

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2019

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-38268

ALLENA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Securities registered pursuant to Section 12(b) of the Act:

Delaware

(State or other jurisdiction of
incorporation or organization)

45-2729920

(I.R.S. Employer
Identification No.)

One Newton Executive Park, Suite 202

Newton, Massachusetts

(Address of principal executive offices)

02462

(Zip Code)

Registrant's telephone number, including area code: (617) 467-4577

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ALNA	The Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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

Non-accelerated filer

Accelerated filer

Small 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 November 1, 2019, the registrant had 23,465,665 shares of common stock, \$0.001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. These statements include all matters that are not related to present facts or current conditions or that are not historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. The words “anticipate,” “believe,” “could,” “continue,” “should,” “predict,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “will,” “may,” “would,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on 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 financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q, regarding, among other things:

- our ability to continue as a going concern, including without limitation our ability to continue to advance the clinical development of our product candidates;
 - our ability to raise additional funds through equity or debt financings or through collaborations, licensing transactions or other sources;
 - our review of the data from the URIROX-1 clinical trial and Study 206 and the related implications for the future clinical, regulatory and commercial potential of reloxaliase;
 - the design and conduct of our Phase 3 clinical program of reloxaliase (formerly referred to as ALLN-177) in enteric hyperoxaluria;
 - our ability to utilize the accelerated approval regulatory pathway for reloxaliase, including the timing of any Biologic License Application, or BLA, submission utilizing the accelerated approval regulatory pathway;
 - the number, designs, results and timing of our clinical trials, including our pivotal Phase 3 program of reloxaliase, and preclinical studies and the timing of the availability of data from these trials and activities;
 - our ability to enroll a sufficient number of patients and the ability of subjects in our clinical trials to adhere to the protocol, including capsule and dietary regimen and urinary collection requirements;
 - the therapeutic benefits, effectiveness and safety of reloxaliase, ALLN-346 and our future product candidates;
 - our expected regulatory pathway, and our ability to receive regulatory approval for our product candidates in the United States, Europe and other geographies;
 - our ability to obtain, on satisfactory terms or at all, the financing required to support operations, development, clinical trials, and commercialization of products;
 - our reliance on third-parties for the planning, conduct and monitoring of clinical trials and for the manufacture of clinical drug supplies and drug product;
 - potential changes in regulatory requirements, and delays or negative outcomes from the regulatory approval process;
 - our estimates of the size and characteristics of the markets that may be addressed by reloxaliase and ALLN-346;
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- the market acceptance of reloxaliase, ALLN-346 or any future product candidates that are approved for marketing in the United States or other countries;
- our ability to successfully commercialize reloxaliase, if approved, with a targeted sales force;
- the safety and efficacy of therapeutics marketed by our competitors that are targeted to indications which our product candidates have been developed to treat;
- our ability to utilize our proprietary technological approach to develop and commercialize ALLN-346 and future product candidates;
- potential collaborators to license and commercialize reloxaliase, if approved, or any products for which we receive regulatory approval in the future outside of the United States;
- our heavy dependence on licensed intellectual property, including our ability to source and maintain licenses from third-party owners;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our ability to attract, retain and motivate key personnel;
- our product development and operational plans, generally;
- our ability to generate revenue and become profitable;
- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act; and
- our estimates and expectations regarding our capital requirements, cash and expense levels, liquidity sources and our need for additional financing.

These risks are not exhaustive. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. No forward-looking statement is a guarantee of future performance.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to the registration statement of which this Quarterly Report on Form 10-Q is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, 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.

Table of Contents

	<u>Page</u>
PART I.	
	<u>FINANCIAL INFORMATION</u>
Item 1.	<u>Financial Statements (Unaudited)</u>
	<u>Condensed Consolidated Balance Sheets</u>
	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss</u>
	<u>Condensed Consolidated Statements of Stockholders' Equity</u>
	<u>Condensed Consolidated Statements of Cash Flows</u>
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
Item 4.	<u>Controls and Procedures</u>
PART II.	
	<u>OTHER INFORMATION</u>
Item 1.	<u>Legal Proceedings</u>
Item 1A.	<u>Risk Factors</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
Item 3.	<u>Defaults Upon Senior Securities</u>
Item 4.	<u>Mine Safety Disclosures</u>
Item 5.	<u>Other Information</u>
Item 6.	<u>Exhibits</u>
	<u>Signatures</u>

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Alena Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,419	\$ 61,643
Prepaid expenses and other current assets	2,160	2,826
Total current assets	41,579	64,469
Property and equipment, net	443	514
Operating lease assets	622	—
Other assets	123	246
Total assets	<u>\$ 42,767</u>	<u>\$ 65,229</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,600	\$ 2,138
Accrued expenses and other current liabilities	3,367	3,625
Loan payable, net of discount	2,992	—
Operating lease liabilities	529	—
Total current liabilities	10,488	5,763
Loan payable, net of current portion and discount	6,986	9,980
Operating lease liabilities, net of current portion	102	—
Other liabilities	-	30
Total liabilities	17,576	15,773
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Undesignated preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 125,000,000 shares authorized; 23,465,665 and 20,809,025 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	23	21
Additional paid-in capital	178,753	167,040
Accumulated deficit	(153,585)	(117,605)
Total stockholders' equity	25,191	49,456
Total liabilities and stockholders' equity	<u>\$ 42,767</u>	<u>\$ 65,229</u>

See accompanying notes.

Allena Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Operating expenses:				
Research and development	\$ 10,806	\$ 7,316	\$ 28,523	\$ 19,107
General and administrative	2,532	2,389	7,709	6,706
Total operating expenses	<u>13,338</u>	<u>9,705</u>	<u>36,232</u>	<u>25,813</u>
Loss from operations	(13,338)	(9,705)	(36,232)	(25,813)
Other income (expense):				
Interest income, net	53	180	282	398
Other expense, net	(3)	15	(30)	(5)
Loss on extinguishment of debt	—	—	—	(617)
Other income (expense), net	<u>50</u>	<u>195</u>	<u>252</u>	<u>(224)</u>
Net loss	<u>\$ (13,288)</u>	<u>\$ (9,510)</u>	<u>\$ (35,980)</u>	<u>\$ (26,037)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.57)</u>	<u>\$ (0.46)</u>	<u>\$ (1.66)</u>	<u>\$ (1.26)</u>
Weighted-average common shares outstanding—basic and diluted	<u>23,464,828</u>	<u>20,753,215</u>	<u>21,737,320</u>	<u>20,727,426</u>
Comprehensive loss	<u>\$ (13,288)</u>	<u>\$ (9,510)</u>	<u>\$ (35,980)</u>	<u>\$ (26,037)</u>

See accompanying notes.

Allena Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(in thousands, except share amounts)

Three Months Ended September 30,

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at June 30, 2018	20,752,167	\$ 21	\$ 165,817	\$ (98,484)	\$ 67,354
Exercise of common stock options	4,018	—	6	—	6
Stock-based compensation	—	—	595	—	595
Net loss	—	—	—	(9,510)	(9,510)
Balance at September 30, 2018	<u>20,756,185</u>	<u>\$ 21</u>	<u>\$ 166,418</u>	<u>\$ (107,994)</u>	<u>\$ 58,445</u>
Balance at June 30, 2019	23,462,165	\$ 23	\$ 177,947	\$ (140,297)	\$ 37,673
Issuance of common stock, net of issuance costs	-	—	(10)	—	(10)
Exercise of common stock options	3,500	—	6	—	6
Stock-based compensation	—	—	810	—	810
Net loss	—	—	—	(13,288)	(13,288)
Balance at September 30, 2019	<u>23,465,665</u>	<u>\$ 23</u>	<u>\$ 178,753</u>	<u>\$ (153,585)</u>	<u>\$ 25,191</u>

Nine Months Ended September 30,

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2017	20,694,658	\$ 20	\$ 164,807	\$ (81,957)	\$ 82,870
Exercise of common stock options	61,527	1	86	—	87
Stock-based compensation	—	—	1,512	—	1,512
Issuance costs related to initial public offering	—	—	13	—	13
Net loss	—	—	—	(26,037)	(26,037)
Balance at September 30, 2018	<u>20,756,185</u>	<u>\$ 21</u>	<u>\$ 166,418</u>	<u>\$ (107,994)</u>	<u>\$ 58,445</u>
Balance at December 31, 2018	20,809,025	\$ 21	\$ 167,040	\$ (117,605)	\$ 49,456
Issuance of common stock, net of issuance costs	2,632,092	2	9,434	—	9,436
Exercise of common stock options	10,539	—	19	—	19
Issuance of common stock through employee stock purchase plan ("ESPP")	14,009	—	49	—	49
Stock-based compensation	—	—	2,211	—	2,211
Net loss	—	—	—	(35,980)	(35,980)
Balance at September 30, 2019	<u>23,465,665</u>	<u>\$ 23</u>	<u>\$ 178,753</u>	<u>\$ (153,585)</u>	<u>\$ 25,191</u>

See accompanying notes.

Allena Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (35,980)	\$ (26,037)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,211	1,512
Depreciation expense	121	44
Non-cash interest expense	6	159
Loss on extinguishment of debt	—	617
Changes in assets and liabilities:		
Prepaid expenses and other current assets	666	(639)
Operating lease assets	369	—
Other assets	123	(102)
Accounts payable	1,534	(1)
Accrued expenses	(389)	1,300
Operating lease liabilities	(368)	—
Other liabilities	—	18
Net cash used in operating activities	(31,707)	(23,129)
Cash flows from investing activities:		
Purchases of property and equipment	(122)	(156)
Net cash used in investing activities	(122)	(156)
Cash flows from financing activities:		
Proceeds from (payments of issuance costs) the issuance of common stock, net of issuance costs	9,559	(186)
Proceeds from exercise of stock options	19	87
Proceeds from issuance of stock through ESPP	49	—
Proceeds from loan payable	—	10,000
Repayment of loan payable	—	(10,492)
Debt issuance costs paid	—	(33)
Other	(22)	(26)
Net cash provided by (used in) financing activities	9,605	(650)
Net decrease in cash and cash equivalents	(22,224)	(23,935)
Cash and cash equivalents, beginning of period	61,643	94,494
Cash and cash equivalents, end of period	<u>\$ 39,419</u>	<u>\$ 70,559</u>
Supplemental disclosures:		
Cash paid in connection with operating lease liabilities	\$ 398	\$ —
Right-of-use assets obtained in exchange of operating lease obligations	\$ 992	\$ —

See accompanying notes.

Allena Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)
(in thousands, except share and per share data)

1. Nature of Business

Allena Pharmaceuticals, Inc. (the “Company”) is a late-stage clinical biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. The Company is focused on metabolic disorders that result in excess accumulation of certain metabolites that can cause kidney stones, damage the kidney, and potentially lead to chronic kidney disease (“CKD”), and end-stage renal disease. The Company’s lead product candidate, reloxaliase (formerly known as ALLN-177), is a first-in-class, oral enzyme therapeutic that it is developing for the treatment of hyperoxaluria, a metabolic disorder commonly associated with kidney stones, CKD and other serious kidney diseases. The Company was incorporated under the laws of the State of Delaware on June 24, 2011 and is located in Newton, Massachusetts.

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, reliance on third party manufacturers, ability to transition from pilot-scale manufacturing to large-scale production of products and the need to obtain adequate additional financing to fund the development of its product candidates.

Liquidity and Going Concern

The Company had an accumulated deficit of \$153.6 million at September 30, 2019, and will require substantial additional capital to fund operations. The future success of the Company is dependent on its ability to identify and develop its product candidates and ultimately upon its ability to attain profitable operations. At September 30, 2019, the Company had \$39.4 million of cash and cash equivalents. The Company’s available cash and cash equivalents as of September 30, 2019 are not sufficient to fund the Company’s current operating plan for at least the next twelve months following the filing of this Quarterly Report on Form 10-Q. Management expects to seek additional funds through equity or debt financings or through collaborations, licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into collaboration or licensing transactions. The Company may implement cost reduction strategies, which may include amending, delaying, limiting, reducing, or terminating one or more of its ongoing or planned clinical trials of its product candidates. These factors raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company’s unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (“FASB”). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2018 and notes thereto, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 7, 2019. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited financial statements with the exception of the 2019 adoption of the new leasing standard as discussed below. In the opinion of the Company’s management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments which are necessary to present fairly the Company’s financial position as of September 30, 2019, the results of its operations for the three and nine months ended September 30, 2019 and September 30, 2018 and cash flows for the nine months ended September 30, 2019 and September 30, 2018. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results for the year ending December 31, 2019, or for any future period.

Principles of Consolidation

The consolidated financial statements include the accounts of Allena Pharmaceuticals, Inc. and its wholly owned subsidiaries Allena Pharmaceuticals Security Corporation (“Security Corporation”), which was incorporated in December 2014, and Allena Pharmaceuticals Ireland Limited, which was incorporated in March 2017. All intercompany transactions and balances have been eliminated.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. ASC Topic 820, *Fair Value Measurement* (“ASC 820”), establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The hierarchy defines three levels of valuation inputs, of which the first two are considered observable and the last is considered unobservable:

- Level 1 inputs: Quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs: Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
- Level 3 inputs: Unobservable inputs developed using estimates or assumptions developed by the Company, which reflect those that a market participant would use in pricing the asset or liability.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Leases

The Company adopted ASU No. 2016-02, *Leases (Topic 842)* (“ASC 842”) on January 1, 2019. After the adoption of ASC 842, the Company determines at the inception of an arrangement whether the arrangement contains a lease. If a lease is identified in an arrangement, the Company recognizes a right-of-use asset and liability on its balance sheet and determines whether the lease should be classified as a finance or operating lease. The Company does not recognize assets or liabilities for leases with lease terms of less than 12 months.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases.

Finance and operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease. If the rate implicit is not readily determinable, the Company utilizes its incremental borrowing rate at the lease commencement date. Operating lease assets are further adjusted for prepaid or accrued lease payments. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as imputed interest expense and (ii) a portion that reduces the finance liability associated with the lease.

The Company separates lease and non-lease components when determining which lease payments to include in the calculation of its lease assets and liabilities. Variable lease payments are expensed as incurred. If a lease includes an option to extend or terminate the lease, the Company reflects the option in the lease term if it is reasonably certain it will exercise the option.

Operating leases are recorded in “Operating lease assets,” “Operating lease liabilities” and “Operating lease liabilities, net of current portion” on the Company’s condensed consolidated balance sheet. The Company did not have any finance leases recorded on its condensed consolidated balance sheet as of September 30, 2019.

The remainder of the Company’s significant accounting policies are described in the Annual Report filed on Form 10-K for the year ended December 31, 2018 that was filed with the United States Securities and Exchange Commission on March 7, 2019.

