into that certain Loan and Security Agreement dated as of January 6, 2016 (as amended, the "Prior Loan Agreement").

B. Borrower has requested, and Bank has agreed, to amend and restate the Prior Loan Agreement in its entirety. Bank and Borrower hereby agree that the Prior Loan Agreement is amended and restated in its entirety as set forth below.

C. Borrower wishes to obtain credit from time to time from Bank, and Bank desires to extend credit to Borrower. This Agreement sets forth the terms on which Bank will advance credit to Borrower, and Borrower will repay the amounts owing to Bank.

AGREEMENT

The parties agree as follows:

1. DEFINITIONS AND CONSTRUCTION.

1.1 Definitions. As used in this Agreement, all capitalized terms shall have the definitions set forth on Exhibit A. Any term used in the Code and not defined herein shall have the meaning given to the term in the Code.

1.2 Accounting Terms. Any accounting term not specifically defined on Exhibit A shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP (except for non-compliance with ASC 718 in monthly reporting). The term "financial statements" shall include the accompanying notes and schedules.

2. LOAN AND TERMS OF PAYMENT.

2.1 Credit Extensions.

(a) Promise to Pay. Borrower promises to pay to Bank, in lawful money of the United States of America, the aggregate unpaid principal amount of all Credit Extensions made by Bank to Borrower, together with interest on the unpaid principal amount of such Credit Extensions at rates in accordance with the terms hereof.

(b) Term Loan.

(i) Subject to and upon the terms and conditions of this Agreement, Bank agrees to make one (1) or more term loans to Borrower in an aggregate principal amount not to exceed Sixteen Million Dollars ($16,000,000) (each a "Term Loan" and collectively the "Term Loans").

Eleven Million Dollars ($11,000,000) of the Term Loans (“Tranche A”) shall be advanced to the Borrower on the Closing Date. The proceeds of the Tranche A Term Loans shall be used first to refinance Borrower’s existing Indebtedness to Bank and the UNC Debt, with any amounts remaining thereafter used for general working capital purposes and for capital expenditures.

The remaining Five Million Dollars ($5,000,000) of the Term Loans (“Tranche B”) shall be available through the Tranche B Availability End Date, provided that Borrower achieves the Performance Milestone. Funds will be available under Tranche B as soon as Borrower delivers to Bank evidence satisfactory to Bank that Borrower has achieved the Performance Milestone. Each Tranche B Term Loan, except the last Tranche B Term Loan, must be in a minimum amount of $500,000. The proceeds of the Tranche B Term Loans shall be used for general working capital purposes and for capital expenditures.

(ii) Interest shall accrue from the date of each Term Loan at the rate specified in Section 2.2(a), and during the Interest-Only Period interest on the applicable Term Loan shall be payable monthly beginning on the first day of the month next following such Term Loan, and continuing on the same day of each month thereafter. Any Term Loans that are outstanding on the last day of the Interest-Only Period shall be payable in equal monthly installments of principal, plus all accrued interest, beginning on the next day after the last day of the Interest-Only Period (the “Conversion Date”), and continuing on the same day of each month thereafter in amounts that would fully amortize each applicable Term Loan, as of the Conversion Date, over the Repayment Period. All amounts remaining due in connection with the Term Loans and any other amounts due under this Agreement shall be immediately due and payable on the Term Loan Maturity Date. Term Loans, once repaid, may not be reborrowed. Subject to payment of the Prepayment Fee as set forth in Section 2.4(c) hereof, Borrower may prepay any Term Loan without any penalty or additional premium.

(iii) When Borrower desires to obtain a Term Loan, Borrower shall notify Bank (which notice shall be irrevocable) by facsimile transmission or email to be received no later than 3:30 p.m. Eastern time on the day on which the Term Loan is to be made. Such notice shall be given by a Loan Advance/Paydown Request Form in substantially the form of Exhibit C. The notice shall be signed by an Authorized Officer. Bank shall be entitled to rely on any notice given by a person whom Bank reasonably believes to be an Authorized Officer, and Borrower shall indemnify and hold Bank harmless for any damages, loss, costs and expenses suffered by Bank as a result of such reliance.

(c) Usage of Credit Card Services Under the Credit Card Line.

(i) Usage Period. Subject to and upon the terms and conditions of this Agreement, at any time from the Closing Date through the Credit Card Maturity Date, Borrower may use the Credit Card Services (as defined below) in amounts and upon terms as provided in Section 2.1(c)(ii) below.

(ii) Credit Card Services. Subject to and upon the terms and conditions of this Agreement, Borrower may request corporate credit cards and standard and e-commerce merchant account services from Bank (collectively, the “Credit Card Services”).

The aggregate limit of the corporate credit cards and merchant credit card processing reserves shall not exceed the Credit Card Line. The terms and conditions (including repayment and fees) of such Credit Card Services shall be subject to the terms and conditions of Bank's standard forms of application and agreement for the Credit Card Services, which Borrower hereby agrees to execute.

(iii) Collateralization of Obligations Extending Beyond Maturity. If Borrower has not cash secured its obligations with respect to any Credit Card Services by the Credit Card Maturity Date, then, effective as of such date, the balance in any deposit accounts held by Bank and the certificates of deposit or time deposit accounts issued by Bank in Borrower's name (and any interest paid thereon or proceeds thereof, including any amounts payable upon the maturity or liquidation of such certificates or accounts), shall automatically secure such obligations to the extent of the then continuing or outstanding Credit Card Services. Borrower authorizes Bank to hold such balances in pledge and to decline to honor any drafts thereon or any requests by Borrower or any other Person to pay or otherwise transfer any part of such balances for so long as the applicable Credit Card Services are outstanding or continue.

2.2 Interest Rates, Payments, and Calculations.

(a) Interest Rates.

(i) Term Loans. Except as set forth in Section 2.2(b), the Term Loans shall bear interest, on the outstanding daily balance thereof, at a variable annual rate equal to the greater of: (A) the Prime Rate then in effect; or (B) five percent (5.00%).

(b) Late Fee; Default Rate. If any payment is not made within 15 days after the date such payment is due, Borrower shall pay Bank a late fee equal to the lesser of (i) 5% of the amount of such unpaid amount or (ii) the maximum amount permitted to be charged under applicable law. All Obligations shall bear interest, from and after the occurrence and during the continuance of an Event of Default, at a rate equal to 5 percentage points above the interest rate applicable immediately prior to the occurrence of the Event of Default.

(c) Payments. Borrower authorizes Bank to, at its option, charge such interest, all Bank Expenses, all Periodic Payments, and any other amounts due and owing in accordance with the terms of this Agreement against any of Borrower's deposit accounts, in which case those amounts shall thereafter accrue interest at the rate then applicable hereunder. Any interest not paid when due shall be compounded by becoming a part of the Obligations, and such interest shall thereafter accrue interest at the rate then applicable hereunder. All payments shall be free and clear of any taxes, withholdings, duties, impositions or other charges (other than income, branch profits and franchise taxes), to the end that Bank will receive the entire amount of any Obligations payable hereunder, regardless of source of payment.

(d) Computation. In the event the Prime Rate is changed from time to time hereafter, the applicable rate of interest hereunder shall be increased or decreased, effective as of the day the Prime Rate is changed, by an amount equal to such change in the Prime Rate. All interest chargeable under the Loan Documents shall be computed on the basis of a 360-day year for the actual number of days elapsed.

2.3 Crediting Payments. Other than any time after the occurrence and during the continuance of an Event of Default, Bank shall credit a wire transfer of funds, check or other item of payment to such deposit account or Obligation as Borrower specifies. After the occurrence and during the continuance of an Event of Default, Bank shall have the right, in its sole discretion, to immediately apply any wire transfer of funds, check, or other item of payment Bank may receive to conditionally reduce Obligations, but such applications of funds shall not be considered a payment on account unless such payment is of immediately available federal funds or unless and until such check or other item of payment is honored when presented for payment. Notwithstanding anything to the contrary contained herein, any wire transfer or payment received by Bank after 5:30 p.m. Eastern time shall be deemed to have been received by Bank as of the opening of business on the immediately following Business Day. Whenever any payment to Bank under the Loan Documents would otherwise be due (except by reason of acceleration) on a date that is not a Business Day, such payment shall instead be due on the next Business Day, and additional fees or interest, as the case may be, shall accrue and be payable for the period of such extension.

2.4 Fees. Borrower shall pay to Bank the following:

(a) Facility Fee. On or before the Closing Date, a fee equal to Five Thousand Dollars ($5,000), which shall be nonrefundable;

(b) Bank Expenses. On the Closing Date, all Bank Expenses incurred through the Closing Date, and, after the Closing Date, all Bank Expenses, as and when they become due.

(c) Prepayment Fee. A fee (the “Prepayment Fee”) in connection with any prepayment of the Term Loan under Section 2.1(b) in an amount equal to (i) two percent (2%) of the principal amount of Term Loan so prepaid if the Term Loan is prepaid within one (1) year of the Closing Date, (ii) one percent (1.00%) of the principal amount of the Term Loan so prepaid if the Term Loan is prepaid between one (1) year and two (2) years after the Closing Date, or (iii) Zero Dollars ($0) if repaid more than two (2) years after the Closing Date.

(d) Near-Term Success Fee. If a Liquidity Event occurs prior to October 31, 2019, Borrower shall pay to Bank a fee (the “Near-Term Success Fee”) of: (i) $187,000 if Borrower has not received a Tranche B Term Loan, or (ii) $225,000 if Borrower has received a Tranche B Term Loan. This Section 2.4(d) shall survive any termination of this Agreement.

(e) Long-Term Success Fee. If a Liquidity Event occurs on or after October 31, 2019, Borrower shall pay to Bank a fee (the “Long-Term Success Fee”) of: (i) $275,000 if Borrower has not received a Tranche B Term Loan, or (ii) $375,000 if Borrower has received a Tranche B Term Loan. This Section 2.4(e) shall survive any termination of this Agreement.