Recently Adopted Accounting Pronouncements

In 2016, the FASB issued ASC 842, which amends a number of aspects of lease accounting and requires entities to recognize right-of-use assets and liabilities on the balance sheet. ASC 842 was effective on January 1, 2019. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements* (“ASU 2018-11”), which offers a transition option to entities adopting ASC 842. Under ASU 2018-11, entities can elect to apply ASC 842 using a modified-retrospective adoption approach resulting in a cumulative effect adjustment to accumulated deficit at the beginning of the year in which the new lease standard is adopted, rather than adjustments to the earliest comparative period presented in their financial statements. The Company adopted ASC 842 using the modified-retrospective method.

The Company elected the package of transition practical expedients for leases that commenced prior to January 1, 2019, allowing it not to reassess (i) whether any expired or existing contracts contain leases, (ii) the lease classification for any expired or existing leases and (iii) the initial indirect costs for any existing leases.

The Company recorded, upon adoption of ASC 842 on January 1, 2019, right-of-use assets of \$1.0 million and corresponding liabilities of \$1.0 million related to its operating leases. The Company did not have any leases at January 1, 2019 that would qualify as finance leases. These adjustments had no impact on the Company’s consolidated statement of operations and had no impact on the Company’s accumulated deficit. Refer to Note 6, “Commitments and Contingencies,” for further information regarding the Company’s leases as well as certain disclosures required by ASC 842.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. The new standard largely aligns the accounting for share-based payment awards issued to employees and nonemployees by expanding the scope of ASC 718 to apply to nonemployee share-based transactions, as long as the transaction is not effectively a form of financing. The Company adopted ASU 2018-07 on January 1, 2019. The adoption did not have a material impact on the Company’s consolidated financial statements.

Recently Issued Accounting Pronouncements

In 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (“ASU 2018-15”), which clarifies the accounting for implementation costs in cloud computing arrangements. The new guidance will become effective for the Company on January 1, 2020. Early adoption is permitted. The Company does not expect the adoption of ASU 2018-15 will have a material impact on its consolidated financial statements.

In 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”), which modifies the disclosure requirements on fair value measurements. The new guidance will become effective for the Company on January 1, 2020. Early adoption is permitted. The Company does not expect the adoption of ASU 2018-13 will have a material impact on its disclosures.

In 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), which requires entities to record expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity’s current estimate of credit losses expected to be incurred. For available-for-sale debt securities in unrealized loss positions, ASU 2016-13 requires allowances to be recorded instead of reducing the amortized cost of the investment. ASU 2016-13 is effective on January 1, 2020. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-13 will have a material impact on its condensed consolidated financial statements.

3. Net Loss per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company has computed diluted net loss per common share after giving consideration to all potentially dilutive common shares, including options to purchase common stock, restricted common stock, convertible preferred stock and warrants to purchase convertible preferred stock, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and basic and diluted loss per share have been the same.

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	\$ (13,288)	\$ (9,510)	\$ (35,980)	\$ (26,037)
Net loss attributable to common stockholders	\$ (13,288)	\$ (9,510)	\$ (35,980)	\$ (26,037)
Denominator:				
Weighted-average common shares—basic and diluted	23,464,828	20,753,215	21,737,320	20,727,426
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.57)	\$ (0.46)	\$ (1.66)	\$ (1.26)

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares):

	Nine Months Ended September 30,	
	2019	2018
Warrants	9,040	9,040
Stock options	3,173,344	2,134,904
Total	3,182,384	2,143,944

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value at September 30, 2019 and December 31, 2018, and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

Description	September 30, 2019	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds, included in cash and cash equivalents	\$ 39,419	\$ 39,419	\$ —	\$ —
Total assets	\$ 39,419	\$ 39,419	\$ —	\$ —
Assets:				
December 31, 2018				
Money market funds, included in cash and cash equivalents	\$ 61,415	\$ 61,415	\$ —	\$ —
Total assets	\$ 61,415	\$ 61,415	\$ —	\$ —

At September 30, 2019 and December 31, 2018, all of the Company's cash equivalents were comprised of money market funds.

There were no changes to the valuation methods during the three and nine months ended September 30, 2019 and the year ended December 31, 2018. There were no transfers within the fair value hierarchy during the three and nine months ended September 30, 2019 and the year ended December 31, 2018.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their carrying values. The Company believes the terms of the loan payable reflect current market conditions for an instrument with similar terms and maturity, therefore the carrying value of the Company's debt approximates its fair value based on Level 3 of the fair value hierarchy.

5. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Payroll and employee-related expenses	\$ 1,986	\$ 1,690
Third-party research and development expenses	950	1,514
Professional fees	276	299
Loan interest	43	46
Other	112	76
Total accrued expenses	<u>\$ 3,367</u>	<u>\$ 3,625</u>

6. Commitments and Contingencies

The Company is a party to operating leases for approximately 7,795 square feet of office space in Newton, MA (Newton Lease), and for approximately 7,564 square feet of laboratory and office space in Sudbury, MA (Sudbury Lease). The Newton Lease expires on December 31, 2020 and the Sudbury Lease expires on February 28, 2021. Annualized base rent for the Newton Lease and the Sudbury lease is approximately \$0.3 million and \$0.2 million, respectively.

Aggregate Lease Information Related to the Application of ASC 842

Maturities of the Company's operating lease liabilities in accordance with ASC 842 as of September 30, 2019 are as follows (in thousands):

Remainder of 2019	\$ 89
2020	539
2021	30
Total maturities	658
Less: Amount representing interest	(27)
Present value of operating lease liabilities	<u>\$ 631</u>

Lease costs included in the Company's condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2019 were \$0.1 million and \$0.4 million, respectively. The Company's operating leases had a weighted average remaining lease term of 1.2 years and a weighted average discount rate of 5.5% at September 30, 2019.

Additional Lease Information Related to the Application of ASC 840

The following information is disclosed in accordance with ASC 840, *Leases (Topic 840)* ("ASC 840"), which was applicable until December 31, 2018. As of December 31, 2018, future minimum commitments under the Company's operating leases with initial terms of more than one year were as follows (in thousands):

	December 31, 2018
2019	\$ 487
2020	539
2021	30
	<u>\$ 1,056</u>

During the three and nine months ended September 30, 2018, rent expense was \$0.1 million and \$0.4 million, respectively.

7. Loan and Security Agreement

In August 2014, the Company entered into a Loan Agreement with Silicon Valley Bank (“SVB”) and borrowed \$7.0 million under the loan. In May 2016, the Loan Agreement was amended (“Amended Loan Agreement”) to borrow up to \$10.0 million with a portion of the proceeds to be used to pay down the outstanding balance of the original \$7.0 million of advances. At the time of the Amended Loan Agreement, SVB advanced a gross amount of \$7.5 million to the Company. Net proceeds received by the Company were \$1.6 million after deducting \$5.3 million for repayment of the original advances and \$0.6 million for final interest due upon maturity or prepayment of the original advances. In December 2016, upon the achievement of certain milestones, SVB advanced the remaining \$2.5 million available under the Amended Loan Agreement.

The borrowings were secured by a lien on all Company assets, excluding intellectual property. The May 2016 and December 2016 advances had a floating per annum interest rate equal to the greater of 4.0% or 0.5% above the prime rate. In December 2016, the interest only period was extended to 18 months. Upon the expiration of the interest only period, amounts borrowed were to be repaid over 30 equal monthly payments of principal and interest. At its option, the Company could prepay all, but not less than all, of the outstanding borrowings subject to a prepayment premium as defined in the Amended Loan Agreement. The Company was also required to make a final payment equal to 8.25% of the total borrowings (“Final Payment”) on the earliest of the loan maturity date, an acceleration of the loan as defined in the Amended Loan Agreement or at the time of prepayment.

On June 29, 2018, the Company terminated the Amended Loan Agreement and repaid the \$7.7 million outstanding principal balance and the Final Payment to SVB. The Company recorded a loss on extinguishment of debt of \$0.6 million in the Statement of Operations in the nine months ended September 30, 2018, accordingly.

On June 29, 2018 the Company also entered into a loan agreement (“PWB Loan Agreement”) with Pacific Western Bank (“PWB”) providing up to \$12.0 million of borrowings, of which \$10.0 million was advanced on June 29, 2018. The remaining \$2.0 million of borrowings available under the PWB Loan Agreement are available to the Company through one additional advance request until the end of the interest only period as defined below. Borrowings are secured by a lien on all Company assets, excluding intellectual property, and amounts borrowed have a floating per annum interest rate of the greater of 5.0% or the prime rate. The PWB Loan Agreement has a term of 48 months and an initial interest only period of 18 months. If the Company receives at least \$50M of gross proceeds from the sale of its equity securities or upfront cash payment from a strategic partnership prior the expiration of the initial interest only period, the interest only period will be extended an additional six months. Upon the expiration of the initial interest only period on December 31, 2019, amounts borrowed will be repaid over 30 equal monthly payments of principal plus accrued but unpaid interest. If the interest only period is extended an additional six months, amounts borrowed will be repaid over 24 equal monthly payments of principal plus accrued but unpaid interest beginning July 1, 2020. At its option, the Company may prepay all, but not less than all, of the outstanding borrowings subject to a prepayment premium as defined in the PWB Loan Agreement. Upon the closing of one or more financings, in which the Company receives aggregate gross proceeds of at least \$25 million, a success fee of \$300,000 will be due and payable to PWB. The Company’s obligation to pay this Success Fee survives termination of the Agreement.

The PWB Loan Agreement contains negative covenants restricting the Company’s activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and certain other business transactions. There are no financial covenants associated with the PWB Loan Agreement. The obligations under the PWB Loan Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company’s business, operations or financial or other condition. The Company has determined that the risk of subjective acceleration under the material adverse events clause is remote and therefore has classified the outstanding principal based on scheduled principal payments.

The Company evaluated the PWB Loan Agreement for embedded features that require bifurcation, noting certain features were required to be bifurcated, but were concluded to be de minimis in value at September 30, 2019 and December 31, 2018.

8. Stockholders’ Equity

Common Stock

The holders of common stock are entitled to one vote for each share held. Common stockholders are not entitled to receive dividends, unless declared by the Board of Directors.

On June 28, 2019, the Company completed a registered direct offering in which the Company issued and sold 2,632,092 shares of its common stock, at a purchase price of \$3.80 per share, for gross proceeds of \$10.0 million through a securities purchase agreement with the investors. The shares of common stock sold in this offering were being offered pursuant to the Company's shelf registration statement on Form S-3 filed with the Securities and Exchange Commission, which was declared effective on December 26, 2018. As a result of the registered direct offering, the Company received approximately \$9.6 million after deducting offering costs.

The Company has reserved for future issuances the following shares of common stock as of September 30, 2019 and December 31, 2018:

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Warrants	9,040	9,040
Stock options	5,084,163	4,262,341
Employee stock purchase plan	<u>391,733</u>	<u>405,742</u>
Total	<u>5,484,936</u>	<u>4,677,123</u>

9. Stock Incentive Plan

On October 31, 2017, the Company adopted the 2017 Stock Option and Incentive Plan ("2017 Plan"). Upon the adoption of the 2017 Plan, no further grants would be made under the 2011 Stock Incentive Plan ("2011 Plan"). The 2017 Plan initially provided for the grant of awards for 2,038,021 shares of common stock. In addition to the shares available for grant under the 2017 Plan, any awards outstanding under the 2011 Plan as of the October 31, 2017 are cancelled, forfeited or otherwise terminated without being exercised, the number of shares underlying such awards will be available for future grant under the 2017 Plan. The 2017 Plan also provides that an additional number of shares will automatically be added to the shares authorized for issuance under the 2017 Plan on January 1 of each year. The number of shares added each year will be equal to the lesser of: (i) 4% of the outstanding shares on the immediately preceding December 31 or (ii) such amount as determined by the Compensation Committee of the registrant's Board of Directors. On January 1, 2018, the shares available for grant under the 2017 Plan was automatically increased by 827,786 shares. On January 1, 2019, the shares available for grant under the 2017 Plan was automatically increased by an additional 832,361 shares.

All of the Company's employees, officers, directors, consultants and advisors are eligible to be granted options, restricted stock units ("RSUs"), and other share-based awards under the terms of the 2017 Plan. As of September 30, 2019, 1,910,819 shares of common stock were available for future grant under the 2017 Plan.

All stock option grants are nonstatutory stock options except option grants to employees (including officers and directors) intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Incentive stock options may not be granted at less than the fair market value of the Company's common stock on the date of grant, as determined in good faith by the Board of Directors at its sole discretion. Nonqualified stock options may be granted at an exercise price established by the Board of Directors at its sole discretion (which has not been less than fair market value on the date of grant) and the vesting periods may vary. Vesting periods are generally four years and are determined by the Board of Directors or a delegated subcommittee. Stock options become exercisable as they vest. Options granted under both the 2011 Plan and 2017 Plan expire no more than 10 years from the date of grant.

Stock-based compensation expense included in the Company's statements of operations and comprehensive loss is as follows (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Research and development	\$ 329	\$ 157	\$ 895	\$ 391
General and administrative	481	438	1,316	1,121
Total	<u>\$ 810</u>	<u>\$ 595</u>	<u>\$ 2,211</u>	<u>\$ 1,512</u>

The fair value of each stock option granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model, with the following range of assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Risk-free interest rate	1.4%-1.8%	2.8%	1.4%-2.6%	2.3%-2.8%
Expected dividend yield	—%	—%	—%	—%
Expected term (in years)	6.0	5.6-6.1	5.5-6.8	5.5-6.1
Expected volatility	83%	84%-85%	82%-83%	81%-89%

A summary of the stock option activity under the 2011 and 2017 Plans is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	2,141,527	4.32	7.7	\$ 4,959
Granted	1,073,350	6.60		
Exercised	(10,539)	1.76		
Cancelled	(30,994)	7.43		
Outstanding at September 30, 2019	<u>3,173,344</u>	\$ 5.07	7.8	\$ 3,074
Exercisable at September 30, 2019	<u>1,598,115</u>	\$ 3.34	6.6	\$ 2,900

As of September 30, 2019, total unrecognized stock-based compensation expense relating to unvested stock options was \$7.0 million. This amount is expected to be recognized over a weighted-average period of 2.8 years.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2018 that was filed with the United States Securities and Exchange Commission, or the SEC, on March 7, 2019.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a late-stage, clinical biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. We are focused on metabolic disorders that result in excess accumulation of certain metabolites that can cause kidney stones, damage the kidney, and potentially lead to chronic kidney disease, or CKD, and end-stage renal disease. Our lead product candidate, reloxaliase (formerly known as ALLN-177), is a first-in-class, oral enzyme therapeutic that we are developing for the treatment of hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, CKD and other serious kidney diseases. There are currently no approved therapies for the treatment of hyperoxaluria.

We have conducted a robust clinical development program of reloxaliase, including three Phase 2 clinical trials, which demonstrated reductions of urinary oxalate excretion in patients with secondary hyperoxaluria, particularly in patients with enteric hyperoxaluria. Reloxaliase has also been well tolerated in clinical trials to date. Based on these data, the high unmet medical need, the enzyme's specific mechanism of action, and the significant market opportunity, we are initially developing reloxaliase for adult patients with enteric hyperoxaluria.

In March 2018, we initiated URIROX-1™ (URIROX-1) (formerly Study 301), the first of our two anticipated Phase 3 clinical trials in support of our planned Biologic License Application, or BLA, for reloxaliase in patients with enteric hyperoxaluria. In November 2019, we announced topline data from the URIROX-1 trial. In the fourth quarter of 2018, we initiated URIROX-2 (formerly Study 302), our second pivotal Phase 3 trial of reloxaliase in patients with enteric hyperoxaluria. We expect to report topline data from URIROX-2 in the second half of 2021.

The FDA has advised us that it agrees with our strategy to pursue a BLA submission for reloxaliase using the accelerated approval regulatory pathway. We plan to analyze the full data set from the URIROX-1 trial and apply these insights to our ongoing clinical development of reloxaliase, including potentially the adaptive design elements of the URIROX-2 trial. We currently expect to submit a BLA filing to the FDA after 400 patients have been randomized and followed for six months in URIROX-2. For the long-term follow-up phase of the trial, subjects would continue in URIROX-2 for a minimum treatment period of two years to confirm clinical benefit post-approval.

In addition to our Phase 3 program of reloxaliase for enteric hyperoxaluria, we are also evaluating reloxaliase in Study 206, a Phase 2 basket trial in adults and adolescents with primary hyperoxaluria or enteric hyperoxaluria with hyperoxalemia, which we initiated in March 2018. We announced interim data from Study 206 in June 2019 and additional data in November 2019. Based on these results, we are currently exploring a possible registrational path for reloxaliase for patients with EH and advanced CKD.

In addition, we have designed our second product candidate, ALLN-346, an orally administered, novel urate degrading enzyme, for patients with hyperuricemia and gout in the setting of advanced CKD. Hyperuricemia, or elevated levels of uric acid in the blood, results from overproduction or insufficient excretion of urate, or often a combination of the two. ALLN-346 has demonstrated a robust reduction in both plasma and urine uric acid levels in an established urate oxidase knock-out mouse model, a severe animal model of hyperuricemia with advanced CKD and kidney damage due to urate crystal deposition. We presented preclinical data for ALLN-346 in October at the 2018 American College of Rheumatology (ACR/ARHP) Annual Meeting. We are advancing our preclinical program for ALLN-346 and scaling our manufacturing processes for clinical studies. Subject to the successful completion of these activities, we expect to file an IND for ALLN-346 with the FDA in the fourth quarter of 2019 and to initiate our first clinical trial of ALLN-346 in patients with hyperuricemia in the first half of 2020.

On November 6, 2017, we completed our initial public offering, or IPO, in which we issued and sold 5,333,333 shares of our common stock at a public offering price of \$14.00 per share, for aggregate gross proceeds of \$74.7 million. The underwriters partially exercised their over-allotment option on December 1, 2017, and purchased 16,969 shares of our common stock, for aggregate gross proceeds of \$0.2 million. As a result of the IPO, we received approximately \$67.0 million in net proceeds after deducting \$7.9 million of underwriting discounts and commissions and offering costs.

On June 28, 2019, we completed a registered direct offering in which we issued and sold 2,632,092 shares of our common stock, at a purchase price of \$3.80 per share, for gross proceeds of \$10.0 million through a securities purchase agreement with the investors. The shares of common stock sold in this offering were being offered pursuant to our shelf registration statement on Form S-3 filed with the Securities and Exchange Commission, which was declared effective on December 26, 2018. As a result of the registered direct offering, we received approximately \$9.6 million in net proceeds after deducting offering costs.

Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, producing drug substance and drug product material for use in preclinical studies and clinical trials, and conducting preclinical studies of our product candidates and clinical trials for our lead product candidate, reloxaliase. We do not have any products approved for sale and have not generated any revenue to date.

As of September 30, 2019, we had cash and cash equivalents totaling \$39.4 million. Based on our current operating plans, we do not have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. We will require additional capital to sustain our operations, including our reloxaliase development program. We expect to seek additional funds through equity or debt financings or through collaborations, licensing transactions or other sources. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. We may implement cost reduction strategies, which may include amending, delaying, limiting, reducing or terminating one or more of our ongoing or planned clinical trials of our product candidates. These factors raise substantial doubt about our ability to continue as a going concern. For more information, refer to “—Liquidity and Capital Resources” below and Note 1 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

We have incurred significant net operating losses in every year since our inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our net losses were \$13.3 million and \$9.5 million for the three months ended September 30, 2019 and 2018, respectively, and \$36.0 million and \$26.0 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of \$153.6 million. Based on our current operating plan, we anticipate that our expenses will increase significantly as we:

- conduct our ongoing Phase 3 clinical trials of our lead product candidate, reloxaliase;
- explore potential clinical development of reloxaliase in patients with EH and advanced CKD;
- manufacture additional material for our pivotal Phase 3 clinical program and potential future clinical studies we might conduct for our product candidates;
- scale up our manufacturing process for reloxaliase to prepare for the filing of a potential BLA and commercialization if our clinical development program is successful;
- advance the development of ALLN-346;
- conduct research on the discovery and development of additional product candidates;
- seek regulatory and marketing approvals for product candidates that successfully complete clinical trials, if any;

- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval in geographies in which we plan to commercialize our products ourselves;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, technical, operational, and financial personnel, to execute our business plan; and
- add clinical, scientific, operational, financial and management information systems to support our product development and potential future commercialization efforts, and to enable us to operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate. Additionally, we currently use contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, to carry out our preclinical and clinical development activities. We do not yet have a sales organization. If we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we may seek to fund our operations through public or private equity or debt financings or other sources, including strategic collaborations. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current product candidates, or any additional product candidates, if developed.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales or any other source and do not expect to generate any revenue from the sale of products for the foreseeable future. If our development efforts for reloxaliase or other product candidates that we may develop in the future are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts and the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- costs incurred under agreements with third parties, including CROs, that conduct research and development, preclinical studies and clinical trials on our behalf;
- costs related to production of preclinical and clinical materials, including fees paid to CMOs;
- consulting, licensing and professional fees related to research and development activities;
- costs of purchasing laboratory supplies and non-capital equipment used in our research and development activities;
- costs related to compliance with clinical regulatory requirements; and
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, patient enrollment, or information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and may be reflected in our consolidated financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

The following summarizes our most advanced current research and development programs:

- reloxaliase is our lead product candidate which we are developing for the treatment of hyperoxaluria. Substantially all of our research and development costs to date have been used to fund this program.
- ALLN-346 is our second product candidate which we are developing for patients with hyperuricemia and CKD. We began incurring external research and development costs for this program in 2016.

We typically use our employee and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs and other internal costs to specific product candidates or development programs.

The following table summarizes our research and development expenses by program (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Reloxaliase external costs	\$ 5,230	\$ 4,488	\$ 13,714	\$ 12,158
ALLN-346 external costs	1,858	378	4,468	747
Employee compensation and benefits	2,907	1,836	8,173	5,023
Other	811	614	2,168	1,179
Total research and development expenses	\$ 10,806	\$ 7,316	\$ 28,523	\$ 19,107

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, primarily due to the increased size and duration of later-stage clinical trials. Since inception, we have incurred \$78.7 million of external research and development costs for reloxaliase and \$6.9 million of external research and development costs for ALLN-346. We expect that our research and development costs will continue to increase for the foreseeable future as we conduct and initiate additional clinical trials of reloxaliase, scale our manufacturing processes and advance development of ALLN-346.

The successful development of reloxaliase, ALLN-346 and other potential future product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of these product candidates. We are also unable to predict when, if ever, we will generate revenue and material net cash inflows from the commercialization and sale of any of our product candidates for which we may obtain marketing approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of preclinical studies, clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful enrollment in, and completion of, clinical trials for reloxaliase;
- successful data from our clinical program of reloxaliase that supports an acceptable benefit-risk profile of reloxaliase in the intended populations;
- establishing an appropriate safety profile for ALLN-346 and any potential future product candidate with studies to enable the filing of an investigational new drug application;
- approval of INDs for ALLN-346 and any potential future product candidate to commence planned or future clinical trials;
- significant and changing government regulation and regulatory guidance;
- timing and receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with CMOs for third-party commercial manufacturing of our product candidates;
- obtaining and maintaining patent and other intellectual property protection and regulatory exclusivity for our product candidates;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the product, if and when approved, by patients, the medical community and third-party payors; and
- maintenance of a continued acceptable safety profile of the drugs following approval.

A change in the outcome of any of these variables with respect to the development, manufacture or commercialization enabling activities of any of our product candidates could mean a significant change in the costs, timing and viability associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and professional fees for accounting, auditing, tax and consulting services.

We expect that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, attorneys and accountants, among other expenses.

Interest Income (Expense), Net

Interest income (expense), net, primarily consists of interest income earned on our cash and cash equivalents, and interest expense incurred on our credit facility, amortized debt discount related to the fair value of the warrants issued in conjunction with the advances under the credit facility and debt issuance costs.

Other Income (Expense), Net

Other income (expense), net, primarily consists of gain (loss) on foreign currency transactions.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no changes to our critical accounting policies appearing in the Annual Report filed on Form 10-K for the year ended December 31, 2018.

Our significant accounting policies are described in detail in the notes to our consolidated financial statements appearing in the Annual Report filed on Form 10-K for the year ended December 31, 2018. There have been no changes to our significant accounting policies, other than our significant accounting policy for leases described in the notes to the condensed consolidated financial statements appearing in this Quarterly Report filed on Form 10-Q.

Results of Operations

Comparison of the three months ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Dollar Change
	2019	2018	
Operating expenses:			
Research and development	\$ 10,806	\$ 7,316	\$ 3,490
General and administrative	2,532	2,389	143
Total operating expenses	13,338	9,705	3,633
Loss from operations	(13,338)	(9,705)	(3,633)
Other income (expense):			
Interest income, net	53	180	(127)
Other expense, net	(3)	15	(18)
Other income (expense), net	50	195	(145)
Net loss	<u>\$ (13,288)</u>	<u>\$ (9,510)</u>	<u>\$ (3,778)</u>

Research and Development Expense

Research and development expense increased by \$3.5 million from \$7.3 million for the three months ended September 30, 2018 to \$10.8 million for the three months ended September 30, 2019. The following table summarizes our research and development expenses for the three months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Dollar Change
	2019	2018	
Clinical development external costs	\$ 4,149	\$ 2,954	\$ 1,195
Manufacturing external costs	2,416	1,906	510
Employee compensation and benefits	2,907	1,836	1,071
Other	1,334	620	714
Total research and development expenses	<u>\$ 10,806</u>	<u>\$ 7,316</u>	<u>\$ 3,490</u>

The \$3.5 million increase in research and development expense was primarily attributable to the following:

- Our clinical development external costs increased by \$1.2 million from \$3.0 million for the three months ended September 30, 2018 to \$4.1 million for the three months ended September 30, 2019:
 - We incurred \$2.0 million of URIROX-2 Study expenses for the three months ended September 30, 2019. We initiated this study in the fourth quarter of 2018. During the three months ended September 30, 2018, we incurred \$0.4 million of costs for initial preparation and start-up costs for this study;
 - Partially offsetting the increase attributable to the URIROX-2 Study was a decrease of \$0.4 million in costs related to the URIROX-1 Study. We incurred \$1.6 million and \$2.0 million of costs for the URIROX-1 Study during the three months ended September 20, 2019 and 2018, respectively; and
 - We incurred \$0.3 million and \$0.4 million of costs for our 206 Study during the three months ended September 30, 2019 and 2018, respectively.

- Our manufacturing external costs increased by \$0.5 million from \$1.9 million for the three months ended September 30, 2018 to \$2.4 million for the three months ended September 30, 2019:
 - We incurred formulation and development related costs for ALLN-346 of \$1.3 million and \$0.2 million during the three months ended September 30, 2019 and 2018, respectively; and
 - Partially offsetting the increase attributable to ALLN-346 formulation and development costs was a decrease of \$0.6 million of costs related to clinical batch production for our Phase 3 clinical program. We incurred \$0.7 million of costs in the three months ended September 30, 2019 for the production of clinical batches to support our URIROX-2 Study. We incurred a total \$1.3 million of costs for the three months ended September 30, 2018 for our Phase 3 clinical program, consisting of \$0.4 million of costs for the production of engineering batches and \$0.9 million of drug product costs.
- Our employee compensation and benefits costs increased by \$1.0 million for the three months ended September 30, 2019, primarily due to an increase in headcount from 32 employees at September 30, 2018 to 45 employees at September 30, 2019, which resulted in an increase in salaries, wages and benefit costs.

General and Administrative Expenses

General and administrative expense increased by \$0.1 million from \$2.4 million for three months ended September 30, 2018 to \$2.5 million for the three months ended September 30, 2019. The following table summarizes our general and administrative expenses for the three months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Dollar Change
	2019	2018	
Employee compensation and benefits	\$ 1,229	\$ 1,128	\$ 101
Consulting and professional services	781	796	(15)
Market research and commercialization planning	110	109	1
Other	412	356	56
Total general and administrative expenses	\$ 2,532	\$ 2,389	\$ 143

The increase in general and administrative expense was primarily attributable to an increase of \$0.1 million in employee compensation and benefits costs.

Interest Income (Expense), net

Interest income (expense), net consists of interest income earned on our cash and cash equivalents and interest expense charged on our outstanding debt. We had net interest income of \$0.1 million and \$0.2 million for the three months ended September 30, 2019 and 2018, respectively.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,		Dollar Change
	2019	2018	
Operating expenses:			
Research and development	\$ 28,523	\$ 19,107	\$ 9,416
General and administrative	7,709	6,706	1,003
Total operating expenses	36,232	25,813	10,419
Loss from operations	(36,232)	(25,813)	(10,419)
Other income (expense):			
Interest income (expense), net	282	398	(116)
Other income (expense), net	(30)	(5)	(25)
Loss on extinguishment of debt	—	(617)	617
Other income (expense), net	252	(224)	476
Net loss	\$ (35,980)	\$ (26,037)	\$ (9,943)

Research and Development Expenses

Research and development expense increased by \$9.4 million from \$19.1 million for the nine months ended September 30, 2018 to \$28.5 million for the nine months ended September 30, 2019. The following table summarizes our research and development expenses for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,		Dollar Change
	2019	2018	
Clinical development external costs	\$ 11,026	\$ 7,639	\$ 3,387
Manufacturing external costs	6,658	4,278	2,380
Employee compensation and benefits	8,173	5,023	3,150
Other	2,666	2,167	499
Total research and development expenses	\$ 28,523	\$ 19,107	\$ 9,416

The \$9.4 million increase in research and development expense was primarily attributable to the following:

- Our clinical development external costs increased by \$3.4 million from \$7.6 million for the nine months ended September 30, 2018 to \$11.0 million for the nine months ended September 30, 2019:
 - We initiated our URIROX-2 Study during the fourth quarter of 2018. Expenses for this study were \$5.2 million for the nine months ended September 30, 2019. During the nine months ended September 30, 2018, we incurred \$0.7 million of costs for initial preparation and start-up costs for this study;
 - Partially offsetting the increase in URIROX-2 costs was a decrease of URIROX-1 costs of \$1.1 million from \$5.2 million for the nine months ended September 30, 2018 to \$4.1 million for the nine months ended September 30, 2019. This study was initiated during the first quarter of 2018 and patients were fully enrolled as of September 30, 2019; and
 - We incurred \$1.0 million of costs for our 206 Study during each of the nine months ended September 30, 2019 and 2018. This study was also initiated during the first quarter of 2018.
- Our manufacturing external costs increased by \$2.4 million from \$4.3 million for the nine months ended September 30, 2018 to \$6.7 million for the nine months ended September 30, 2019.
 - We incurred formulation and development related costs for ALLN-346 of \$3.6 million and \$0.4 million during the nine months ended September 30, 2019 and 2018, respectively;
 - We incurred \$0.8 million and \$3.0 million of costs at our CMO for the production of clinical and engineering batches of reloxaliase for our Phase 3 clinical program during the nine months ended September 30, 2019 and 2018, respectively; and
 - We incurred formulation and development costs for reloxaliase of \$1.6 million and \$0.6 million for the nine months ended September 30, 2019 and 2018, respectively.
- Our employee compensation and benefits costs increased by \$3.2 million for the nine months ended September 30, 2019, primarily due to an increase in headcount from 32 employees at September 30, 2018 to 45 employees at September 30, 2019 as we grew our clinical and technical operations teams to support our Phase 3 program for reloxaliase, which resulted in an increase in salaries, wages and benefit costs.