For the avoidance of doubt, under no circumstances shall Borrower be required to pay both the Near-Term Success Fee described in Section 2.4(d) and the Long-Term Success Fee described in Section 2.4(e).

2.5 Term. This Agreement shall become effective on the Closing Date and, subject to Section 12.7, shall continue in full force and effect for so long as any Obligations (other than inchoate indemnity obligations) remain outstanding or Bank has any obligation to make Credit Extensions under this Agreement. Notwithstanding the foregoing, Bank shall have the right to terminate its obligation to make Credit Extensions under this Agreement immediately and without notice upon the occurrence and during the continuance of an Event of Default.

3. CONDITIONS OF LOANS.

3.1 Conditions Precedent to Closing. The agreement of Bank to enter into this Agreement on the Closing Date is subject to the condition precedent that Bank shall have received, in form and substance satisfactory to Bank, each of the following items and completed each of the following requirements:

(a) this Agreement;

(b) an officer's certificate of Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Agreement;

(c) payment of the fees and Bank Expenses then due specified in Section 2.4, which may be debited from any of Borrower's accounts with Bank;

(d) current SOS Reports indicating that except for Permitted Liens, there are no other security interests or Liens of record in the Collateral;

(e) current financial statements, including audited statements (or such other level required by the Investment Agreement) for Borrower's most recently ended fiscal year, together with an unqualified opinion (or an opinion qualified only for going concern so long as Borrower's investors provide additional equity as needed), company prepared consolidated and consolidating balance sheets, income statements, and statements of cash flows for the most recently ended month in accordance with Section 6.2, and such other updated financial information as Bank may reasonably request;

(f) current Compliance Certificate in accordance with Section 6.2;

(g) evidence satisfactory to Bank that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and additional insured clauses or endorsements in favor of Bank,

(h) an updated Borrower Information Certificate;

(i) a payoff letter from the University of North Carolina at Chapel Hill covering the UNC Debt; and

(j) such other documents or certificates, and completion of such other matters, as Bank may reasonably request.

3.2 Conditions Precedent to all Credit Extensions. The obligation of Bank to make each Credit Extension, including the initial Credit Extension, is contingent upon the Borrower's compliance with Section 3.1 above, and is further subject to the following conditions:

(a) timely receipt by Bank of the Loan Advance/Paydown Request Form as provided in Section 2.1;

(b) Borrower shall have transferred substantially all of its Cash assets into operating accounts held with Bank and otherwise be in compliance with Section 6.6 hereof;

(c) in Bank's sole discretion, there has not been a Material Adverse Effect; and

(d) the representations and warranties contained in Section 5 shall be true and correct in all material respects on and as of the date of such Loan Advance/Paydown Request Form and on the effective date of each Credit Extension as though made at and as of each such date, and no Event of Default shall have occurred and be continuing, or would exist after giving effect to such Credit Extension (provided, however, that those representations and warranties expressly referring to another date shall be true and correct in all material respects as of such date, and provided further that any representation or warranty that contains a materiality qualification therein shall be true and correct in all respects). The making of each Credit Extension shall be deemed to be a representation and warranty by Borrower on the date of such Credit Extension as to the accuracy of the facts referred to in this Section 3.2.

4. CREATION OF SECURITY INTEREST.

4.1 Grant of Security Interest. Borrower grants and pledges to Bank a continuing security interest in the Collateral to secure prompt repayment of any and all Obligations and to secure prompt performance by Borrower of each of its covenants and duties under the Loan Documents. Except for Permitted Liens or as disclosed in the Schedule, such security interest constitutes a valid, first priority security interest in the presently existing Collateral, and will constitute a valid, first priority security interest in later-acquired Collateral. Borrower also hereby agrees not to sell, transfer, assign, mortgage, pledge, lease, grant a security interest in, or encumber any of its Intellectual Property except for Permitted Transfers. Notwithstanding any termination of this Agreement or of any filings undertaken related to Bank's rights under the Code, Bank's Lien on the Collateral shall remain in effect for so long as any Obligations (other than inchoate indemnity obligations) are outstanding.

4.2 Perfection of Security Interest. Borrower authorizes Bank to file at any time financing statements, continuation statements, and amendments thereto that (i) either specifically describe the Collateral or describe the Collateral as all assets of Borrower of the kind pledged hereunder, and (ii) contain any other information required by the Code for the sufficiency of filing office acceptance of any financing statement, continuation statement, or amendment, including whether Borrower is an organization, the type of organization and any organizational identification number issued to Borrower, if applicable. Borrower shall have possession of the

Collateral, except where expressly otherwise provided in this Agreement or where Bank chooses to perfect its security interest by possession in addition to the filing of a financing statement. Where Collateral is in possession of a third party bailee, Borrower shall take such steps as Bank reasonably requests for Bank to (i) subject to Section 7.11 below, obtain an acknowledgment, in form and substance satisfactory to Bank, of the bailee that the bailee holds such Collateral for the benefit of Bank, and (ii) obtain "control" of any Collateral consisting of investment property, deposit accounts, letter-of-credit rights or electronic chattel paper (as such items and the term "control" are defined in Revised Article 9 of the Code) by causing the securities intermediary or depositary institution or issuing bank to execute a control agreement in form and substance satisfactory to Bank. Borrower will not create any chattel paper without placing a legend on the chattel paper acceptable to Bank indicating that Bank has a security interest in the chattel paper. Borrower from time to time may deposit with Bank specific cash collateral to secure specific Obligations; Borrower authorizes Bank to hold such specific balances in pledge and to decline to honor any drafts thereon or any request by Borrower or any other Person to pay or otherwise transfer any part of such balances for so long as the specific Obligations are outstanding. Borrower shall take such other actions as Bank requests to perfect its security interests granted under this Agreement.

5. REPRESENTATIONS AND WARRANTIES.

Borrower represents and warrants as follows:

5.1 Due Organization and Qualification. Borrower and each Subsidiary is duly existing under the laws of the state in which it is organized and qualified and licensed to do business in any state in which the conduct of its business or its ownership of property requires that it be so qualified, except where the failure to do so would not reasonably be expected to cause a Material Adverse Effect.

5.2 Due Authorization; No Conflict. The execution, delivery, and performance of the Loan Documents are within Borrower's powers, have been duly authorized, and are not in conflict with nor constitute a breach of any provision contained in Borrower's Certificate of Incorporation or Bylaws, nor will they constitute an event of default under any material agreement by which Borrower is bound. Borrower is not in default under any agreement by which it is bound, including that certain Amended and Restated License Agreement dated December 15, 2008 by and between the University of North Carolina at Chapel Hill and Borrower, except to the extent such default would not reasonably be expected to cause a Material Adverse Effect.

5.3 Collateral. Borrower has rights in or the power to transfer the Collateral, and its title to the Collateral is free and clear of Liens, adverse claims, and restrictions on transfer or pledge except for Permitted Liens. Other than movable items of personal property such as laptop computers, all Collateral having an aggregate book value in excess of $100,000, is located solely in the Collateral States. All Inventory is in all material respects of good and merchantable quality, free from all material defects, except for Inventory for which adequate reserves have been made. Except as set forth in the Schedule, none of the Borrower's Cash is maintained or invested with a Person other than Bank or Bank's affiliates.

5.4 Intellectual Property. Borrower is the sole owner (except for Intellectual Property jointly owned with the University of North Carolina ("UNC") or GlaxoSmithKline ("GSK")) or licensee of the Intellectual Property, and owns or control the Intellectual Property created (whether solely or jointly with UNC or GSK) or purchased by Borrower, except for licenses granted by Borrower in the ordinary course of business. To Borrower's knowledge, each of the Copyrights, Trademarks and Patents created or purchased by Borrower is valid and enforceable, and no part of the Intellectual Property created or purchased by Borrower has been judged invalid or unenforceable, in whole or in part, and no claim has been made to Borrower that any part of the Intellectual Property created or purchased by Borrower violates the rights of any third party except to the extent such claim would not reasonably be expected to cause a Material Adverse Effect.

5.5 Name; Location of Chief Executive Office. Except as disclosed in the Schedule, Borrower has not done business under any name other than that specified on the signature page hereof, and its exact legal name is as set forth in the first paragraph of this Agreement. The chief executive office of Borrower is located at the address indicated in Section 10 hereof.

5.6 Litigation. Except as set forth in the Schedule, there are no actions or proceedings pending by or against Borrower or any Subsidiary before any court or administrative agency in which a likely adverse decision would reasonably be expected to have a Material Adverse Effect.

5.7 No Material Adverse Change in Financial Statements. All consolidated and consolidating financial statements related to Borrower and any Subsidiary that are delivered by Borrower to Bank fairly present in all material respects Borrower's consolidated and consolidating financial condition as of the date thereof and Borrower's consolidated and consolidating results of operations for the period then ended. There has not been a material adverse change in the consolidated or in the consolidating financial condition of Borrower since the date of the most recent of such financial statements submitted to Bank.

5.8 Solvency, Payment of Debts. Borrower is able to pay its debts (including trade debts) as they mature; the fair saleable value of Borrower's assets (including goodwill minus disposition costs) exceeds the fair value of its liabilities; and Borrower is not left with unreasonably small capital after the transactions contemplated by this Agreement.

5.9 Compliance with Laws and Regulations. Borrower and each Subsidiary have met the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. No event has occurred resulting from Borrower's failure to comply with ERISA that is reasonably likely to result in Borrower's incurring any liability that could have a Material Adverse Effect. Borrower is not an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940. Borrower is not engaged principally, or as one of its important activities, in the business of extending credit for the purpose of purchasing or carrying margin stock (within the meaning of Regulations T and U of the Board of Governors of the Federal Reserve System). Borrower has not violated any statutes, laws, ordinances or rules applicable to it, the violation of which would reasonably be expected to have a Material Adverse Effect. Borrower and each Subsidiary have filed or caused to be filed all tax returns required to be filed, and have paid, or have made adequate provision for the payment of, all taxes reflected therein except those being contested in good faith with adequate reserves under GAAP or where the failure to file such returns or pay such taxes would not reasonably be expected to have a Material Adverse Effect.

5.10 Subsidiaries. Borrower does not own any stock, partnership interest or other equity securities of any Person, except for Permitted Investments.

5.11 Government Consents. Borrower and each Subsidiary have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all governmental authorities that are necessary for the continued operation of Borrower's business as currently conducted, except where the failure to do so would not reasonably be expected to cause a Material Adverse Effect.

5.12 Inbound Licenses. Except as disclosed on the Schedule, Borrower is not a party to, nor is bound by, any material license or other agreement important for the conduct of Borrower's business that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such license or agreement important for the conduct of Borrower's business, other than this Agreement or the other Loan Documents.

5.13 Full Disclosure. No representation, warranty or other statement made by Borrower in any certificate or written statement furnished to Bank taken together with all such certificates and written statements furnished to Bank contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained in such certificates or statements not misleading in light of the circumstances in which they were made, it being recognized by Bank that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not to be viewed as facts and that actual results during the period or periods covered by any such projections and forecasts may differ from the projected or forecasted results.

6. AFFIRMATIVE COVENANTS.

Borrower covenants that, until payment in full of all outstanding Obligations (other than inchoate indemnity obligations), and for so long as Bank may have any commitment to make a Credit Extension hereunder, Borrower shall do all of the following:

6.1 Good Standing and Government Compliance. Borrower shall maintain its and each of its Subsidiaries' corporate existence and good standing in the respective states of formation, shall maintain qualification and good standing in each other jurisdiction in which the failure to so qualify would reasonably be expected to have a Material Adverse Effect, and shall furnish to Bank the organizational identification number issued to Borrower by the authorities of the state in which Borrower is organized, if applicable. Borrower shall meet, and shall cause each Subsidiary to meet, the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. Borrower shall comply, and shall cause each Subsidiary to comply, with all statutes, laws, ordinances and government rules and regulations to which it is subject, and shall maintain, and shall cause each of its Subsidiaries to maintain, in force all licenses, approvals and agreements, the loss of which or failure to comply with which would reasonably be expected to have a Material Adverse Effect.

6.2 Financial Statements, Reports, Certificates, Collateral Audits.

(a) Borrower shall deliver to Bank: (i) as soon as available, but in any event within 30 days after the end of each calendar month, a company prepared consolidated and consolidating balance sheet, income statement, and statement of cash flows covering Borrower's operations during such period, along with accounts payable agings, all in a form reasonably acceptable to Bank and certified by a Responsible Officer; (ii) as soon as available, but in any event within 180 days after the end of Borrower's fiscal year, audited (or such other level as is required by the Investment Agreement) consolidated and consolidating financial statements of Borrower prepared in accordance with GAAP, consistently applied, together with an opinion which is either unqualified (provided that the opinion may contain a qualification as to going concern typical for venture backed companies similar to Borrower) or otherwise consented to in writing by Bank on such financial statements of an independent certified public accounting firm reasonably acceptable to Bank; (iii) annual budget approved by Borrower's Board of Directors as soon as available but not later than sixty (60) days after the end of each fiscal year during the term hereof; (iv) if applicable, copies of all statements, reports and notices sent or made available generally by Borrower to its security holders or to any holders of Subordinated Debt and all reports on Forms 10-K and 10-Q filed (including, but not limited to, quarterly clinical program updates) with the Securities and Exchange Commission; (v) promptly upon receipt of notice thereof, a report of any legal actions pending or threatened against Borrower or any Subsidiary that could reasonably be expected to result in damages or costs to Borrower or any Subsidiary of $500,000 or more; (vi) promptly upon receipt, each management letter prepared by Borrower's independent certified public accounting firm regarding Borrower's management control systems; and (vii) such budgets, sales projections, operating plans or other financial information as Bank may reasonably request from time to time.

(b) Within 30 days after the last day of each month, Borrower shall deliver to Bank with the monthly financial statements a Compliance Certificate certified as of the last day of the applicable month and signed by a Responsible Officer in substantially the form of Exhibit D hereto.

(c) As soon as possible and in any event within three (3) calendar days after becoming aware of the occurrence or existence of an Event of Default hereunder, a written statement of a Responsible Officer setting forth details of the Event of Default, and the action which Borrower has taken or proposes to take with respect thereto.

(d) Borrower shall deliver to Bank the notices required in Section 7.2.

(e) Bank (through any of its officers, employees, or agents) shall have the right, upon reasonable prior notice, from time to time during Borrower's usual business hours but no more than twice a year (unless an Event of Default has occurred and is continuing), to inspect Borrower's Books and to make copies thereof and to check, test, inspect, audit and appraise the Collateral at Borrower's expense in order to verify Borrower's financial condition or the amount, condition of, or any other matter relating to, the Collateral.

Borrower may deliver to Bank on an electronic basis any certificates, reports or information required pursuant to this Section 6.2, and Bank shall be entitled to rely on the information contained in the electronic files, provided that Bank in good faith believes that the files were delivered by a Responsible Officer. Borrower shall include a submission date on any certificates and reports to be delivered electronically.

6.3 Inventory and Equipment; Returns. Borrower shall keep all Inventory and Equipment in good and merchantable condition, free from all material defects except for Inventory and Equipment (i) sold in the ordinary course of business, and (ii) for which adequate reserves have been made, in all cases in the United States and such other locations as to which Borrower gives prior written notice. Returns and allowances, if any, as between Borrower and its account debtors shall be on the same basis and in accordance with the usual customary practices of Borrower, as they exist on the Closing Date. Borrower shall promptly notify Bank of all returns and recoveries and of all disputes and claims involving inventory having a book value of more than $200,000.

6.4 Taxes. Borrower shall make, and cause each Subsidiary to make, due and timely payment or deposit of all material federal, state, and local taxes, assessments, or contributions required of it by law, including, but not limited to, those laws concerning income taxes, F.I.C.A., F.U.T.A. and state disability, and will execute and deliver to Bank, on demand, proof satisfactory to Bank indicating that Borrower or a Subsidiary has made such payments or deposits and any appropriate certificates attesting to the payment or deposit thereof; provided that Borrower or a Subsidiary need not make any payment if the amount or validity of such payment is contested in good faith by appropriate proceedings and is reserved against (to the extent required by GAAP) by Borrower or such Subsidiary.

6.5 Insurance. Borrower, at its expense, shall (i) keep the Collateral insured against loss or damage, and (ii) maintain liability and other insurance, in each case as ordinarily insured against by other owners in businesses similar to Borrower’s. All such policies of insurance shall be in such form, with such companies, and in such amounts as reasonably satisfactory to Bank. All policies of property insurance shall contain a lender’s loss payable endorsement, in a form satisfactory to Bank, showing Bank as lender's loss payee. All liability insurance policies shall show, or have endorsements showing, Bank as an additional insured. Any such insurance policies shall specify that the insurer must give at least twenty (20) days’ notice to Bank before canceling its policy for any reason. Within thirty (30) days of the Closing Date, Borrower shall cause to be furnished to Bank a copy of its policies including any endorsements covering Bank or showing Bank as an additional insured. Upon Bank’s request, Borrower shall deliver to Bank certified copies of the policies of insurance and evidence of all premium payments. Proceeds payable under any casualty policy will, at Borrower’s option, be payable to Borrower to replace the property subject to the claim, provided that any such replacement property shall be deemed Collateral in which Bank has been granted a first priority security interest, provided that if an Event of Default has occurred and is continuing, all proceeds payable under any such policy shall, at Bank’s option, be payable to Bank to be applied on account of the Obligations.

6.6 Primary Depository. Subject to the provisions of Section 3.2(b), as of the Closing Date, Borrower shall maintain, and shall cause all of its Subsidiaries to maintain, all depository and operating accounts with Bank and all investment accounts with Bank or Bank’s affiliates; provided that prior to Borrower maintaining any investment accounts with Bank's affiliates, Borrower, Bank, and any such affiliate shall have entered into a securities account control agreement with respect to any such investment accounts, in form and substance satisfactory to Bank. Notwithstanding the above, Borrower shall be permitted to maintain an aggregate amount not to exceed $100,000 in one or more accounts outside of Bank.

6.7 Financial Covenants. Borrower shall at all times maintain the following financial ratios and covenants:

(a) Minimum Cash at Bank. Monitored on a daily basis, a balance of Cash at Bank of not less Eight Million Five Hundred Thousand Dollars ($8,500,000) (the "Minimum Cash Threshold"); provided however, that the Minimum Cash Threshold shall be decreased to Six Million Dollars ($6,000,000) if Borrower provides evidence reasonably acceptable to Bank that Borrower has achieved the Funding Milestone. Notwithstanding the foregoing, up to two (2) times per calendar year, Borrower may allow its balance of Cash at Bank to be below the applicable Minimum Cash Threshold, so long as (i) Borrower's balance of Cash at Bank shall not at any time be less than Two Hundred Fifty Thousand Dollars ($250,000) below the applicable Minimum Cash Threshold, and (ii) Borrower's balance of Cash at Bank shall not remain below the applicable Minimum Cash Threshold for more than three (3) consecutive Business Days per occurrence.

6.8 Protection of Intellectual Property.

(a) Borrower shall promptly give Bank written notice on a quarterly basis of any applications or registrations of intellectual property rights filed with the United States Patent and Trademark Office during such fiscal year, including the date of such filing and the registration or application numbers, if any.