We expect that our research and development expenses will increase in future periods as we continue our clinical development of reloxaliase, scale our manufacturing processes for reloxaliase and advance development of ALLN-346.

General and Administrative Expenses

General and administrative expense increased by \$1.0 million from \$6.7 million for the nine months ended September 30, 2018 to \$7.7 million for the nine months ended September 30, 2019. The following table summarizes our general and administrative expenses for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,		Dollar Change
	2019	2018	
Employee compensation and benefits	\$ 3,514	\$ 3,196	\$ 318
Consulting and professional services	2,440	1,972	468
Market research and commercialization planning	527	490	37
Other	1,228	1,048	180
Total general and administrative expenses	<u>\$ 7,709</u>	<u>\$ 6,706</u>	<u>\$ 1,003</u>

The increase in general and administrative expense was primarily attributable to the following:

- Our employee compensation and benefits costs increased by \$0.3 million for the nine months ended September 30, 2019, primarily due an increase in employee salaries, wages, benefit costs and stock-based compensation;
- Our consulting and professional services costs increased by \$0.5 million for the nine months ended September 30, 2019. The increase was related to increased legal costs and investor and public relations costs; and
- Our market research and commercialization planning costs were \$0.5 million for each of the nine months ended September 30, 2019 and 2018, respectively. During the nine months ended September 30, 2019, we incurred costs of \$0.4 million for a study with an independent third party to perform a market assessment for enteric hyperoxaluria. During the nine months ended September 30, 2018 we incurred costs of \$0.2 million as we engaged this independent third party to conduct a study to assess the market opportunity for reloxaliase in Europe and Asia. We also incurred costs of \$0.1 million as we engaged another independent third party to conduct market research for reloxaliase.

Interest Income (Expense), net

Interest income (expense), net consists of interest income earned on our cash and cash equivalents, interest expense charged on our outstanding debt, and amortization of our debt discount. We had net interest income of \$0.3 million and \$0.4 million for the nine months ended September 30, 2019 and 2018, respectively.

Loss on Extinguishment of Debt

On June 29, 2018, we terminated our loan agreement with SVB. As a result, we recorded a loss on extinguishment of debt of \$0.6 million representing the unamortized portion of the debt discount and final payment fee associated with the loan.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations from inception through September 30, 2019 through gross proceeds of \$96.0 million from sales of our convertible preferred stock, borrowings of \$10.0 million under our credit facilities, net proceeds from our IPO of \$67.0 million which was completed in November 2017 and net proceeds of \$9.6 million from our registered direct offering which was completed in June 2019. Our total cash and cash equivalents was \$39.4 million at September 30, 2019.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2019 and 2018 (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Net cash used in operations	\$ (31,707)	\$ (23,129)
Net cash used in investing activities	(122)	(156)
Net cash provided by (used in) financing activities	9,605	(650)
Net decrease in cash and cash equivalents	<u>\$ (22,224)</u>	<u>\$ (23,935)</u>

Net Cash Used in Operating Activities

The cash used in operating activities resulted primarily from our net losses adjusted for changes in components of working capital.

Net cash used in operating activities was \$31.7 million for the nine months ended September 30, 2019 compared to \$23.1 million for the nine months ended September 30, 2018. The increase in cash used in operating activities of \$8.6 million was attributable to:

- an increase in net loss of \$9.9 million; and
- an increase of \$1.3 million in changes in the components of working capital, including increases in accounts payable and other assets, partially offset by a decrease in accrued expenses and prepaid expenses.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$0.1 million and \$0.2 million for the nine months ended September 30, 2019 and 2018, respectively. Cash used in investing activities related to purchases of property and equipment.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was \$9.6 million for the nine months ended September 30, 2019 compared to net cash used in financing activities of \$0.7 million for the nine months ended September 30, 2018. The net cash provided by financing activities for the nine months ended September 30, 2019 consisted primarily of \$9.6 million of net proceeds from the issuance and sale of 2,632,092 shares of our common stock completed on June 28, 2019 through a registered direct offering. The net cash used in financing activities for the nine months ended September 30, 2018 included \$10.5 million to pay off our credit facility with Silicon Valley Bank and \$0.2 million for payments of initial public offering costs that were included in accounts payable and accrued expenses at December 31, 2017. These payments were partially offset by \$10.0 million of proceeds received under our new credit facility with Pacific Western Bank, or PWB, and \$0.1 million received from the exercise of stock options.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development for, initiate later stage clinical trials for, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of September 30, 2019, we had cash and cash equivalents totaling \$39.4 million. Based on our current operating plans, we do not have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. We will require additional capital to sustain our operations, including our reloxaliase development program. We expect to seek additional funds through equity or debt financings or through collaborations, licensing transactions or other sources. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when needed would have a material adverse effect on our business, results of operations and financial condition. We may implement cost reduction strategies, which may include amending, delaying, limiting, reducing, or terminating one or more of our ongoing or planned clinical trials of our product candidates. These factors raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business for the foreseeable future. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Going Concern

Our future capital requirements will depend on many factors, including:

- the costs of conducting ongoing and any future clinical trials of reloxaliase;
- the costs of manufacturing additional material for our pivotal Phase 3 clinical program, Phase 2 basket clinical trial and potential future clinical studies we might conduct for reloxaliase;
- the costs of scaling up our manufacturing process for reloxaliase to prepare for the filing of a potential BLA and commercialization if our clinical development program is successful;
- the advancement of ALLN-346;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing and clinical trials for other potential product candidates we may develop, if any;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and our research and development activities; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. With the exception of our credit facility, we do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2019, all of our cash equivalents were comprised of short-term money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the cash equivalents in our portfolio and the low risk profile of our cash equivalents, an immediate 10% change in interest rates would not have a material effect on the fair market value of our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three and nine months ended September 30, 2019 and 2018.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q 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

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. If any such risks or uncertainties actually occur, our business, financial condition or operating results could differ materially from the plans, projections and other forward-looking statements included in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report and in our other public filings. The trading price of our common stock could decline due to any of these risks, and as a result, you may lose all or part of your investment.

Those risk factors below denoted with a “” are newly added or have been materially updated from our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 7, 2019.*

Risks Related to Our Financial Position and Need for Additional Capital

*** We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.**

We may be forced to amend, delay, limit, reduce or terminate the scope of our development programs and/or limit or cease our operations if we are unable to obtain additional funding. As of September 30, 2019, we had cash and cash equivalents totaling \$39.4 million. Based on our current operating plans, we do not have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. We will require additional capital to sustain our operations, including our reloxaliase development program. We expect to seek additional funds through equity or debt financings or through collaborations, licensing transactions or other sources. However, there can be no assurance that we will be able to complete any such transaction on acceptable terms or otherwise. The failure to obtain sufficient funds on commercially acceptable terms when needed would have a material adverse effect on our business, results of operations and financial condition. We may implement cost reduction strategies, which may include amending, delaying, limiting, reducing, or terminating one or more of our ongoing or planned clinical trials of our product candidates. These factors raise substantial doubt about our ability to continue as a going concern.

*** We have incurred significant losses since inception, expect to incur significant and increasing losses for at least the next several years, have not generated any revenue, may never generate any revenue, and may never achieve or maintain profitability.**

We have incurred significant annual net operating losses in every year since our inception. We expect to continue to incur significant and increasing net operating losses for at least the next several years. Our net losses were \$ 13.3 million and \$9.5 million for the three months ended September 30, 2019 and 2018, respectively and \$36.0 million and \$26.0 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of \$ 153.6 million. We have not generated any revenue, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through private placements of convertible preferred stock, our initial public offering, or IPO, in November 2017, our registered direct offering in June 2019 and our credit facilities. We have devoted substantially all of our financial resources and efforts to research and development of reloxaliase and general and administrative expense to support such research and development. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders’ (deficit) equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- conduct future clinical trials of our lead product candidate, reloxaliase, including our pivotal Phase 3 clinical program in adult patients with enteric hyperoxaluria;
- manufacture additional material for these potential future clinical trials;
- scale up our manufacturing process for reloxaliase to prepare for the submission of a potential BLA and commercialization if our clinical development program is successful;
- advance the development of ALLN-346;

- seek to identify and develop additional product candidates;
- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- obtain, maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, manufacturing, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development programs.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are, or any future collaborator is, able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. Successful commercialization will require achievement of key milestones, including initiating and successfully completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, if any, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our stock price.

We have a limited operating history, no products approved for sale and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We commenced operations in 2011. Our operations to date have been limited to financing and staffing our company and developing our product candidates. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

*** We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.**

Since our inception, most of our resources have been dedicated to the nonclinical and clinical development of our lead product candidate, reloxaliase. As of September 30, 2019, we had working capital of \$31.1 million and capital resources consisting of cash and cash equivalents of \$39.4 million. Based on our current operating plans, we will continue to expend substantial resources for the foreseeable future as we continue clinical development, seek regulatory approval, and prepare for the commercialization of reloxaliase and develop ALLN-346 and any other product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting nonclinical studies and clinical trials, obtaining regulatory approvals, sales and marketing, and manufacturing and supply. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of reloxaliase and any future product candidates. In addition, as noted above, we have identified conditions and events that raise substantial doubt as to our ability to continue as a going concern if we are unable to obtain funding on a timely basis.

Based on our current operating plans, we do not have sufficient cash and cash equivalents to fund our operating expenses and capital expenditures for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity, debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future funding requirements will depend on many factors, including, but not limited to:

- the time and cost necessary to complete our pivotal Phase 3 clinical program and obtain regulatory approvals for reloxaliase and the costs of post-marketing studies that could be required by regulatory authorities;
- the costs of manufacturing clinical trial supplies of reloxaliase;
- our ability to successfully commercialize reloxaliase;
- the selling and marketing costs associated with reloxaliase, including the cost and timing of building our sales and marketing capabilities;
- the amount of sales and other revenues from reloxaliase, including the sales price and the availability of adequate third-party reimbursement;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the progress, timing, scope and costs of our nonclinical studies and clinical trials, including the ability to enroll patients in a timely manner for potential future clinical trials;
- our ability to comply with the covenants under our current and future credit facilities;
- the time and cost necessary to respond to technological and market developments; and
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate:

- clinical trials or other development activities for reloxaliase, ALLN-346 or any other product candidate;
- our preclinical research and development activities; or
- our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize reloxaliase or any future product candidate.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

As of September 30, 2019, we had \$10.0 million of outstanding borrowings under our credit facility with Pacific Western Bank, or PWB. We currently make monthly interest payments. Beginning in January 2020, we will be required to make payments of principal and interest on these borrowings in monthly installments through June 2022. Subject to the restrictions in this existing credit facility, we could in the future incur additional indebtedness beyond our borrowings from PWB.

Our outstanding indebtedness, including any additional indebtedness beyond our borrowings from PWB, combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our existing credit facility or any other debt instruments. Failure to make payments or comply with other covenants under our existing credit facility or such other debt instruments could result in an event of default and acceleration of amounts due. Under our loan and security agreement with PWB, the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, assets or condition is an event of default. If an event of default occurs and PWB accelerates the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which includes substantially all of our assets other than our intellectual property. In addition, the covenants under our existing credit facility, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

Risks Related to Drug Development, Regulatory Approval and Commercialization

We are heavily dependent on the regulatory approval of reloxaliase (formerly referred to as ALLN-177) in the United States and Europe, and subsequent commercial success of reloxaliase, both of which may never occur.

We are a late-stage biopharmaceutical company with no products approved by regulatory authorities or available for commercial sale. We have generated no revenue to date and do not expect to do so for the foreseeable future. As a result, our future success is currently dependent upon the clinical trial results, regulatory approval and commercial success of reloxaliase in one or more of the indications for which we seek approval. Our ability to generate revenues in the near term will depend on our ability to obtain regulatory approval and successfully commercialize reloxaliase on our own in the United States, if approved. We may experience delays in obtaining regulatory approval in the United States for reloxaliase, if it is approved at all, and our stock price may be negatively impacted. Even if we receive regulatory approval, the timing of the commercial launch of reloxaliase in the United States is dependent upon a number of factors, including, but not limited to, hiring sales and marketing personnel, pricing and reimbursement timelines, the production of sufficient quantities of commercial drug product and implementation of marketing and distribution infrastructure.

In addition, we have incurred and expect to continue to incur significant expenses as we continue to pursue the approval of reloxaliase in the United States, Europe and elsewhere. We plan to devote a substantial portion of our effort and financial resources in order to continue to grow our operational capabilities. This represents a significant investment in the clinical and regulatory success of reloxaliase, which is uncertain. The success of reloxaliase, if approved, and revenue from commercial sales, will depend on several factors, including:

- execution of an effective sales and marketing strategy for the commercialization of reloxaliase;
- acceptance by patients, the medical community and third-party payors;
- our success in educating physicians and patients about the benefits, administration and use of reloxaliase;
- the incidence and prevalence of patient populations with enteric hyperoxaluria in those markets in which reloxaliase is approved;
- the prevalence and severity of side effects, if any, experienced by patients treated with reloxaliase;
- the availability, perceived advantages, cost, safety and efficacy of alternative treatments, including potential alternate treatments that may currently be available or in development or may later be available or in development or regulatory approval or marketing of a generic, biosimilar, or any other version of oxalate decarboxylase, the active enzyme in reloxaliase;
- successful implementation of our manufacturing processes that are included in our new biologics license application, or BLA, and production of sufficient quantities of commercial drug product;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs, good laboratory practices, or GLP, and good clinical practices, or GCPs; and
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity and otherwise protecting our rights in our intellectual property portfolio.