(b) Except for Permitted Transfers, Borrower shall (i) protect, defend and maintain the validity and enforceability of the trade secrets, Trademarks, Patents and Copyrights material to the business of Borrower, (ii) use commercially reasonable efforts to detect infringements of such Trademarks, Patents and Copyrights and promptly advise Bank in writing of material infringements detected and (iii) not allow any material Trademarks, Patents or Copyrights to be abandoned, forfeited or dedicated to the public without the written consent of Bank, which shall not be unreasonably withheld.

(c) Bank shall have the right, but not the obligation, to take, at Borrower's sole expense, any actions that Borrower is required under this Section 6.8 to take but which Borrower fails to take, after 15 days' notice to Borrower. Borrower shall reimburse and indemnify Bank for all reasonable costs and reasonable out-of-pocket expenses incurred in the reasonable exercise of its rights under this Section 6.8.

6.9 Consent of Inbound Licensors. Prior to entering into or becoming bound by any material inbound license or similar agreement, Borrower shall: (i) provide written notice to Bank of the material terms of such license or agreement with a description of its likely impact on Borrower's business or financial condition; and (ii) in good faith use commercially reasonable efforts to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for

Borrower's interest in such licenses or contract rights to be deemed Collateral and for Bank to have a security interest in it that might otherwise be restricted by the terms of the applicable license or agreement, whether now existing or entered into in the future, provided, however, that the failure to obtain any such consent or waiver shall not constitute a default under this Agreement.

6.10 Creation/Acquisition of Subsidiaries. In the event any Borrower or any Subsidiary of any Borrower creates or acquires any Subsidiary, Borrower or such Subsidiary shall promptly notify Bank of such creation or acquisition, and Borrower or such Subsidiary shall take all actions reasonably requested by Bank to achieve any of the following with respect to such "***New Subsidiary***" (defined as a Subsidiary formed after the date hereof during the term of this Agreement): (i) to cause New Subsidiary to become either a co-Borrower hereunder, if such New Subsidiary is organized under the laws of the United States, or a secured guarantor with respect to the Obligations; and (ii) to grant and pledge to Bank a perfected security interest in 100% of the stock, units or other evidence of ownership held by Borrower or its Subsidiaries of any such New Subsidiary which is organized under the laws of the United States, and 65% of the stock, units or other evidence of ownership held by Borrower or its Subsidiaries of any such New Subsidiary which is not organized under the laws of the United States.

6.11 Further Assurances. At any time and from time to time Borrower shall execute and deliver such further instruments and take such further action as may reasonably be requested by Bank to effect the purposes of this Agreement.

7. NEGATIVE COVENANTS.

Borrower covenants and agrees that, so long as any credit hereunder shall be available and until the outstanding Obligations (other than inchoate indemnity obligations) are paid in full or for so long as Bank may have any commitment to make any Credit Extensions, Borrower will not do any of the following without Bank's prior written consent, which shall not be unreasonably withheld:

7.1 Dispositions. Convey, sell, lease, license, transfer or otherwise dispose of (collectively, to "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, or move cash balances on deposit with Bank to accounts opened at another financial institution, other than Permitted Transfers.

7.2 Change in Name, Location, Executive Office, or Executive Management; Change in Business; Change in Fiscal Year; Change in Control. Change its name or the state of Borrower's formation or relocate its chief executive office without 30 days prior written notification to Bank; replace or suffer the departure of its chief executive officer or chief financial officer without delivering written notification to Bank within 10 days; fail to appoint an interim replacement or fill a vacancy in the position of chief executive officer or chief financial officer for more than 30 consecutive days; suffer a change on its board of directors which results in the failure of at least one partner of either New Enterprise Associates or Canaan Partners or their Affiliates to serve as a voting member, in such case without having used best efforts to deliver at least fifteen (15) days prior written notification to Bank; take action to liquidate, wind up, or otherwise cease to conduct business in the ordinary course; engage in any business, or permit any of its Subsidiaries to engage in any business, other than or reasonably related or incidental to the businesses currently engaged in by Borrower; change its fiscal year end; have a Change in Control.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with or into any other business organization (other than mergers or consolidations of a Subsidiary into another Subsidiary or into Borrower), or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person except where (a) each of the following conditions is applicable: (i) the consideration paid in connection with such transactions (including assumption of liabilities) does not in the aggregate exceed $250,000 during any fiscal year, (ii) no Event of Default has occurred, is continuing or would exist after giving effect to such transactions, (iii) such transactions do not result in a Change in Control, and (iv) Borrower is the surviving entity; or (b) the Obligations are repaid in full concurrently with the closing of any merger or consolidation of Borrower in which Borrower is not the surviving entity; provided, however, that Borrower shall not, without Bank's prior written consent, enter into any binding contractual arrangement with any Person to attempt to facilitate a merger or acquisition of Borrower, unless (i) no Event of Default exists when such agreement is entered into by Borrower, (ii) such agreement does not give such Person the right to claim any fee, payment or damages from any parties, other than from Borrower or Borrower's investors, in connection with a sale of Borrower's stock or assets pursuant to or resulting from an assignment for the benefit of creditors, an asset turnover to Borrower's creditors (including, without limitation, Bank), foreclosure, bankruptcy or similar liquidation, and (iii) Borrower notifies Bank in advance of entering into such an agreement (provided, the failure to give such notification shall not be deemed a material breach of this Agreement).

7.4 Indebtedness. Create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary so to do, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except Indebtedness to Bank.

7.5 Encumbrances. Create, incur, assume or allow any Lien with respect to its property, or assign or otherwise convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries so to do, except for Permitted Liens, or covenant to any other Person (other than (i) the licensors of in-licensed property with respect to such property or (ii) the lessors of specific equipment or lenders financing specific equipment with respect to such leased or financed equipment) that Borrower in the future will refrain from creating, incurring, assuming or allowing any Lien with respect to any of Borrower's property.

7.6 Distributions. Pay any dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock, except that Borrower may (i) repurchase the stock of former employees or directors pursuant to stock repurchase agreements in an aggregate amount not to exceed $250,000 in any fiscal year, as long as an Event of Default does not exist prior to such repurchase or would not exist after giving effect to such repurchase, and (ii) repurchase the stock of former employees or directors pursuant to stock repurchase agreements by the cancellation of indebtedness owed by such former employees or directors to Borrower regardless of whether an Event of Default exists.

7.7 Investments. Directly or indirectly acquire or own an Investment in, or make any Investment in or to any Person, or permit any of its Subsidiaries so to do, other than Permitted Investments, or maintain or invest any of its investment property with a Person other than Bank or permit any Subsidiary to do so unless such Person has entered into a control agreement with Bank, in form and substance satisfactory to Bank, or suffer or permit any Subsidiary to be a party to, or be bound by, an agreement that restricts such Subsidiary from paying dividends or otherwise distributing property to Borrower.

7.8 Capitalized Expenditures. Make Capitalized Expenditures in excess of (a) $500,000 in the aggregate during Borrower's fiscal year ending December 31, 2018, (b) $1,250,000 in the aggregate during Borrower's fiscal year ending December 31, 2019, or (c) $500,000 in any fiscal year of Borrower thereafter; provided that any unused amount of Capital Expenditures in any fiscal year up to $500,000 may be added to the limitations under this Section 7.8 and used by Borrower in the subsequent fiscal year.

7.9 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower except for (i) transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's length transaction with a non-affiliated Person, and (ii) the sale of Borrower's equity securities in bona fide transactions with Borrower's existing investors that do not result in a Change in Control.

7.10 Subordinated Debt. Make any payment in respect of any Subordinated Debt, or permit any of its Subsidiaries to make any such payment, except in compliance with the terms of such Subordinated Debt, or amend any provision affecting Bank's rights contained in any documentation relating to the Subordinated Debt without Bank's prior written consent.

7.11 Inventory and Equipment. Store the Inventory or the Equipment of an aggregate book value in excess of $250,000 with a bailee, warehouseman, collocation facility or similar third party unless the third party has been notified of Bank's security interest and Bank (a) has received an acknowledgment from the third party that it is holding or will hold the Inventory or Equipment for Bank's benefit or (b) is in possession of the warehouse receipt, where negotiable, covering such Inventory or Equipment. Except for Inventory sold in the ordinary course of business and for movable items of personal property having an aggregate book value not in excess of $250,000, and except for such other locations as Bank may approve in writing, Borrower shall keep the Inventory and Equipment only at the location set forth in Section 10 and such other locations of which Borrower gives Bank prior written notice and as to which Bank is able to take such actions as may be necessary or advisable to perfect its security interest or to obtain a bailee's acknowledgment of Bank's rights in the Collateral.

7.12 No Investment Company; Margin Regulation. Become or be controlled by an "investment company," within the meaning of the Investment Company Act of 1940, or become principally engaged in, or undertake as one of its important activities, the business of extending credit for the purpose of purchasing or carrying margin stock, or use the proceeds of any Credit Extension for such purpose.

8. EVENTS OF DEFAULT.

Any one or more of the following events shall constitute an Event of Default by Borrower under this Agreement:

8.1 Payment Default. If Borrower fails to pay any of the Obligations when due;

8.2 Covenant Default.

(a) If Borrower fails to perform any obligation under Sections 6.2 (financial reporting), 6.4 (taxes), 6.5 (insurance), 6.6 (primary accounts), or 6.7 (financial covenants), or violates any of the covenants contained in Article 7 of this Agreement; or

(b) If Borrower fails or neglects to perform or observe any other material term, provision, condition, covenant contained in this Agreement, in any of the Loan Documents, or in any other present or future agreement between Borrower and Bank and as to any default under such other term, provision, condition or covenant that can be cured, has failed to cure such default within 10 days after Borrower receives notice thereof or any officer of Borrower becomes aware thereof; provided, however, that if the default cannot by its nature be cured within the 10 day period or cannot after diligent attempts by Borrower be cured within such 10 day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional reasonable period (which shall not in any case exceed 30 days) to attempt to cure such default, and within such reasonable time period the failure to have cured such default shall not be deemed an Event of Default but no Credit Extensions will be made;

8.3 Material Adverse Effect. If there occurs any circumstance or any circumstances which would reasonably be expected to have a Material Adverse Effect;

8.4 Attachment. If any material portion of Borrower’s assets is attached, seized, subjected to a writ or distress warrant, or is levied upon, or comes into the possession of any trustee, receiver or person acting in a similar capacity and such attachment, seizure, writ or distress warrant or levy has not been removed, discharged or rescinded within ten (10) days, or if Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or any material part of its business affairs, or if a judgment or other claim becomes a lien or encumbrance upon any material portion of Borrower’s assets, or if a notice of lien, levy, or assessment is filed of record with respect to any material portion of Borrower’s assets by the United States Government, or any department, agency, or instrumentality thereof, or by any state, county, municipal, or governmental agency, and the same is not paid within ten (10) days after Borrower receives notice thereof, provided that none of the foregoing shall constitute an Event of Default where such action or event is stayed or an adequate bond has been posted pending a good faith contest by Borrower (provided that no Credit Extensions will be made during such cure period);

8.5 Insolvency. If Borrower becomes insolvent, or if an Insolvency Proceeding is commenced by Borrower, or if an Insolvency Proceeding is commenced against Borrower and is not dismissed or stayed within forty-five (45) days (provided that no Credit Extensions will be made prior to the dismissal of such Insolvency Proceeding);

8.6 Other Agreements. If (a) there is a default or other failure to perform in any agreement to which Borrower is a party with a third party or parties (i) resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of $500,000, (ii) in connection with any material lease of real property that gives the landlord the right to terminate such lease, or (iii) that would reasonably be expected to have a Material Adverse Effect, or (b) any default or event of default (however designated) shall occur with respect to any Subordinated Debt which is not cured within any applicable cure period;

8.7 Judgments. If a final, uninsured judgment or judgments for the payment of money in an amount, individually or in the aggregate, of at least $500,000 shall be rendered against Borrower and shall remain unsatisfied and unstayed for a period of 10 days (provided that no Credit Extensions will be made prior to the satisfaction or stay of the judgment); or

8.8 Misrepresentations. If any material misrepresentation or material misstatement exists now or hereafter in any warranty or representation set forth herein or in any certificate delivered to Bank by any Responsible Officer pursuant to this Agreement or to induce Bank to enter into this Agreement or any other Loan Document.

9. BANK'S RIGHTS AND REMEDIES.

9.1 Rights and Remedies. Upon the occurrence and during the continuance of an Event of Default, Bank may, at its election, without notice of its election and without demand, do any one or more of the following, all of which are authorized by Borrower:

(a) Declare all Obligations, whether evidenced by this Agreement, by any of the other Loan Documents, or otherwise, immediately due and payable (provided that upon the occurrence of an Event of Default described in Section 8.5 (insolvency), all Obligations shall become immediately due and payable without any action by Bank);

(b) Demand that Borrower (i) deposit cash with Bank in an amount equal to the amount of any Letters of Credit remaining undrawn, as collateral security for the repayment of any future drawings under such Letters of Credit, and (ii) pay in advance all Letter of Credit fees scheduled to be paid or payable over the remaining term of the Letters of Credit, and Borrower shall promptly deposit and pay such amounts;

(c) Cease advancing money or extending credit to or for the benefit of Borrower under this Agreement or under any other agreement between Borrower and Bank;

(d) Settle or adjust disputes and claims directly with account debtors for amounts, upon terms and in whatever order that Bank reasonably considers advisable;

(e) Make such payments and do such acts as Bank considers necessary or reasonable to protect its security interest in the Collateral. Borrower agrees to assemble the Collateral if Bank so requires, and to make the Collateral available to Bank as Bank may designate. Borrower authorizes Bank to enter the premises where the Collateral is located, to take and maintain possession of the Collateral, or any part of it, and to pay, purchase, contest, or compromise any encumbrance, charge, or lien which in Bank's determination appears to be prior or superior to its security interest and to pay all expenses incurred in connection therewith. With respect to any of Borrower's owned premises, Borrower hereby grants Bank a license to enter into possession of such premises and to occupy the same, without charge, in order to exercise any of Bank's rights or remedies provided herein, at law, in equity, or otherwise;

(f) place a "hold" on any account maintained with Bank and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any control agreement or similar agreements providing control of any Collateral;

(g) Set off and apply to the Obligations any and all (i) balances and deposits of Borrower held by Bank, and (ii) indebtedness at any time owing to or for the credit or the account of Borrower held by Bank;

(h) Ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell (in the manner provided for herein) the Collateral. Bank is hereby granted a license or other right, solely pursuant to the provisions of this Section 9.1, to use, without charge, Borrower's labels, patents, copyrights, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any property of a similar nature, as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section 9.1, Borrower's rights under all licenses and all franchise agreements shall inure to Bank's benefit;

(i) Sell the Collateral at either a public or private sale, or both, by way of one or more contracts or transactions, for cash or on terms, in such manner and at such places (including Borrower's premises) as Bank determines is commercially reasonable, and apply any proceeds to the Obligations in whatever manner or order Bank deems appropriate. Bank may sell the Collateral without giving any warranties as to the Collateral. Bank may specifically disclaim any warranties of title or the like. This procedure will not be considered adversely to affect the commercial reasonableness of any sale of the Collateral. If Bank sells any of the Collateral upon credit, Borrower will be credited only with payments actually made by the purchaser, received by Bank, and applied to the indebtedness of the purchaser. If the purchaser fails to pay for the Collateral, Bank may resell the Collateral and Borrower shall be credited with the proceeds of the sale;

(j) Bank may credit bid and purchase at any public sale;

(k) Apply for the appointment of a receiver, trustee, liquidator or conservator of the Collateral, without notice and without regard to the adequacy of the security for the Obligations and without regard to the solvency of Borrower, any guarantor or any other Person liable for any of the Obligations; and

(l) Any deficiency that exists after disposition of the Collateral as provided above will be paid immediately by Borrower.

Bank may comply with any applicable state or federal law requirements in connection with a disposition of the Collateral and compliance will not be considered adversely to affect the commercial reasonableness of any sale of the Collateral.

9.2 Power of Attorney. Effective only upon the occurrence and during the continuance of an Event of Default, Borrower hereby irrevocably appoints Bank (and any of

Bank's designated officers, or employees) as Borrower's true and lawful attorney to: (a) send requests for verification of Accounts or notify account debtors of Bank's security interest in the Accounts; (b) endorse Borrower's name on any checks or other forms of payment or security that may come into Bank's possession; (c) sign Borrower's name on any invoice or bill of lading relating to any Account, drafts against account debtors, schedules and assignments of Accounts, verifications of Accounts, and notices to account debtors; (d) dispose of any Collateral; (e) make, settle, and adjust all claims under and decisions with respect to Borrower's policies of insurance; (f) settle and adjust disputes and claims respecting the accounts directly with account debtors, for amounts and upon terms which Bank determines to be reasonable; and (g) file, in its sole discretion, one or more financing or continuation statements and amendments thereto, relative to any of the Collateral; provided Bank may exercise such power of attorney to sign the name of Borrower on any of the documents described in clause (g) above, regardless of whether an Event of Default has occurred. The appointment of Bank as Borrower's attorney in fact, and each and every one of Bank's rights and powers, being coupled with an interest, is irrevocable until all of the Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Bank's obligation to provide advances hereunder is terminated.

9.3 Accounts Collection. At any time after the occurrence and during the continuation of an Event of Default, Bank may notify any Person owing funds to Borrower of Bank's security interest in such funds and verify the amount of such Account. Borrower shall collect all amounts owing to Borrower for Bank, receive in trust all payments as Bank's trustee, and immediately deliver such payments to Bank in their original form as received from the account debtor, with proper endorsements for deposit.

9.4 Bank Expenses. If Borrower fails to pay any amounts or furnish any required proof of payment due to third persons or entities, as required under the terms of this Agreement, then Bank may do any or all of the following after reasonable notice to Borrower: (a) make payment of the same or any part thereof; and/or (b) obtain and maintain insurance policies of the type discussed in Section 6.5 of this Agreement, and take any action with respect to such policies as Bank deems prudent. Any amounts so paid or deposited by Bank shall constitute Bank Expenses, shall be immediately due and payable, and shall bear interest at the then applicable rate hereinabove provided, and shall be secured by the Collateral. Any payments made by Bank shall not constitute an agreement by Bank to make similar payments in the future or a waiver by Bank of any Event of Default under this Agreement.

9.5 Bank's Liability for Collateral. Bank has no obligation to clean up or otherwise prepare the Collateral for sale. All risk of loss, damage or destruction of the Collateral shall be borne by Borrower.

9.6 No Obligation to Pursue Others. Bank has no obligation to attempt to satisfy the Obligations by collecting them from any other person liable for them and Bank may release, modify or waive any collateral provided by any other Person to secure any of the Obligations, all without affecting Bank's rights against Borrower. Borrower waives any right it may have to require Bank to pursue any other Person for any of the Obligations.

9.7 Remedies Cumulative. Bank's rights and remedies under this Agreement, the Loan Documents, and all other agreements shall be cumulative. Bank shall have all other rights and remedies not inconsistent herewith as provided under the Code, by law, or in equity. No exercise by Bank of one right or remedy shall be deemed an election, and no waiver by Bank of any Event of Default on Borrower's part shall be deemed a continuing waiver. No delay by Bank shall constitute a waiver, election, or acquiescence by it. No waiver by Bank shall be effective unless made in a written document signed on behalf of Bank and then shall be effective only in the specific instance and for the specific purpose for which it was given. Borrower expressly agrees that this Section 9.7 may not be waived or modified by Bank by course of performance, conduct, estoppel or otherwise.