We may also fail in our efforts to develop and commercialize future product candidates, including ALLN-346 for patients with hyperuricemia and chronic kidney disease, or CKD. If this were to occur, we would continue to be heavily dependent on the regulatory approval and successful commercialization of reloxaliase, our development costs may increase and our ability to generate revenue or profits, or to raise additional capital, could be impaired.

*** Results of earlier studies, or interim data from ongoing trials, may not be predictive of future clinical trial results, and planned or ongoing studies may not establish an adequate safety or efficacy profile for reloxaliase and other product candidates that we may pursue to justify proceeding to an application for regulatory approval or be worthy of regulatory approval if such an application is made.**

The results of preclinical studies and clinical trials of reloxaliase conducted to date and future studies and trials of reloxaliase, including our pivotal Phase 3 clinical trials, and other product candidates that we may pursue, may not be predictive of the results of subsequent clinical trials. For example, in November 2019 we announced topline data from our URIROX-1 clinical trial, our first Phase 3 pivotal trial of reloxaliase; these data may not be replicated in subsequent studies and trials of reloxaliase. Additionally, interim results of a clinical trial do not necessarily predict final results. In June and November 2019, respectively, we announced interim data from our ongoing Study 206 of reloxaliase; these data may not be replicated in subsequent studies and trials of reloxaliase, in particular well-controlled clinical trials. Data, our interpretation of data and results from our Phase 2 clinical trials of reloxaliase in adults with enteric hyperoxaluria, or interim results from Study 206, do not ensure that we will achieve similar results in our ongoing pivotal Phase 3 clinical trials in enteric hyperoxaluria or in clinical trials of reloxaliase in other patient populations, including patients being treated in our ongoing Study 206. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and early-stage clinical trials have nonetheless failed to replicate results in later-stage clinical trials and subsequently failed to obtain marketing approval. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

In particular, as is common with Phase 2 clinical trials, particularly clinical trials first conducted in a patient population with disease, we explored numerous endpoints and analyzed the data from our Phase 2 clinical trials of reloxaliase in a number of ways. Prior to obtaining approval for reloxaliase, we expect that the results of our URIROX-1 and URIROX-2 trials will have to demonstrate statistically significant improvement in the percent change from baseline in 24-hour urinary oxalate, or UOx, during Weeks 1-4, comparing reduction in the average UOx excretion across Weeks 1-4 with reloxaliase to placebo, the primary efficacy endpoint of both of our Phase 3 clinical trials. To date, two of our randomized Phase 2 clinical trials of reloxaliase (Study 713 and Study 649) did not demonstrate statistically significant results in the pre-specified primary endpoints. The design of our later-stage clinical trials differs in significant ways from our Phase 2 clinical trials of reloxaliase, which we believe may cause the outcome of these later-stage trials to differ from what we observed in our Phase 2 clinical trials. These differences include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design.

Product candidates in Phase 3 clinical trials, such as reloxaliase in our pivotal Phase 3 clinical program, may fail to demonstrate sufficient efficacy despite having progressed through initial clinical trials, even if certain analyses of primary or secondary endpoints in those early trials showed potential treatment effects. Some of the data we present on the use of reloxaliase for the treatment of enteric hyperoxaluria is drawn from pre-specified analyses and other data is from post-hoc analyses. While we believe all the data from the Phase 2 program were useful in informing the design of our pivotal Phase 3 program, and will remain useful for clinical trials evaluating reloxaliase, the post-hoc analyses involve the inherent bias of post-hoc rendering of data and choice of analytical methods. Further, while Study 713 was the largest randomized, controlled trial ever conducted in hyperoxaluria, only 18 subjects with enteric hyperoxaluria, the indication we intend to evaluate in our pivotal Phase 3 program, enrolled in the trial. Thus, we have limited data on the activity or safety of reloxaliase in the target population for our ongoing Phase 3 clinical program.

The primary efficacy endpoint in our pivotal Phase 3 program is percent change from baseline in 24-hour urinary oxalate, which is a biochemical measurement of the daily amount of oxalate handling by the kidney and therefore its reduction would indicate lessening of potential kidney damage by oxalate. However, based on published scientific literature and data generated in our own clinical trials, daily urinary oxalate excretion is a biomarker that demonstrates significant variability between patients and day-to-day for the same patient. This variability in 24 hour urinary oxalate excretion, especially in enteric hyperoxaluria patients, can be attributed to changes in diet, metabolic activity, hydration status or other factors. It can also be attributed to the manner in which these measurements are taken. In our completed Phase 2 clinical trials, we relied heavily on the efforts and contributions of investigative clinical sites and study patients to comply with accurate timing of 24 hour urine collection, with the complete collection of all of the patient's urine during a given 24 hour period and with the proper handling of collected urine specimens, including storage, documentation, sample handling and shipping to the testing laboratory. Following our completed Phase 2 clinical trials, we conducted a post-hoc review of these collection procedures. Although we are not aware of any case where the data reported in our prior clinical trials was inaccurate, due to the variability inherent in these data collection techniques, we cannot provide assurance that in all cases the data reported in our clinical trials accurately reflect the actual biochemical responses experienced by patients in these trials. We believe that capturing multiple measurements of 24 hour a time-weighted average of daily urinary oxalate excretion over the course of a clinical trial mitigates the risks of inherent variability, dietary change and sample handling associated with the testing of each individual 24 hour urine specimen, but no assurance can be given that any such variability will be fully addressed by this approach.

In addition, due to this variability in 24 hour urinary oxalate excretion, we may observe reductions in 24 hour urinary oxalate excretion in the placebo arms of our placebo-controlled trials. For example, although our URIROX-1 clinical trial met its primary endpoint with a 14.3% least square mean treatment difference relative to placebo, we did observe a higher reduction in urinary oxalate in the placebo group than we observed in our Phase 2 study, Study 713. As noted above, factors like diet and metabolic activity can play a role in urinary oxalate excretion, and these factors and others could partially explain the level of reduction observed in the URIROX-1 trial, which trial involved eight 24-hour urine collections over the course of the 28 days of the trial. Based on our review of the scientific literature, we expect that dietary restrictions and lifestyle changes would be difficult to maintain over real-world periods of time longer than a four-week study such as the URIROX-1, and that it is unlikely that the level of urinary oxalate reduction observed in the placebo arm of the URIROX-1 trial would ultimately have a clinically meaningful benefit to patients. However, if such observations are observed in URIROX-2 or future clinical trials that we conduct, it may have an adverse impact on the clinical benefit our trials demonstrate relative to placebo, which in turn could have an adverse impact on our ability to obtain regulatory approval for reloxaliase, on an accelerated approval basis or otherwise.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if early stage clinical trials are successful, we may need to conduct additional clinical trials for product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the U.S. Food and Drug Administration, or FDA, and comparable foreign regulators to market and sell these product candidates. Our failure to demonstrate the required characteristics to support marketing approval for reloxaliase or any other product candidate we may choose to develop in any ongoing or future clinical trials would substantially harm our business, prospects, financial condition and results of operations.

*** Although we have reached alignment with the FDA on the design of URIROX-2, our second pivotal Phase 3 trial of reloxaliase in patients with enteric hyperoxaluria, and our strategy to pursue a BLA submission for reloxaliase using the accelerated approval regulatory pathway, the clinical data we generate from our Phase 3 clinical program and/or the data we derive from third party datasets may not be sufficient to meet the FDA requirements for filing and obtaining marketing authorization via the accelerated approval regulatory pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.**

We may seek an accelerated approval development pathway for our product candidates, and we intend to do so for reloxaliase. Under the accelerated approval provisions of the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations, the FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic advantage over available therapies and demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval development pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical profile or risks and benefits for accelerated approval. The FDA may require that any such confirmatory study be initiated or substantially underway prior to the submission of an application for accelerated approval. If such post-approval studies fail to confirm the drug's clinical profile or risks and benefits, the FDA may withdraw its approval of the drug.

We have reached alignment with the FDA on the design of URIROX-2, our second pivotal Phase 3 clinical trial of reloxaliase in patients with enteric hyperoxaluria, and the FDA has advised us that they agree with our overall strategy to obtain accelerated approval for this product candidate. The data generated from the URIROX-1 and URIROX-2 trials could thus potentially form the basis of an accelerated approval of reloxaliase using reduction in UOx as a surrogate endpoint, with the final results from the URIROX-2 trial used to confirm clinical benefit post-approval. We believe 24 hour urinary oxalate excretion is an appropriate metric of the therapeutic effect of reloxaliase because 24 hour urinary oxalate excretion is a biochemical measurement of the daily amount of oxalate handling by the kidney and therefore its reduction would indicate lessening of potential kidney damage by oxalate. However, the data generated in our clinical trials may not be sufficient to support an accelerated approval of reloxaliase, or any approval.

The FDA has advised us that part of its assessment of the adequacy of the URIROX-2 trial to support accelerated approval will be both the size of the effect seen on UOx in this trial and the predictive model from this UOx reduction effect that further supports a relationship between UOx levels and stone formation rates, which model can be informed by data generated in the URIROX-2 trial or other data sources. This approach is consistent with the FDA's published guidance on the accelerated approval pathway, which provides that clinical data from a single clinical trial can be used to both support accelerated approval and verify the clinical benefit. This guidance also stipulates that the protocol and statistical analysis plan should clearly account for an analysis of the surrogate endpoint data to provide support for accelerated approval, with continuation of the randomized trial(s) to obtain data on the clinical endpoint that will be the basis for verifying the clinical benefit. In light of this guidance, URIROX-2 incorporates adaptive design elements that, through sample size re-estimations (at n=240 and n=400), will, if necessary, allow for increases in sample size and duration of treatment, based on accrued kidney stone disease progression rates and the conditional probability of achieving ultimate statistical success in the long-term follow-up phase of the trial as reviewed by the FDA. However, the data generated in our clinical trials may not be sufficient to provide additional support for the relationship between UOx levels and stone formation rates or to demonstrate the conditional probability of achieving ultimate statistical success. Based on the interim data we generate in the URIROX-2 trial, we may be required to increase the number of patients treated and/or extend the follow-up period before we are able to submit a BLA for reloxaliase seeking accelerated approval, if ever. If we are required to increase the number of patients treated and/or extend the follow-up period in our clinical trials, it could have a material adverse effect on our expected clinical and regulatory timelines, business, prospects, financial condition and results of operations.

We expect that our data package for accelerated approval would include a conditional power estimate based on the effect of reloxaliase on reducing kidney stone disease progression as assessed with interim data from the URIROX-2 trial, the effects of reloxaliase on reduction of UOx in the URIROX-1 and URIROX-2 trials, and further support for the model relating UOx levels to kidney stone disease progression, including but not limited to available data obtained in the URIROX-2 trial. We expect we will continue to work with scientific experts to identify additional third-party datasets to further substantiate the relationship between urinary oxalate levels and the risk of kidney stones and kidney dysfunction. The FDA has advised us that we have not yet provided sufficient data regarding UOx excretion necessary to support its use as a surrogate endpoint for these clinical trials and questioned whether changes in UOx of the magnitude expected would be reasonably likely to predict clinical benefit. We have provided the FDA with the details of analyses we conducted using available data collected from a third-party clinical database, in order to demonstrate an increased probability of kidney stone events in patients with enteric hyperoxaluria and increasing UOx levels. The FDA has advised us that it remains concerned about the strength of this relationship, based in part on the limited clinical data currently available and whether other factors may play a role in the production of kidney stones. The data we generate from the URIROX-1 and URIROX-2 trials, together with additional data we identify from third-party datasets, may not be sufficient to satisfy the FDA that we have generated a model that supports a relationship between UOx levels and stone formation rates and as necessary to use the accelerated approval regulatory pathway for reloxaliase. If we are unable to reach consensus with the FDA on the magnitude of UOx reduction significant enough to predict clinical benefit, we may be required to demonstrate effectiveness by showing an effect on stone formation directly, or conduct one or more additional clinical trials to demonstrate this effect, prior to the submission of a BLA for reloxaliase.

Furthermore, even if we generate clinical data sufficient to support a BLA submission seeking accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. For example, the FDA may require demonstration that we have initiated or made substantial progress in our clinical follow-up of trial subjects, or any such clinical outcomes trial, prior to the submission of our BLA for accelerated approval of reloxaliase. The FDA notes in its guidance that when the same trial is used to support accelerated approval and verify clinical benefit, the data to verify the clinical benefit may be, in some cases, nearly complete by the time of accelerated approval. In addition, if another company receives full approval from the FDA to market a product for treatment of enteric hyperoxaluria, our ability to seek and obtain accelerated approval for reloxaliase in the same or similar indication may be materially adversely affected. The FDA or foreign regulatory authorities also could require us to conduct further studies or trials prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate would result in a longer time period to obtain approval for and commercialize such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Even if we receive accelerated approval from the FDA for reloxaliase or any of our other product candidates, we will be subject to rigorous post-marketing requirements, including the completion of confirmatory post-market clinical trial(s) to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post-market study with due diligence, a post-market study does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading. We anticipate that whether the reduction in kidney stone reduction we observe in our Phase 3 clinical program for reloxaliase is sufficient to demonstrate a clinical benefit will ultimately be a review issue with FDA.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate that we may choose to develop would result in a longer time period prior to commercializing such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

*** Foreign regulators may not agree with our proposed Phase 3 clinical program for reloxaliase, in which case we may be required to modify our planned clinical trials, or run additional clinical trials, before we can submit foreign applications for marketing approval for reloxaliase.**

In January 2019 we announced that we had reached alignment with the FDA on both the design of URIROX-2, our second pivotal Phase 3 trial of reloxaliase in patients with enteric hyperoxaluria, and our strategy to pursue a BLA submission for reloxaliase using the accelerated approval regulatory pathway. However, our Phase 3 program may not be sufficient to support the submission of applications for marketing approval in foreign jurisdictions, including the European Union. Although our preliminary discussions with regulatory authorities in select countries within the European Union lead us to believe our Phase 3 program, if successful, may be sufficient to support the submission of an MAA in Europe via the conditional approval pathway, which is similar to the FDA's accelerated approval pathway, these discussions are not binding on such authorities or the EMA. Accordingly, no assurance can be given that our Phase 3 program will be sufficient to support the submission of an MAA in Europe, and we may be required to modify the design of these planned trials, or run additional clinical trials, before seeking marketing approval. Any of these decisions could have a material adverse effect on our expected clinical and regulatory timelines, business, prospects, financial condition and results of operations.

Because we are developing product candidates for the treatment of diseases in which there is little clinical trial experience and, in some cases, using new endpoints or methodologies, there is increased risk that the FDA or other regulatory authorities may not consider the endpoints of our clinical program to provide clinically meaningful results and that these results may be hard to analyze.

There are no pharmacologic therapies approved to treat the underlying causes of hyperoxaluria. In addition, it should be noted that no therapeutic agents have previously been approved by the FDA on the basis of a biochemical measurement of 24 hour urinary oxalate excretion, endpoints used in our Phase 2 clinical program and for our pivotal Phase 3 clinical program. The FDA retains discretion to reserve judgment on whether our clinical endpoints and the results we obtain in our pivotal Phase 3 clinical program sufficiently demonstrate clinical meaningfulness until the FDA reviews the data included in our planned BLA submission, which will not occur for several years from now, if at all. As a result, the design and conduct of clinical trials for the treatment of hyperoxaluria, and the underlying conditions and disorders that drive the metabolic disease, are subject to increased risk.

Moreover, even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance, in either or both of the Phase 3 clinical trials that we believe will be necessary for approval. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the secondary efficacy endpoints in the trials. The FDA also could give overriding weight to other efficacy endpoints, even if we achieve statistically significant results on the primary endpoint, if we do not achieve statistically significant or clinically meaningful results on any of our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the EU and other countries may take similar positions.

In addition, we are conducting a Phase 2 clinical trial of reloxaliase utilizing an open-label, basket trial design that will enroll subsets of patients suffering from complications of severe hyperoxaluria, including adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria, both of which can lead to systemic oxalosis. We have not yet evaluated reloxaliase in patients with primary hyperoxaluria and as such we have not yet demonstrated proof-of-concept in this patient population. Basket trial designs permit the exploration of a study drug in patient populations with common biochemical markers, such as patients afflicted with different forms of cancer, but the same genetic mutation. Although all patients enrolled in our Phase 2 trial will have elevated urinary oxalate levels, the underlying cause of their hyperoxaluria may be different. We cannot predict whether the design of our pivotal Phase 3 clinical program, Study 206 or any other future trials that we may conduct may successfully demonstrate reloxaliase or any future product candidate's safety and efficacy.

If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulators, such as the European Medicines Agency, or EMA, impose similar restrictions. We, and any future collaborators, may never receive such approvals. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we, or they, will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We have not previously submitted a BLA to the FDA or similar drug approval applications to comparable foreign regulators for any of our product candidates. Any inability to complete preclinical and clinical development successfully could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if (1) we, or any future collaborators, are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we, or they contemplate, (2) we, or any future collaborators, are unable to successfully complete clinical trials of our product candidates or other testing, (3) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (4) there are unacceptable safety concerns associated with our product candidates, we, or any future collaborators, may:

- incur additional unplanned costs;
- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Our failure to successfully complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business, prospects, financial condition and results of operations.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Our Phase 3 clinical program for reloxaliase consists of two Phase 3 clinical trials of reloxaliase in adult patients with enteric hyperoxaluria. We have also conducted scientific advisory meetings with regulatory authorities in three countries within the European Union, or the EU. Even though we have received and incorporated guidance from these regulatory authorities, foreign regulators could disagree that we have satisfied their requirements to commence our clinical trials in those jurisdictions. Further, the FDA or other regulatory authorities could change their position on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. We may need to conduct additional clinical trials or other testing for, among other things, drug-drug interactions, the generation of formate (i.e. a metabolic byproduct resulting from the degradation of oxalate by reloxaliase) and increased dosages of our product candidates. Successful completion of our clinical trials is a prerequisite to submitting a BLA to the FDA and a Marketing Authorization Application, or MAA, in Europe for each product candidate and, consequently, the ultimate approval and commercial marketing of reloxaliase, ALLN-346 and any product candidates we may develop in the future. We do not know whether any of our clinical trials will be completed on schedule, if at all.

We may experience delays in initiating or completing our planned clinical trials or additional preclinical studies or clinical trials in the future, and we may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience delays in recruiting, or be unable to recruit, a sufficient number of suitable patients to participate in our clinical trials;
- the patients and sites who participate in our trials may not comply with protocols, such as compliance with the capsule and timing regimen and urine collection requirements, rendering the results insufficient or uninterpretable;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third party contractors may fail to comply with regulatory or legal requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- the occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- any changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates; and
- the FDA or other comparable foreign regulators may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other comparable foreign regulators. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, GCP or our clinical protocols, inspection of the clinical trial operations or trial sites by the FDA or other comparable foreign regulators resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our drug development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any delays in our preclinical or clinical development programs may significantly harm our business, prospects, financial condition and results of operations.

The regulatory approval processes of the FDA and comparable foreign regulators are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for reloxaliase or our other product candidates, our business will be substantially harmed.

We are not permitted to market reloxaliase or any of our other product candidates in the United States or the EU, until we receive approval of a BLA from the FDA or an MAA from the EMA, respectively. Prior to submitting a BLA to the FDA or an MAA to the EMA for approval of any of our product candidates for a specific indication, we are required to complete preclinical studies and clinical trials.

Successfully initiating and completing our clinical program and obtaining approval of a BLA or an MAA is a complex, lengthy, expensive and uncertain process, and the FDA, the EMA or other comparable foreign regulators may delay, limit or deny approval of any of our candidates for many reasons, including, among others:

- we may not be able to demonstrate that our product candidates are safe and effective to the satisfaction of the FDA or the EMA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or the EMA for marketing approval;
- the FDA or the EMA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or the EMA may require that we conduct additional clinical trials;
- the FDA or the EMA or other applicable foreign regulators may not approve the formulation, labeling or specifications of reloxaliase or our other product candidates;
- the CROs that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or the EMA may find the data from preclinical studies and clinical trials insufficient to demonstrate that the clinical and other benefits of reloxaliase and our other product candidates outweigh their safety risks;
- the FDA or the EMA may disagree with our interpretation of data from our preclinical studies and clinical trials, including our characterization of observed toxicities;
- the FDA or the EMA may not accept data generated at our clinical trial sites;
- if our BLAs or MAAs, if and when submitted, are reviewed by the FDA or the EMA, as applicable, the regulatory agency may have difficulties scheduling the necessary review meetings in a timely manner, may recommend against approval of our application or may recommend that the FDA or the EMA, as applicable, require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy as a condition of approval or post-approval, and the EMA may grant only conditional approval or impose specific obligations as a condition for marketing authorization, or may require us to conduct post-authorization safety studies;
- the FDA, the EMA or other applicable foreign regulators may find deficiencies with or not approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the FDA or the EMA may change their approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market reloxaliase or any of our other product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

In addition to the United States and Europe, we or potential collaborators intend to market our product candidates, if approved, in other international markets. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary from country-to-country and may require additional testing. Moreover, the time required to obtain approval may differ from that required to obtain FDA or EMA approval. In addition, in many countries, a product candidate must be approved for reimbursement before it can be approved for sale in that country, even if regulatory approval has been obtained. Approval by the FDA or the EMA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA or the EMA. The regulatory approval process in other international markets may include all of the risks associated with obtaining FDA or EMA approval.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA's and other comparable foreign regulators' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of reloxaliase and any future product candidates we may develop. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or other countries or jurisdictions. 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 harm our business, prospects, financial condition and results of operations.

If we are required to conduct additional clinical trials or other studies with respect to reloxaliase or any future product candidates we may develop beyond those that we currently contemplate, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of reloxaliase and any future product candidates we may develop, we may obtain approval of indications that are not as broad as intended or we may not be able to obtain regulatory approval at all. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for reloxaliase or any future product candidates we may develop. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

If we experience delays or difficulties in the enrollment or continuation of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue 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 as required by the FDA or comparable foreign regulators, or if a significant number of patients withdraw of our clinical trials. In particular, because we are focused on patients with enteric hyperoxaluria with respect to our Phase 3 development of reloxaliase, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Patient enrollment may be affected by other factors including, but not limited to:

- the severity of the disease under investigation;
- the design of the clinical trial;
- the size and nature of the patient population;
- the eligibility criteria for the clinical trial in question;
- the availability of appropriate screening tests for study subjects;
- the perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies or treatment approaches;
- the efforts to facilitate timely enrollment in clinical trials;
- the ability to obtain and maintain patient consents and the risk that patients enrolled in clinical trials will not complete a clinical trial;
- the patient referral practices of physicians;

- the ability of patients to comply with the protocol, including capsule and timing regimen and urine collection requirements;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the extent to which our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates.

In addition, patients may withdraw from our clinical trials prematurely, which could also have a negative effect on our ability to complete our clinical trials or obtain and retain regulatory approvals. For example, both of our Phase 3 clinical trials for reloxaliase are randomized, double-blind and placebo controlled, and our URIROX-2 trial is intended to potentially enable a BLA submission using the accelerated approval pathway, following which patients would continue in the study for a minimum treatment period of two years to confirm clinical benefit post-approval. Patients enrolled in our Phase 3 clinical trials may elect to withdraw from the trial prematurely, particularly in the event we are able to obtain an accelerated approval. If a significant number of patients withdraw from the trial prematurely it could potentially jeopardize the interpretability of the results from our clinical trials, which could have a material adverse effect on our ability to obtain, or retain, regulatory approval for reloxaliase.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulators. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. Although the incidences of adverse events that were considered related to study drug in our Phase 2 trials were low and no drug-related serious or severe adverse events were observed, it is possible that our Phase 3 clinical program or future clinical trials we conduct may not demonstrate a favorable safety profile. In addition, while we have not observed reloxaliase to be absorbed into the bloodstream in our clinical trials to date, it is possible absorption could occur in our Phase 3 clinical trials, particularly with a target population of patients with enteric hyperoxaluria, who are predisposed to chronic hyperabsorption. We may also need to conduct additional clinical trials or other testing for, among other things, drug-drug interactions, the generation of formate and increased dosages of our product candidates. In the event of adverse safety issues, our trials could be suspended or terminated and the FDA or comparable foreign regulator could order us to cease further development of or deny approval of reloxaliase for any or all targeted indications. Any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If reloxaliase or our other product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.

If the FDA, the EMA or a comparable foreign regulator approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the drug 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 drug. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug approvals;
- drug seizure or detention, or refusal to permit the import or export of the drug; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more product candidates we develop, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do, and reducing or eliminating our commercial opportunity.

Our industry is highly competitive and subject to rapid and significant technological change as researchers learn more about diseases and develop new technologies and treatments. Our potential competitors include primarily large pharmaceutical, biotechnology companies and specialty pharmaceutical companies. Key competitive factors affecting the commercial success of reloxaliase, ALLN-346 and any other product candidates we may develop are likely to be efficacy, safety and tolerability profile, reliability, convenience of administration, price and reimbursement.

There is no approved pharmacologic therapy for the reduction of urinary oxalate excretion in patients with hyperoxaluria, either primary or secondary. Existing treatment options for hyperoxaluria generally are non-specific and include high fluid intake to increase urine output to more than two to three liters per day, a diet low in salt and oxalate, oral citrate and/or calcium and/or magnesium supplementation and orthophosphate and Vitamin B6, exclusively for the specific subset of responsive patients with the most severe form of primary hyperoxaluria (PH1).

We are aware of other companies pursuing oxalate reduction in both primary and secondary hyperoxaluria. For example, Alnylam is conducting an ongoing pivotal Phase 3 study under the Accelerated Approval pathway for the treatment of patients with primary hyperoxaluria Type 1. Dicerna is conducting ongoing clinical development for the treatment of primary hyperoxaluria Types 1-3. Oxthera AB (Sweden) and Captozyme (U.S.) are developing orally delivered products to degrade oxalate in the stomach and GI tract. Oxthera is conducting Phase 3 clinical trials for Oxabact, *Oxalobacter formigenes*, indicated for the treatment of primary hyperoxaluria.

Several of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a small number of our competitors. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval of drugs and achieving widespread market acceptance. Our competitors' drugs, or drugs they may develop in the future, may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render reloxaliase or any future product candidates we may develop obsolete or non-competitive before we can recover the expenses of developing and commercializing reloxaliase or any future product candidates we may develop. Our competitors may also obtain FDA or other regulatory approval of their products more rapidly than we may obtain approval of ours. Our competitors could develop and the FDA could approve a generic or biosimilar version of oxalate decarboxylase, the active enzyme in reloxaliase. We anticipate that we will face intense and increasing competition as new drugs enter the market and more advanced technologies become available. If we are unable to compete effectively, our opportunity to generate revenue from the sale of reloxaliase or any future product candidates we may develop, if approved, will be adversely affected.

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Our ability to successfully identify patients and acquire a significant market share will be necessary for us to achieve profitability and growth.

We focus our research and product development on treatments for hyperoxaluria and hyperuricemia. The precise incidence and prevalence for these diseases are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. For example, we estimate there are approximately 200,000 to 250,000 patients in the United States with enteric hyperoxaluria and kidney stones. In addition, an estimated 375,000 patients in the United States have refractory gout and CKD, the target population for our ALLN-346 product candidate. These estimates have been derived from a variety of sources, including the scientific literature and market research projects with third-party consultants, and may prove to be incorrect. Further, new studies and future developments in patient care or treatment paradigms may change the estimated incidence or prevalence of this disorder. The number of patients may turn out to be lower than expected. The potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for one or more of our product candidates, because certain of our potential target populations are small, including our target populations for which reloxaliase has received orphan drug designation, we may never achieve profitability despite obtaining such significant market share.

Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for such product candidate may be smaller than we estimate.

We have never obtained marketing approval for a product candidate or commercialized a product. Even if one of our product candidates is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any one of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential advantages of the product compared to alternative treatments;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- the potential absence of the results of a late-stage clinical trial with a clinically meaningful primary endpoint;

- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of our sales, marketing and distribution support;
- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products as well as competitive products;
- availability and amount of reimbursement from government payors, managed care plans and other third-party payors;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for our product candidates are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities, which would adversely affect our results of operations and our business.

Our proprietary technological approach is a new approach to the design and development of stable, non-absorbable oral enzyme therapies and may not result in any additional product candidates or ultimately any products of commercial value.

We have developed our proprietary know-how in enzyme technology which allows us to design, formulate and deliver non-absorbed and stable enzymes orally and in sufficient doses for activity in the GI tract. While the general therapeutic approach of deploying a non-absorbed drug into the GI tract to reduce metabolic disease burden in patients with kidney disease has been proven successful in several therapeutic categories, we cannot assure you that our technological approach will ultimately work for reloxaliase, ALLN-346, or any other product candidates we may develop. In addition, while we believe our enzyme therapeutic candidates will not be absorbed, future clinical trials may find this not to be true. We also cannot guarantee that any other aspects of our proprietary technological approach will yield product candidates that could receive regulatory approval, enter clinical development and, ultimately, be commercially valuable.

*** We only have a limited number of employees to manage and operate our business.**

As of November 1, 2019, we had 55 full-time, part-time, or short-term employees. Our focus on the development of reloxaliase and ALLN-346 requires us to optimize cash utilization and to manage and operate our business in a highly efficient manner. We will need to hire and retain a significant number of new employees to execute our clinical development and manufacturing plans. We cannot provide assurance that we will be able to hire and/or retain adequate staffing levels to develop reloxaliase, or ALLN-346 or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

We currently have no sales and marketing organization and, as a company, have not commercialized any products. If we are unable to establish effective sales and marketing capabilities in the United States and access them in Europe and other international markets, we may not succeed in commercializing our product candidates.