9.8 Demand; Protest. Except as otherwise provided in this Agreement, Borrower waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment and any other notices relating to the Obligations.

10. NOTICES.

Unless otherwise provided in this Agreement, all notices or demands by any party relating to this Agreement or any other agreement entered into in connection herewith shall be in writing and (except for financial statements and other reporting required pursuant to Section 6.2 of this Agreement, which shall be sent as directed in the monthly reporting forms provided by Bank) shall be personally delivered or sent by a recognized overnight delivery service, certified mail, postage prepaid, return receipt requested, or by telefacsimile or electronic mail to Borrower or to Bank, as the case may be, at its addresses set forth below:

If to Borrower: LIQUIDIA TECHNOLOGIES, INC.
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560-6837
Attn: In-house Counsel
FAX: (919) 328-4402

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@square1bank.com

with a copy to: Pacific Western Bank
406 Blackwell Street, Suite 240
Durham, North Carolina 27701
Attn: Mara Huntington

FAX: (919) 314-3090

The parties hereto may change the address at which they are to receive notices hereunder, by notice in writing in the foregoing manner given to the other.

11. CHOICE OF LAW AND VENUE; JURY TRIAL WAIVER.

This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of North Carolina, without regard to principles of conflicts of law. Jurisdiction shall lie in the State of North Carolina. All disputes, controversies, claims, actions and similar proceedings arising with respect to Borrower's account or any related agreement or transaction shall be brought in the General Court of Justice of North Carolina sitting in Durham County, North Carolina or the United States District Court for the Middle District of North Carolina, except as provided below with respect to arbitration of such matters. BANK AND BORROWER EACH ACKNOWLEDGE THAT THE RIGHT TO TRIAL BY JURY IS A CONSTITUTIONAL ONE, BUT THAT IT MAY BE WAIVED. EACH OF THEM, AFTER CONSULTING OR HAVING HAD THE OPPORTUNITY TO CONSULT, WITH COUNSEL OF THEIR CHOICE, KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVES ANY RIGHT ANY OF THEM MAY HAVE TO A TRIAL BY JURY IN ANY LITIGATION BASED UPON OR ARISING OUT OF THIS AGREEMENT OR ANY RELATED INSTRUMENT OR LOAN DOCUMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT OR ANY COURSE OF CONDUCT, DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN), OR ACTION OF ANY OF THEM. THESE PROVISIONS SHALL NOT BE DEEMED TO HAVE BEEN MODIFIED IN ANY RESPECT OR RELINQUISHED BY BANK OR BORROWER, EXCEPT BY A WRITTEN INSTRUMENT EXECUTED BY EACH OF THEM. If the jury waiver set forth in this Section 11 is not enforceable, then any dispute, controversy, claim, action or similar proceeding arising out of or relating to this Agreement, the Loan Documents or any of the transactions contemplated therein shall be settled by final and binding arbitration held in Durham County, North Carolina in accordance with the then current Commercial Arbitration Rules of the American Arbitration Association by one arbitrator appointed in accordance with those rules. The arbitrator shall apply North Carolina law to the resolution of any dispute, without reference to rules of conflicts of law or rules of statutory arbitration. Judgment upon any award resulting from arbitration may be entered into and enforced by any state or federal court having jurisdiction thereof. Notwithstanding the foregoing, the parties may apply to any court of competent jurisdiction for preliminary or interim equitable relief, or to compel arbitration in accordance with this Section. The costs and expenses of the arbitration, including without limitation, the arbitrator's fees and expert witness fees, and reasonable attorneys' fees, incurred by the parties to the arbitration may be awarded to the prevailing party, in the discretion of the arbitrator, or may be apportioned between the parties in any manner deemed appropriate by the arbitrator. Unless and until the arbitrator decides that one party is to pay for all (or a share) of such costs and expenses, both parties shall share equally in the payment of the arbitrator's fees as and when billed by the arbitrator.

12. GENERAL PROVISIONS.

12.1 Successors and Assigns. This Agreement shall bind and inure to the benefit of the respective successors and permitted assigns of each of the parties and shall bind all persons who become bound as a debtor to this Agreement; provided, however, that neither this Agreement nor any rights hereunder may be assigned by Borrower without Bank's prior written consent, which consent may be granted or withheld in Bank's sole discretion. Bank shall have the right without the consent of or notice to Borrower to sell, assign, transfer, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights and benefits hereunder.

12.2 Indemnification. Borrower shall defend, indemnify and hold harmless Bank and its officers, directors, employees, affiliates, advisors and agents (each, an "Indemnified Party") against: (a) all obligations, demands, claims, and liabilities claimed or asserted by any other party in connection with the transactions contemplated by this Agreement; and (b) all losses or Bank Expenses in any way suffered, incurred, or paid by Bank, its officers, employees and agents as a result of or in any way arising out of, following, or consequential to transactions between Bank and Borrower whether under this Agreement, or otherwise (including without limitation reasonable attorneys' fees and expenses), except for losses, claims and Bank Expenses caused by an Indemnified Party's gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and non-appealable order.

12.3 Time of Essence. Time is of the essence for the performance of all obligations set forth in this Agreement.

12.4 Severability of Provisions. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

12.5 Amendments in Writing, Integration. All amendments to or terminations of this Agreement or the other Loan Documents must be in writing. All prior agreements, understandings, representations, warranties, and negotiations between the parties hereto with respect to the subject matter of this Agreement and the other Loan Documents, if any, are merged into this Agreement and the Loan Documents.

12.6 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement. Executed copies of the signature pages of this Agreement sent by facsimile or transmitted electronically in Portable Document Format ("PDF"), or any similar format, shall be treated as originals, fully binding and with full legal force and effect, and the parties waive any rights they may have to object to such treatment.

12.7 Survival. All covenants, representations and warranties made in this Agreement shall continue in full force and effect so long as any Obligations remain outstanding or Bank has any obligation to make any Credit Extension to Borrower. The obligations of Borrower to indemnify Bank with respect to the expenses, damages, losses, costs and liabilities described in Section 12.2 shall survive until all applicable statute of limitations periods with respect to actions that may be brought against Bank have run.

12.8 Confidentiality and Publicity.

(a) Borrower shall not, and shall not permit any of its Affiliates to: (i) publish or disclose any materials containing Bank's name, including in any press release or otherwise in connection with any advertising or marketing, without first obtaining Bank's prior written consent, or (ii) use Bank's name (or the name of any of its Affiliates) in connection with its operations or business.

(b) In handling any confidential information, Bank shall exercise commercially reasonable efforts to maintain in confidence, in accordance with its customary procedures for handling confidential information, all written non-public information furnished to Bank on a confidential basis clearly identified at the time of delivery as such ("Confidential Information") other than any such Confidential Information that becomes generally available to the public or becomes available to the Bank from a source other than Borrower and that is not known to Bank to be subject to confidentiality obligations; provided, that Bank and its Affiliates shall have the right to disclose Confidential Information to: (i) such Person's Affiliates; (ii) such Person or such Person's Affiliates' lenders, funding sources, or financing sources; (iii) such Person's or such Person's Affiliates' directors, officers, trustees, partners, members, managers, employees, agents, advisors, representatives, attorneys, equity owners, professional consultants, portfolio management services and rating agencies; (iv) any successor or assign of Bank; (v) any Person to whom Bank offers to sell, assign or transfer any Credit Extension or any part thereof or any interest or participation therein; (vi) any Person that provides statistical analysis and/or information services to Bank or its Affiliates; and (vii) any Person (A) to the extent required by it by law, (B) as may be required in connection with the examination, audit, or similar investigation of Bank, (C) in response to any subpoena or other legal process or informal investigative demand, (D) in connection with any litigation, or (E) in connection with the actual or potential exercise or enforcement of any right or remedy under any Loan Document. The obligations of Bank and its Affiliates under this Section 12.8 shall supersede and replace any other confidentiality obligations agreed to by Bank or its Affiliates.

12.9 **No Novation**. Nothing contained herein shall in any way impair the Prior Loan Agreement and the other Loan Documents now held for the Obligations, nor affect or impair any rights, powers, or remedies under the Prior Loan Agreement or any Loan Document, it being the intent of the parties hereto that this Agreement shall not constitute a novation of the Prior Loan Agreement or an accord and satisfaction of the Obligations. Except as expressly provided for in this Agreement, the Loan Documents are hereby ratified and reaffirmed and shall remain in full force and effect. Borrower hereby ratifies and reaffirms the validity and enforceability of all of the liens and security interests heretofore granted pursuant to the Loan Documents, as collateral security for the Obligations, and acknowledges that all of such liens and security interests, and all Collateral heretofore pledged as security for the Obligations, continues to be and remains in full force and effect as Collateral for the Obligations from and after the date of this Agreement. Borrower and Bank acknowledge and agree that there are no known Events of Default that have occurred and are continuing as of the Closing Date; provided that the foregoing acknowledgement shall not be deemed to be a consent or waiver with respect to any Event of Default that may have occurred prior to the date hereof of which Bank is not currently aware, or which may hereafter occur, under the Prior Loan Agreement, this Agreement or any other Loan Document; nor shall the foregoing acknowledgement limit or impair in any way Bank's rights and remedies with respect to any such Event of Default.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

LIQUIDIA TECHNOLOGIES, INC.