At present, we have no sales or marketing employees and we rely on part-time consultants. We cannot guarantee that we will be successful in marketing reloxaliase for enteric hyperoxaluria in the United States, if approved. We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize reloxaliase in the United States without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of our planned relatively small sales force to obtain access to or inform adequate numbers of nephrologists, urologists or other practitioners at kidney stone clinics;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the inability of market-access personnel to obtain sufficient levels of pricing and reimbursement in each jurisdiction; and
- unforeseen costs, expenses and delays associated with creating a commercial organization.

If we are not successful in timely recruiting of sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty commercializing reloxaliase, which could harm our business, operating results and financial condition. Expansion of our business into the EU and other international markets will require significant management attention and additional financial resources. We currently intend to explore commercializing reloxaliase, if approved, in Europe and other international markets by entering into collaboration agreements with other biopharmaceutical companies, and we may not be successful in entering into these collaboration agreements. In the event that we do enter into such agreements, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Additional factors and risks that may inhibit our efforts to commercialize reloxaliase in foreign markets include:

- our inability to directly control commercial activities because we are relying on third parties, should we enter into third-party collaborations;
- varying pricing in different foreign markets, which could adversely affect pricing in the United States or other countries;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer collection times for accounts receivable;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- the imposition of governmental price controls, political and economic instability, trade restrictions and changes in tariffs;
- foreign currency exchange rate fluctuations;
- our customers' ability to obtain adequate reimbursement for reloxaliase in foreign markets at all, either at all or at prices that exceed our costs; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Our future revenues may depend heavily on the success of the efforts of these third parties. We may not be able to establish a commercial operation in a cost-effective manner or realize a positive return on this investment, even with the assistance of one or more third-party collaborators, should we choose to enter into such an arrangement. In addition, we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel.

If we or third-party collaborators are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure or if we do not successfully enter into additional collaboration arrangements with third parties, we may not be able to successfully commercialize reloxaliase and any future product candidates we may develop in foreign markets, which could impair our business, operating results and financial condition.

Even with the potential assistance of third-party collaborators, we may not be successful in establishing a commercial operation in foreign markets for numerous reasons, including, but not limited to, failing to attract, retain and motivate the necessary skilled personnel and failing to develop a successful marketing strategy. Failure to establish a commercial operation in foreign markets will have a negative outcome on our ability to commercialize reloxaliase and generate revenue.

Additionally, if approved for marketing in one or more countries, we and/or our potential third-party collaborators may encounter unexpected or unforeseen delays in establishing our commercial operations that delay the commercial launch in these countries. These delays may increase the cost of and the resources required for successful commercialization of reloxaliase internationally. We do not have any experience in a commercial launch in Europe or elsewhere.

We expect to expand our development, regulatory, and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, manufacturing, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources and attention. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, which could affect our ability to generate revenue.

The manufacture and packaging of pharmaceutical products such as reloxaliase is subject to FDA requirements and those of similar foreign regulatory bodies. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be harmed.

The manufacture and packaging of pharmaceutical products, such as reloxaliase, if approved, is regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMP regulations who are both capable of manufacturing reloxaliase and willing to do so. We may not be able to identify or secure contracts with manufacturers with suitable capability to manufacture reloxaliase according to FDA requirements on favorable terms or at all. Failure by us or our third-party manufacturers to comply with applicable regulations or requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or voluntary or mandatory recalls of product, operating restrictions and criminal prosecutions, any of which could harm our business. The same requirements and risks are applicable to the suppliers of the key raw material used to manufacture reloxaliase, including the specific bacterial strains that are used to manufacture the oxalate decarboxylase enzyme, which is an active ingredient in reloxaliase.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's cGMPs. Any new facility is subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements. This review may be costly and time consuming and could delay, constrain or prevent the launch or supply of a product.

Furthermore, in order to obtain approval of our product candidates, including reloxaliase, by the FDA and foreign regulatory agencies, we will be required to consistently produce the drug substance and the finished product in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation. We have not yet met with the FDA or foreign regulatory agencies to understand the complete manufacturing requirements which must be met for reloxaliase to receive regulatory approval. Each of our potential suppliers will likely use a different method to manufacture drug substance, which has the potential to increase the risk to us that our manufacturers will fail to meet applicable regulatory requirements. We also need to complete process validation on the finished product in the packaging we propose for commercial sales. This includes testing of stability, measurement of impurities and testing of other product specifications by validated test methods. If the FDA or foreign regulatory agencies do not consider the result of the process validation or required testing to be satisfactory, we may not obtain approval to launch the product or approval, launch or availability of commercial supply after launch may be delayed.

The FDA and similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory, civil actions or penalties which could harm our business.

Manufacture and supply of drug substance, drug product and finished drug product is a complex and technically challenging undertaking, particularly for oral biologics, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after a product has been manufactured and distributed.

Manufacture and supply of drug substance, drug product and finished drug product is technically challenging, particularly for oral biologics. Changes that may be made outside the purview of our direct control can have an impact on the success of our processes, on quality, and on successful delivery of finished drug product. Mistakes and mishandling could affect successful production and supply. Some of these risks include:

- failure to follow cGMP requirements or mishandling of our product while in production or in preparation for transit;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of drug product;
- natural disasters, labor disputes, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations at our manufacturing facilities; and
- latent defects that may become apparent after drug product has been released and which may result in recall or required destruction of drug product.

If any of these risks materialize, it would have a material and adverse impact on our ability to develop, obtain regulatory approval for and market reloxaliase, if approved.

The longer term growth of our business depends on our ability to expand our portfolio of product candidates, which may require substantial financial resources and may ultimately be unsuccessful.

The longer term growth of our business depends upon our ability to develop and commercialize multiple product candidates. In addition to the development and commercialization of reloxaliase for hyperoxaluria, we intend to pursue development of ALLN-346 for hyperuricemia and CKD as well as other product candidates. We may never be able to identify other developmental prospects that we can successfully develop into product candidates, let alone receive regulatory approval of or successfully commercialize such product candidates.

A significant portion of the research that we are conducting involves new technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including, but not limited to:

- the research methodology used may not be successful in identifying potential product candidates; or
- potential product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

There are a number of FDA requirements that we must satisfy before we can commence a clinical trial in the United States. If we are able to identify additional potential product candidates, satisfaction of these regulatory requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on development of other product candidates may impair our ability to continue efforts to develop and commercialize reloxaliase for the treatment of enteric hyperoxaluria and other indications, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of other product candidates, those product candidates may never demonstrate sufficient safety and efficacy to be approved by the FDA or other comparable foreign regulators. If any of these events occur, we may be forced to abandon our development efforts for such program or programs, which would harm our business. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

We may fail to obtain and maintain orphan drug designations from the FDA for our current and future product candidates, as applicable. Even for reloxaliase for which we have received such designation for treatment of primary hyperoxaluria and pediatric hyperoxaluria, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Our strategy includes seeking orphan drug designation where available for our product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application, or NDA, or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity.

The FDA has granted separate orphan drug designations for reloxaliase for treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria. In addition, the European Commission has granted orphan designation for reloxaliase for the treatment of primary hyperoxaluria. Even where we have obtained such designations, we may not be the first to obtain regulatory approval of a product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. We may also fail to meet requirements to maintain orphan drug designation during our continued development of reloxaliase, which is primarily focused on enteric hyperoxaluria. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, once we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states, foreign governments and other jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal civil False Claims Act imposes criminal and civil penalties and authorizes civil whistleblower or qui tam actions against individuals or entities for: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; or making a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and 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 anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false 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 in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and the ownership and investment interests of such physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and 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 information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any of these occurrences may significantly harm our business, financial condition, prospects and results of operations and adversely affect our stock price.

The risk of us being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. For example, the definition of the "remuneration" under the federal Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated.

Additionally, recent healthcare reform legislation has strengthened federal and state healthcare fraud and abuse laws. For example, the ACA amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Furthermore, on January 31, 2019, the Department of Health and Human Services (HHS) and HHS Office of Inspector General (OIG) proposed an amendment to one of the existing Anti-Kickback safe harbors (42 C.F.R. 1001.952(h)) which would prohibit certain pharmaceutical manufacturers from offering rebates to pharmacy benefit managers, or PBMs, in the Medicare Part D and Medicaid managed care programs. The proposed amendment would remove protection for "discounts" from Anti-Kickback enforcement action, and would include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs. At the same time, HHS also proposed to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients, and adds another safe harbor to protect certain administrative fees paid by manufacturers to PBMs. If this proposal is adopted, in whole or in part, it could affect the pricing and reimbursement for any products for which we receive approval in the future. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Legislative or regulatory reform of the health care system in the United States and foreign jurisdictions may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the Affordable Care Act and a related reconciliation bill were signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

- mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk-based Medicaid managed care plans;
- the definition of "average manufacturer price" was revised for reporting purposes, which could increase the amount of Medicaid drug rebates by state;
- the 340B Drug Pricing Program under the Public Health Service Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities;
- pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the "donut hole"; and
- pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs. Since we expect our branded pharmaceutical sales to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 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% per fiscal year, starting in 2013, which will remain in effect until 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products. Other legislative and regulatory initiatives have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. For example, the Drug Supply Chain Security Act of 2013 imposes new obligations on manufacturers of certain pharmaceutical products related to product tracking and tracing. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance documents or interpretations will be changed, or what the impact of such changes on the marketing approvals of reloxaliase, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

The current presidential administration and U.S. Congress have also recently attempted to repeal or "repeal and replace" the Affordable Care Act. Although those efforts did not succeed, we the presidential administration may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the Affordable Care Act. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have on the Affordable Care Act, if any, and any changes will likely take time to unfold. Additionally, since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire Affordable Care Act is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the Affordable Care Act, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". While the Texas District Court Judge, as well as the current presidential administration and the Centers for Medicare and Medicaid Services, have stated that this ruling will have no immediate effect, it is unclear how this decision and subsequent appeals will impact the law and the effect such impact could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further, federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from reloxaliase and any other product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We may fail to comply with evolving European and other privacy laws.

Since we conduct clinical trials in the European Economic Area, or the EEA, we are subject to additional European data privacy laws. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. Further, the impact of the impending "Brexit", (whereby the United Kingdom is planning to leave the EEA in March of 2019), either with or without a "deal" is uncertain and cannot be predicted at this time.

In the event we continue to conduct clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations

If successful product liability claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, participants in our clinical trials, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- increased FDA warnings on product labels;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We carry product liability insurance in amounts that we believe are sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

During the course of treatment, patients may suffer adverse events, including death, for reasons that may or may not be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our product candidates, if approved, or require us to suspend or abandon our commercialization efforts of any approved product candidates. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We depend heavily on the success of our most advanced program, reloxaliase. Our only other product development program, ALLN-346, is at the preclinical stage. Preclinical testing and clinical trials of product candidates may not be successful. If we are unable to commercialize any product candidates we may develop or experience significant delays in doing so, our business will be materially harmed.

We have invested substantially all of our efforts and financial resources in the identification and development of our most advanced product program, reloxaliase for the treatment of hyperoxaluria. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of reloxaliase and our future product candidates. The success of reloxaliase, ALLN-346 and future product candidates we may identify and develop will depend on many factors, including the following:

- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials for our most advanced program;
- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities in our target indications and potential additional indications;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our medicines;
- launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;
- acceptance of the medicines, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile of the medicines following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our most advanced program or any other product candidates we may develop, which would materially harm our business.

Of the large number of biologics and drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a BLA or NDA to the FDA or an MAA to the EMA. Not all BLAs, NDAs or MAAs that are submitted to a regulatory agency are approved for commercialization. Reloxaliase is an oral biologic product candidate, which is a less common formulation in the biotech industry. Accordingly, there are few oral biologic therapeutics that have achieved regulatory approval. Furthermore, even if we do receive regulatory approval to market our most advanced program or any other product candidates that we may identify and develop, any such approval may be subject to limitations on the indicated uses for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research programs, we cannot assure you that we will successfully develop or commercialize our most advanced program, or any of our other research programs. If we or any of our future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize, our most advanced program or any product candidates we may identify and develop, we may not be able to generate sufficient revenue to continue our business.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulators. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, marketing and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.

Due to the novel nature of our product candidates and the potential for any product candidates we may develop to offer therapeutic benefit, we face uncertainty related to pricing and reimbursement for these product candidates.

Our initial target patient populations are relatively small, as a result of which the pricing and reimbursement of any product candidates we may develop, if approved, must be adequate to support the necessary commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any such product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to any product candidates we may develop (e.g. for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products. In addition, it may be necessary for us to develop new reimbursement models in order to realize adequate value. Payors may not be able or willing to adopt such new models, and patients may be unable to afford that portion of the cost that such models may require them to bear. If we determine such new models are necessary but we are unsuccessful in developing them, or if such models are not adopted by payors, our business, financial condition, results of operations, and prospects could be adversely affected.

We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford our product candidates. Accordingly, sales of any such product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of any product candidates we may develop will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers, and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical, and cost-effectiveness data. There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates we may develop. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

Moreover, the downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates we may develop will be harmed.

In light of the large population of patients with hyperoxaluria who reside outside the United States, our ability to generate meaningful revenues in those jurisdictions may be limited due to the strict price controls and reimbursement limitations imposed by governments outside of the United States.

In some countries, particularly those in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially, if we are not able to market our product to the large population of patients with hyperoxaluria who reside in outside the United States.

Currently we plan to seek regulatory approval to market reloxaliase solely for the treatment of enteric hyperoxaluria in adults and, unless we seek regulatory approval for additional indications, we will be prohibited from marketing reloxaliase for any other indication.

We intend to initially seek approval to market reloxaliase for the treatment of enteric hyperoxaluria in adults. Even if we obtain regulatory approval to market reloxaliase in this indication, we will likely be prohibited from marketing reloxaliase for any other indications. The FDA strictly regulates the promotional claims that may be made about prescription products. While reloxaliase has been studied in patients beyond the enteric subgroup, reloxaliase may not be promoted for uses that are not approved by the FDA as reflected in its approved labeling. Under applicable regulations, the ability of a company to make marketing statements about the effectiveness of its drug outside of the statements made in the label, referred to as “off-label” marketing, is prohibited. If we are found to have promoted such off-label uses, we may become subject to significant liability.

If we fail to comply or are found to have failed to comply with FDA and other regulations prohibiting the promotion of reloxaliase for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations prohibiting the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. If we receive marketing approval for reloxaliase for the treatment of enteric hyperoxaluria in adults, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of reloxaliase for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys’ Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as “qui tam” actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as “whistleblower suits,” are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new therapies to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Dependence on Third Parties

The third parties upon whom we rely for the supply of the drug product and drug substance used in our lead product candidate are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

We do not currently operate manufacturing facilities for clinical or commercial production of any product candidates. We have limited personnel experienced in drug manufacturing and formulation, and we lack the resources and the capabilities to manufacture reloxaliase on a clinical or commercial scale. We do not intend to develop facilities for the manufacture of drug product candidates for clinical trials or products for commercial purposes in the foreseeable future. The drug product and drug substance used in reloxaliase are supplied to us from single-source suppliers. Our ability to successfully develop our product candidates, to supply the drug required for our planned clinical trials, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We do not currently have arrangements in place for a redundant or second-source supply of any such drug product or drug substance in the event any of our current suppliers of such drug product and drug substance cease their operations for any reason.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such drug product and drug substance prior to submission of a BLA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the drug product and drug substance used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the drug product and drug substance used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners to manufacture commercial quantities of our product candidates if and when approved for marketing by the applicable regulatory authorities. We have not secured commercial supply agreements with any contract manufacturers for reloxaliase and can give no assurance that we will enter commercial supply agreements with any contract manufacturers on favorable terms or at all or that we will be able to manufacture our product candidates at commercial scale at the cost we expect. Our contract manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

An element of our strategy is to enter into licensing or collaboration agreements with respect to reloxaliase and future product candidates in certain territories. We may not be able to identify suitable collaborators and, even if we do, our dependence on such relationships may adversely affect our business.