By: /s/ Timothy Albury

Name: Timothy Albury

Title: SVP and Chief Accounting Officer

PACIFIC WESTERN BANK

By: /s/ Lan Zhu

Name: Lan Zhu

Title: Vice President

EXHIBIT A

DEFINITIONS

"Accounts" means all presently existing and hereafter arising accounts, contract rights, payment intangibles and all other forms of obligations owing to Borrower arising out of the sale or lease of goods (including, without limitation, the licensing of software and other technology) or the rendering of services by Borrower and any and all credit insurance, guaranties, and other security therefore, as well as all merchandise returned to or reclaimed by Borrower and Borrower's Books relating to any of the foregoing.

"Affiliate" means, with respect to any Person, any Person that owns or controls directly or indirectly such Person, any Person that controls or is controlled by or is under common control with such Person, and each of such Person's senior executive officers, directors, and general partners.

"Authorized Officer" means someone designated as such in the corporate resolution provided by Borrower to Bank in which this Agreement and the transactions contemplated hereunder are authorized by Borrower's board of directors. If Borrower provides subsequent corporate resolutions to Bank after the Closing Date, the individual(s) designated as "Authorized Officer(s)" in the most recently provided resolution shall be the only "Authorized Officers" for purposes of this Agreement.

"Bank Expenses" means all reasonable costs or expenses (including reasonable attorneys' fees and expenses, whether generated by in-house or by outside counsel) incurred in connection with the preparation, negotiation, administration, and enforcement of the Loan Documents; reasonable Collateral audit fees; and Bank's reasonable attorneys' fees and expenses (whether generated in-house or by outside counsel) incurred in amending, enforcing or defending the Loan Documents (including fees and expenses of appeal), incurred before, during and after an Insolvency Proceeding, whether or not suit is brought.

"Borrower's Books" means all of Borrower's books and records including: ledgers; records concerning Borrower's assets or liabilities, the Collateral, business operations or financial condition; and all computer programs, or tape files, and the equipment, containing such information.

"Business Day" means any day that is not a Saturday, Sunday, or other day on which banks in the State of North Carolina are authorized or required to close.

"Capitalized Expenditures" means current period unfinanced cash expenditures that are capitalized and amortized over a period of time in accordance with GAAP, including but not limited to unfinanced capitalized cash expenditures for capital equipment, unfinanced capitalized manufacturing and labor costs as they relate to inventory, and unfinanced capitalized cash expenditures for software development.

"Cash" means unrestricted cash and cash equivalents.

“Change in Control” shall mean a transaction other than a bona fide equity financing or series of financings on terms and from investors reasonably acceptable to Bank in which any “person” or “group” (within the meaning of Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934) becomes the “beneficial owner” (as defined in Rule 13d-3 under the Securities Exchange Act of 1934), directly or indirectly, of a sufficient number of shares of all classes of stock then outstanding of Borrower ordinarily entitled to vote in the election of directors, empowering such “person” or “group” to elect a majority of the Board of Directors of Borrower, who did not have such power before such transaction.

“Closing Date” means the date of this Agreement.

“Code” means the North Carolina Uniform Commercial Code as amended or supplemented from time to time.

“Collateral” means the property described on Exhibit B attached hereto and all Negotiable Collateral to the extent not described on Exhibit B, except to the extent any such property (i) is non-assignable by its terms without the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections §25-9-406 and §25-9-408 of the Code), (ii) the granting of a security interest therein is contrary to applicable law, provided that upon the cessation of any such restriction or prohibition, such property shall automatically become part of the Collateral, (iii) constitutes the capital stock of a controlled foreign corporation (as defined in the IRC), in excess of 65% of the voting power of all classes of capital stock of such controlled foreign corporations entitled to vote, or (iv) property (including any attachments, accessions or replacements) that is subject to a Lien that is permitted pursuant to clause (c) of the definition of Permitted Liens, if the grant of a security interest with respect to such property pursuant to this Agreement would be prohibited by the agreement creating such Permitted Lien or would otherwise constitute a default thereunder, provided, that such property will be deemed "Collateral" hereunder upon the termination and release of such Permitted Lien.

“Collateral State” means the state or states where the Collateral is located, which is North Carolina.

“Compliance Certificate” means a compliance certificate, in substantially the form of Exhibit D attached hereto, executed by a Responsible Officer of the Borrower.

“Contingent Obligation” means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any indebtedness, lease, dividend, letter of credit or other obligation of another, including, without limitation, any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term “Contingent Obligation” shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement.

"Conversion Date" is defined in Section 2.1(b)(ii).

"Copyrights" means any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, now or hereafter existing, created, acquired or held.

"Credit Card Line" means a Credit Extension of up to $50,000, to be used exclusively for the provision of Credit Card Services.

"Credit Card Maturity Date" means September 30, 2020.

"Credit Card Services" is defined in Section 2.1(c)(ii).

"Credit Extension" means each Term Loan, the Credit Card Services provided under the Credit Card Line, or any other extension of credit by Bank to or for the benefit of Borrower hereunder.

"Equipment" means all present and future machinery, equipment, tenant improvements, furniture, fixtures, vehicles, tools, parts and attachments in which Borrower has any interest.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations thereunder.

"Event of Default" has the meaning assigned in Article 8.

"Funding Milestone" means Borrower has, after the Closing Date and on or prior to October 31, 2019: (i) received at least Forty Million Dollars ($40,000,000) of aggregate gross Cash proceeds from the sale of New Equity or licensing of Borrower's Intellectual Property, and (ii) completed public disclosure of the safety data analysis for LIQ-861 without any materially adverse data.

"GAAP" means generally accepted accounting principles, consistently applied, as in effect from time to time in the United States.

"Indebtedness" means (a) all indebtedness for borrowed money or the deferred purchase price of property or services, including without limitation reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations, and (d) all Contingent Obligations, including but not limited to any sublimit contained herein.

"Insolvency Proceeding" means any proceeding commenced by or against any Person or entity under any provision of the United States Bankruptcy Code, as amended, or under any other bankruptcy or insolvency law, including assignments for the benefit of creditors, formal or informal moratoria, compositions, extension generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"Intellectual Property" means all of Borrower's right, title, and interest in and to the following:

(a) Copyrights, Trademarks and Patents;

(b) Any and all trade secrets, and any and all intellectual property rights in computer software and computer software products now or hereafter existing, created, acquired or held;

(c) Any and all design rights which may be available to Borrower now or hereafter existing, created, acquired or held;

(d) Any and all claims for damages by way of past, present and future infringement of any of the rights included above, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the intellectual property rights identified above;

(e) All licenses or other rights to use any of the Copyrights, Patents or Trademarks, and all license fees and royalties arising from such use to the extent permitted by such license or rights;

(f) All amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents; and

(g) All proceeds and products of the foregoing, including without limitation all payments under insurance or any indemnity or warranty payable in respect of any of the foregoing.

"Interest-Only Extension Milestone" means Borrower has received, after the Closing Date and on or prior to October 31, 2019, at least Forty Million Dollars ($40,000,000) of aggregate gross Cash proceeds from the sale of New Equity or licensing of Borrower's Intellectual Property.

"Interest-Only Period" means the period commencing on the Closing Date and continuing through December 31, 2019; provided however, that if Borrower provides evidence reasonably satisfactory to Bank that Borrower has achieved the Interest-Only Extension Milestone, the Interest-Only Period shall be extended to June 30, 2020.

"Inventory" means all present and future inventory in which Borrower has any interest.

"Investment" means any beneficial ownership of (including stock, partnership or limited liability company interest or other securities) any Person, or any loan, advance or capital contribution to any Person.

"Investment Agreement" means, collectively, Borrower's stock purchase and other agreement(s) pursuant to which Borrower most recently issued its preferred stock.

"IRC" means the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

"Letter of Credit" means a commercial or standby letter of credit or similar undertaking issued by Bank (or any of its correspondent banks) at Borrower's request.

"Lien" means any mortgage, lien, deed of trust, charge, pledge, security interest or other encumbrance.

"Liquidity Event" means Borrower has provided evidence reasonably acceptable to Bank that Borrower has received at least Forty Million Dollars ($40,000,000) of gross Cash proceeds from the sale of New Equity.

"Loan Documents" means, collectively, this Agreement, any note or notes executed by Borrower, and any other document, instrument or agreement entered into in connection with this Agreement, all as amended or extended from time to time.

"Long-Term Success Fee" is defined in Section 2.4(e).

"Material Adverse Effect" means a material adverse effect on (i) the operations, business or financial condition of Borrower and its Subsidiaries taken as a whole, (ii) the ability of Borrower to repay the Obligations or otherwise perform its obligations under the Loan Documents, or (iii) Borrower's interest in, or the value, perfection or priority of Bank's security interest in the Collateral.

"Minimum Cash Threshold" is defined in Section 6.7(a).

"Near-Term Success Fee" is defined in Section 2.4(d).

"Negotiable Collateral" means all of Borrower's present and future letters of credit of which it is a beneficiary, drafts, instruments (including promissory notes), securities, documents of title, and chattel paper, and Borrower's Books relating to any of the foregoing.

"New Equity" means cash proceeds received after the Closing Date from the sale or issuance of Borrower's equity securities to investors.

"Obligations" means all debt, principal, interest, Bank Expenses and other amounts owed to Bank by Borrower pursuant to this Agreement or any other agreement, whether absolute or contingent, due or to become due, now existing or hereafter arising, including any interest that accrues after the commencement of an Insolvency Proceeding and including any debt, liability, or obligation owing from Borrower to others that Bank may have obtained by assignment or otherwise.

"Patents" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Performance Milestone" means, prior to June 30, 2019, Borrower has both (i) completed full enrollment of the LIQ-861 Phase 3 trial (LTI-301), and (ii) not observed any materially adverse data related to the safety of LIQ-861 through the two-week endpoint.

"Periodic Payments" means all installments or similar recurring payments that Borrower may now or hereafter become obligated to pay to Bank pursuant to the terms and provisions of any instrument, or agreement now or hereafter in existence between Borrower and Bank.

"Permitted Indebtedness" means:

(a) Indebtedness of Borrower in favor of Bank arising under this Agreement or any other Loan Document;

(b) Indebtedness existing on the Closing Date and disclosed in the Schedule;

(c) Indebtedness to not to exceed $3,500,000 in the aggregate at any time (including any amounts existing on the Closing Date and disclosed in the Schedule pursuant to clause (b) above) secured by a lien described in clause (c) of the defined term "Permitted Liens," provided such Indebtedness does not exceed at the time it is incurred the lesser of the cost or fair market value of the property financed with such Indebtedness;

(d) Subordinated Debt;

(e) Indebtedness to trade creditors incurred in the ordinary course of business;

(f) Indebtedness incurred in connection with the financing solely of director's and officer's insurance premiums in an aggregate amount at any time outstanding not to exceed the lesser of premiums owed under such policies or $650,000; and

(g) Extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"Permitted Investment" means:

(a) Investments existing on the Closing Date disclosed in the Schedule;

(b) (i) Marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof, (ii) commercial paper maturing no more than one year from the date of creation thereof and currently having rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (iii) Bank's certificates of deposit maturing no more than one year from the date of investment therein, and (iv) Bank's money market accounts; (v) Investments in regular deposit or checking accounts held with Bank or as otherwise permitted by, and subject to the terms and conditions of, Section 6.6 of this Agreement; and (vi) Investments consistent with any investment policy adopted by the Borrower's board of directors;

(c) Investments accepted in connection with Permitted Transfers;

(d) Investments of Subsidiaries in or to other Subsidiaries or Borrower and Investments by Borrower in Subsidiaries not to exceed $250,000 in the aggregate in any fiscal year;

(e) Investments not to exceed $250,000 outstanding in the aggregate at any time consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plan agreements approved by Borrower's Board of Directors;

(f) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;

(g) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business, provided that this subparagraph (g) shall not apply to Investments of Borrower in any Subsidiary;

(h) Joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support, provided that any cash Investments by Borrower do not exceed $500,000 in the aggregate in any fiscal year; and

(i) Investments permitted under Section 7.3.

"Permitted Liens" means the following:

(a) Any Liens existing on the Closing Date and disclosed in the Schedule (excluding Liens to be satisfied with the proceeds of the Credit Extensions) or arising under this Agreement, the other Loan Documents, or any other agreement in favor of Bank;

(b) Liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings and for which Borrower maintains adequate reserves;

(c) Liens not to exceed $3,500,000 in the aggregate (including any Liens existing on the Closing Date and disclosed in the Schedule pursuant to clause (a) above) at any time (i) upon or in any Equipment (other than Equipment financed by a Credit Extension) acquired or held by Borrower or any of its Subsidiaries to secure the purchase price of such Equipment or indebtedness incurred solely for the purpose of financing the acquisition or lease of such Equipment, or (ii) existing on such Equipment at the time of its acquisition, in each case provided that the Lien is confined solely to the property so acquired and improvements thereon, and the proceeds of such Equipment;

(d) Liens incurred in connection with the extension, renewal or refinancing of the indebtedness secured by Liens of the type described in clauses (a) through (c) above, provided that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness being extended, renewed or refinanced does not increase; and

(e) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Sections 8.4 (attachment) or 8.8 (judgments);

(f) Liens securing Subordinated Debt, provided that such Liens do not encumber assets beyond those assets comprising the Collateral;

(g) Liens to secure the payment of worker's compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA), provided that the aggregate of all such Liens shall not exceed $250,000 at any time; and

(h) Leases or subleases of real property granted in the ordinary course of business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses of personal property (other than Intellectual Property) granted in the ordinary course of business which (i) do not interfere in any material respect with the business of Borrower and its Subsidiaries, (ii) do not secure any Indebtedness, and (iii) are not otherwise prohibited by this Agreement.

“Permitted Transfer” means the conveyance, sale, lease, transfer or disposition by Borrower or any Subsidiary of:

(a) Inventory in the ordinary course of business;

(b) licenses and similar arrangements for the use of the property of Borrower or its Subsidiaries in the ordinary course of business;

(c) worn-out, surplus or obsolete Equipment;

(d) grants of security interests and other Liens that constitute Permitted Liens; and

(e) other assets of Borrower or its Subsidiaries that do not in the aggregate exceed $250,000 during any fiscal year.

“Person” means any individual, sole proprietorship, partnership, limited liability company, joint venture, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or governmental agency.

“Prepayment Fee” is defined in Section 2.4(c).

“Prime Rate” means the variable rate of interest, per annum, most recently announced by Bank, as its “prime rate,” whether or not such announced rate is the lowest rate available from Bank; provided that, in the event such rate of interest is less than zero percent (0.00%), such rate shall be deemed to be zero percent (0.00%) for purposes of this Agreement.

“Prior Loan Agreement” is defined in the recitals to this Agreement.

“Repayment Period” is the period commencing on the Conversion Date and continuing through the Term Loan Maturity Date.

“Responsible Officer” means each of the Chief Executive Officer, the Chief Operating Officer (if any), the Chief Financial Officer, Vice President of Finance and the Controller of Borrower, as well as any other officer or employee identified as an Authorized Officer in the corporate resolution delivered by Borrower to Bank in connection with this Agreement.

“Schedule” means the schedule of exceptions attached hereto and approved by Bank, if any.

“SOS Reports” means the official reports from the Secretaries of State of each Collateral State, the state where Borrower’s chief executive office is located, the state of Borrower’s formation and other applicable federal, state or local government offices identifying all current security interests filed in the Collateral and Liens of record as of the date of such report.

“Subordinated Debt” means any debt incurred by Borrower that is subordinated in writing to the debt owing by Borrower to Bank on terms reasonably acceptable to Bank (and identified as being such by Borrower and Bank).

“Subsidiary” means any corporation, partnership or limited liability company or joint venture in which (i) any general partnership interest or (ii) more than 50% of the stock, limited liability company interest or joint venture of which by the terms thereof ordinary voting power to elect the Board of Directors, managers or trustees of the entity, at the time as of which any determination is being made, is owned by Borrower, either directly or through an Affiliate.

“Term Loan Maturity Date” means the date occurring four (4) years after the Closing Date.

“Trademarks” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

“Tranche” means any of Tranche A or Tranche B.

“Tranche A” has the meaning assigned in Section 2.1(b)(i).

“Tranche B” has the meaning assigned in Section 2.1(b)(i).

“Tranche A Term Loan” means the Term Loan made under Tranche A.

“Tranche B Term Loan” or “Tranche B Term Loans” means any Term Loan(s) made under Tranche B.

“Tranche B Availability End Date” means June 30, 2019.

“UNC Debt” means Indebtedness of the Borrower to the University of North Carolina at Chapel Hill, such Indebtedness being unsecured and not evidenced by a promissory note.

DEBTOR **LIQUIDIA TECHNOLOGIES, INC.**

SECURED PARTY: **PACIFIC WESTERN BANK**

EXHIBIT B

COLLATERAL DESCRIPTION ATTACHMENT TO AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

All personal property of Borrower (herein referred to as "Borrower" or "Debtor") whether presently existing or hereafter created or acquired, and wherever located, including, but not limited to:

(a) all accounts (including health-care-insurance receivables), chattel paper (including tangible and electronic chattel paper), deposit accounts, documents (including negotiable documents), equipment (including all accessions and additions thereto), financial assets, general intangibles (including patents, trademarks, copyrights, goodwill, payment intangibles, domain names and software), goods (including fixtures), instruments (including promissory notes), inventory (including all goods held for sale or lease or to be furnished under a contract of service, and including returns and repossessions), investment property (including securities and securities entitlements), letter of credit rights, money, and all of Debtor's books and records with respect to any of the foregoing, and the computers and equipment containing said books and records;

(b) any and all cash proceeds and/or noncash proceeds of any of the foregoing, including, without limitation, insurance proceeds, and all supporting obligations and the security therefor or for any right to payment. All terms above have the meanings given to them in the North Carolina Uniform Commercial Code, as amended or supplemented from time to time, including revised Division 9 of the Uniform Commercial Code-Secured Transactions.

Notwithstanding the foregoing, the Collateral shall not include any of the intellectual property, in any medium, of any kind or nature whatsoever, now or hereafter owned or acquired or received by Borrower, or in which Borrower now holds or hereafter acquires or receives any right or interest (collectively, the "Intellectual Property"); provided, however, that the Collateral shall include all accounts and general intangibles that consist of rights to payment and proceeds from the sale, licensing or disposition of all or any part, or rights in, the foregoing (the "Rights to Payment").

Notwithstanding the foregoing, if a judicial authority (including a U.S. Bankruptcy Court) holds that a security interest in the underlying Intellectual Property is necessary to have a security interest in the Rights to Payment, then the Collateral shall automatically, and effective as of January 6, 2016 include the Intellectual Property to the extent and only to the extent necessary to permit perfection of Bank's security interest in the Rights to Payment, and further provided, however, that Bank's enforcement rights with respect to any security interest in the Intellectual Property shall be absolutely limited to the Rights to Payment only, and Bank shall have no recourse whatsoever with respect to the underlying Intellectual Property.

EXHIBIT C

LOAN ADVANCE/PAYDOWN REQUEST FORM
[Please refer to New Borrower Kit]

EXHIBIT D

COMPLIANCE CERTIFICATE

[Please refer to New Borrower Kit]

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: October 31, 2018

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, Kevin Gordon, 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: October 31, 2018	By:	/s/ Kevin Gordon
	Name:	Kevin Gordon
	Title:	President and 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 September 30, 2018, 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: October 31, 2018	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 September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Kevin Gordon, 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: October 31, 2018	By:	/s/ Kevin Gordon
	Name:	Kevin Gordon
	Title:	President and Chief Financial Officer (Principal Financial Officer)