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies. Our strategy for commercializing reloxaliase and any future product candidates we may develop outside of the United States may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we may seek to partner. Despite our efforts, we may be unable to secure collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities ourselves, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms, and our business may be materially and adversely affected. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we may have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q also apply to the activities of any of our future program collaborators.

Any future collaborations that we enter into may not be successful. Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. In addition, partners may not properly obtain, maintain or, defend or enforce our intellectual property rights, may infringe, misappropriate or otherwise violate third-party intellectual property rights, may misappropriate our trade secrets or may otherwise use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation and potential liability. In the event we grant exclusive rights to such partners, we could be precluded from potential commercialization of our product candidates within the territories in which we have a partner. Furthermore, any termination of our collaboration agreements will terminate any funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development programs.

Further, our potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our product candidates receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our potential future collaborators may harm our business prospects and ability to earn revenues. In addition, we could have disputes with our potential future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of our product candidates or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

We have relied, and will rely in the future, on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not appropriately carry out their contractual duties, fail to conduct high-quality studies or meet expected deadlines, regulatory approval and commercialization of reloxaliase or any future candidates we may develop could be delayed or not obtained at all.

We do not have the ability to conduct all of our clinical trials independently. We have relied will continue to rely on third parties, including clinical investigators, third-party CROs, patients and consultants, to monitor, manage data for, participate in and execute our ongoing nonclinical and planned clinical programs for reloxaliase and other product candidates, and we control only some aspects of their activities. For example, in both our completed Phase 2 clinical trials and ongoing Phase 3 clinical trials we relied and are relying heavily on the efforts and contributions of investigative clinical sites and study patients to comply with a strict treatment regimen (e.g. three capsules per day with meals) and accurate timing of 24 hour urine collection, with the complete collection of all of the patient's urine during a given 24 hour period and with the proper handling of collected urine specimens, including storage, documentation, sample handling and shipping to the testing laboratory. Any failure of these third parties to meet their obligations has had or may in the future have an adverse effect on the results of clinical trials we have conducted or will conduct.

Because we rely on third parties, our internal capacity to perform these functions is limited. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific requirements and standards, including, for example, GLP, the Animal Welfare Act and GCPs. Our reliance on third parties does not relieve us of our regulatory responsibilities. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the relevant regulatory authorities may require us to perform additional clinical trials in support of our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to comply with these regulations may require us to repeat nonclinical studies and clinical trials, which would delay the regulatory approval process.

The third parties conducting our nonclinical studies and clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing clinical and nonclinical programs. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our nonclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approval of or successfully commercialize reloxaliase and any other product candidates we may develop. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture reloxaliase and conduct other aspects of our clinical development activities, we must, at times, share trade secrets and other confidential information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with any collaborators, CROs, manufacturers and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or other confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets and confidential information become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's or other third party's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of certain collaborators, CROs, manufacturers and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors or other third parties may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. Discovery of our trade secrets by a competitor or other third party would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Business and Industry

We depend on the knowledge and skill of our senior management and other key employees, and if we are unable to retain or if we fail to recruit additional highly skilled personnel, our business will be harmed.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, commercial, scientific and medical personnel. We are highly dependent on our management, commercial, scientific and medical personnel. In order to induce valuable employees to remain with us, we have provided employees with stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that we cannot control and, together with our other compensation programs and benefits, may at any time be insufficient to counteract more lucrative offers from other companies.

We are highly dependent upon the principal members of our management team, including Louis Brenner, M.D., our President and Chief Executive Officer and Edward Wholihan, our Chief Financial Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. The loss of any executive or other principal member of our management team would impair our ability to identify, develop and market new products and conduct successful operations.

In addition, our growth will require us to hire a significant number of qualified technical, commercial and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. Other biopharmaceutical companies with which we compete for qualified personnel may have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize reloxaliase and any other product candidates we may develop would be impaired and could adversely affect our growth and financial performance.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other comparable foreign regulators, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Prior to completing our IPO, we adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

In connection with our IPO, we adopted a Code of Business Conduct and Ethics, and have prepared and implemented policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, we cannot assure you that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and

other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

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 the success of 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of 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.

Although 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, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Our business and operations would suffer in the event of computer system failures, cyber-attacks on our systems or deficiency in our cyber security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, our systems safeguard important confidential personal data regarding patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in our operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of reloxaliase and any other product candidates we may develop could be delayed.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize our product candidates successfully may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect or enforce our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business. The patent application and approval process is expensive, complex and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application

is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, 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.

Our pending and future patent applications may not result in patents being issued which protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products, for example, reloxaliase. Alternatively, our competitors may seek to market generic versions of any approved products by submitting abbreviated BLAs to the FDA during which process they may claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We heavily rely on certain in-licensed patents and other intellectual property rights in connection with our development of reloxaliase and, if we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

Our ability to develop and commercialize our lead product candidate, reloxaliase, is heavily dependent on licenses to patent rights and other intellectual property granted to us by third parties. For example, we are party to a license agreement with Althea Technologies, Inc. (now known as Ajinomoto Althea, Inc.), or Althea, under which we received an exclusive, worldwide, royalty-bearing, sublicensable, and, except under certain circumstances, non-transferable license under certain of the patent rights to develop, use, make, have made, market, offer to sell, sell, have sold, distribute, import or otherwise exploit reloxaliase. We may enter into additional license agreements in the future. Our license agreement with Althea imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors, including Althea, may have the right to terminate these license agreements, in which event we might not be able to market our lead product candidate, reloxaliase. Similarly, other licensors may convert an exclusive license to a non-exclusive license, which could adversely affect the value of a product candidate developed under a given license agreement. Termination of any of our license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms.

Further, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. For example, pursuant to our license agreement with Althea, Althea controls such activities for certain patents licensed to us under such agreement. Therefore, we cannot be certain that these patents will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our current or future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

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. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product's approval by the FDA, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In the future, if and when our product candidates, for example, reloxaliase, receive FDA approval, we intend to apply for patent term extensions on patents covering those products in any jurisdiction where these are available. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority 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 may grant more limited extensions than we request. Moreover, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management, business and scientific personnel. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

A court may disagree with our allegations and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Furthermore, the other party could counterclaim that we infringe their intellectual property or counterclaim that a patent we have asserted against them is invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property rights are non-infringed, invalid, or unenforceable. The outcome of any such proceeding is generally unpredictable.

Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, or written description. In addition, validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting and associated rules related to common ownership, which, if successful, could result in a finding that the patent claims at issue are invalid and unenforceable or a loss of patent term, including a patent term adjustment granted by the USPTO. Furthermore, patents may be held unenforceable if someone connected with prosecution of the patent in question withheld relevant information from the USPTO or made a misleading statement during prosecution of the patent. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. It is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a material adverse effect on our business.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the patent laws of some foreign countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, for example, India and China, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, certain foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our drugs or procedures, we may not be able to stop a competitor from marketing drugs that are the same as or similar to our product candidates, which would have a material adverse effect on our business.

If we are sued for infringing intellectual property of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technologies we use in our business. Our competitors or other third parties may assert infringement claims against us, alleging that our product candidates are covered by their patents. We cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. For example, we are aware of companies that have filed patent applications directed to oxalate and uric acid degrading enzymes, some of which have already been allowed or issued, and others may issue in the future. It is possible that additional patent applications are filed and

additional patents directed to these enzymes are granted in the future. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. If a patent holder believes our product candidate infringes its patent rights, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable. However, proving invalidity and unenforceability is difficult. In the United States, for example, providing invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could significantly harm our business and operating results.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnological and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnological and pharmaceutical industries involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system. The first-to-file provisions, however, only became effective on March 16, 2013. It is still not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. 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 weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

Although we have obtained composition of matter patents covering relaxinase and its use in therapy, we also rely on trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect our trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific collaborators, advisors, contractors, contract manufacturers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may be subject to claims by third parties asserting that our employees or we have misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our consultants, advisors and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. Some of these individuals, including certain members of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our consultants, advisors and employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Common Stock

*** The price of our common stock may be volatile and fluctuate substantially.**

On November 6, 2017, we completed the sale of 5,333,333 shares of our common stock in our IPO, at a price to the public of \$14.00 per share. Since our common stock began trading on The NASDAQ Global Select Market on November 6, 2017, our stock has traded at prices as low as \$3.33 per share and as high as \$17.56 per share through November 1, 2019. There has been a public market for our common stock for only a short period of time. Although our common stock is listed on The NASDAQ Global Select Market, an active public market for our common stock may not emerge or be sustained.

In addition, the market price for our common stock may fluctuate significantly in response to a number of factors, including:

- the success of competitive drugs or technologies;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts, and our performance in relation to such estimates;
- variations in our financial results or those of companies that are perceived to be similar to us;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;

- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

As a public company, and particularly after we are no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are currently evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or SOX Section 404, we are required to furnish a report by our management on our internal control over financial reporting in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission, or the SEC. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will likely depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us, or provide favorable coverage. If one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

*** Our directors, executive officers and principal stockholders exercise significant control over our company, which will limit your ability to influence corporate matters.**

As of November 1, 2019, our executive officers, directors and principal stockholders collectively controlled approximately 79.3% of our outstanding common stock, excluding any shares of common stock that such persons may have the right to acquire upon exercise of outstanding options or warrants. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and amended and restated by-laws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

*** A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is otherwise doing well.**

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline significantly. As of November 1, 2019, we had 23,465,665 outstanding shares of common stock, assuming no exercise of outstanding options or warrants. In addition, the 3,173,344 shares subject to outstanding options under our stock option plans as of September 30, 2019, the 1,910,819 shares reserved for future issuance under our stock option plans, the 391,733 shares reserved for future issuance under our employee stock purchase plan and the shares subject to outstanding warrants will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, 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. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In our Annual Report on Form 10-K for the year ended December 31, 2018, we did not include all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if 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.

In addition, the JOBS Act provides that an emerging growth company 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 not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so in the foreseeable future. Our credit facility with PWB also prohibits us from paying cash dividends without the prior written consent of PWB. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

The effects of recently enacted tax legislation and other legislative, regulatory and administrative developments to our business are uncertain. Increased costs related to such developments could adversely affect our financial condition and results of operations.

On December 22, 2017, the President of the United States signed into law H.R. 1, informally titled the Tax Cuts and Jobs Act, or the TCJA. The TCJA makes major changes to the taxation of corporations, including reduction of the corporate tax rate from 35% to 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. The effect of the significant changes made by the TCJA is highly uncertain, and administrative guidance will be required in order to fully evaluate the effect of many provisions on our business and stockholders.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes as a result of our IPO or subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2018, we had federal net operating loss carryforwards of approximately \$111.1 million, and our ability to utilize those net operating loss carryforwards could be limited by an “ownership change” as described above, which could result in increased tax liability to us. The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, net operating losses generated after December 31, 2017 are not subject to expiration.

Volatility in our share price could subject us to securities class action litigation.

Securities class action litigations have often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, would result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2017 Stock Option and Incentive Plan, or the 2017 Plan, we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2017 Plan will automatically increase each year by up to 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors or compensation committee to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2017 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, and our stock price may fall.

As a public reporting company, we are subject to rules and regulations established from time to time by the SEC and the Public Company Accounting Oversight Board, or PCAOB, regarding our internal control over financial reporting. We may not complete improvements to our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the market price of our common stock could decline and you could lose all or part of your investment.

Upon completion of our IPO, we became a public reporting company subject to the rules and regulations established from time to time by the SEC and the PCAOB. These rules and regulations require, among other things that we establish and periodically evaluate procedures with respect to our internal controls over financial reporting. These reporting obligations are likely to place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel.

We are required to document and test our internal controls over financial reporting pursuant to SOX Section 404, so that our management can certify as to the effectiveness of our internal controls over financial reporting which requires us to document and make significant changes to our internal controls over financial reporting. In addition, our independent registered public accounting firm will be required to provide an attestation report on the effectiveness of our internal control over financial reporting at such time as we cease to be an “emerging growth company,” as defined in the JOBS Act, although, as described in the preceding risk factor, we could potentially qualify as an “emerging growth company” for more than five years. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating.

If our senior management is unable to conclude that we have effective internal control over financial reporting, or to certify the effectiveness of such controls, or if our independent registered public accounting firm cannot render an unqualified opinion on management’s assessment and the effectiveness of our internal control over financial reporting once we cease to be an emerging growth company, or if material weaknesses in our internal controls are identified, we could be subject to regulatory scrutiny and a loss of public confidence, which could have a material adverse effect on our business and our stock price. In addition, if we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and adversely affect our results of operations and financial condition.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to reasonably ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures as well as internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are and will be met. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation 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 employees.

Our restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

In the quarter ended September 30, 2019, we did not repurchase any shares of our common stock.

Use of Proceeds from Initial Public Offering of Common Stock

On November 6, 2017, we completed the sale of 5,333,333 shares of our common stock in our IPO at a price to the public of \$14.00 per share. The underwriters partially exercised their over-allotment option on December 1, 2017 and purchased an additional 16,969 shares of our common stock. The offer and sale of the shares in our IPO was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-220857), which was filed with the SEC on October 6, 2017 and amended subsequently and declared effective by the SEC on November 1, 2017. Following the sale of the shares in connection with the closing of our IPO, the offering terminated. The offering did not terminate before all the securities registered in the registration statements were sold. Credit Suisse Securities, LLC (USA), Jefferies LLC and Cowen and Company, LLC acted as lead book-running managers for the offering. Wedbush PacGrow acted as the co-manager for the offering.

We raised approximately \$67.0 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by us. None of these expenses consisted of direct or indirect payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on November 6, 2017. We invested the funds received in cash equivalents in accordance with our investment policy.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description
10.1*	<u>Loan and Security Agreement by and between Allena Pharmaceuticals, Inc. and Pacific Western Bank, dated June 29, 2018, as amended August 1, 2019.</u>
31.1*	<u>Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.</u>
31.2*	<u>Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.</u>
32.1+	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Exchange Act rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350.</u>
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Link Document.

* Filed herewith.

+ The certification furnished in Exhibit 32.1 hereto is deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

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

ALLENA PHARMACEUTICALS, INC.

November 13, 2019

By: /s/ Louis Brenner
Louis Brenner, M.D.
Chief Executive Officer and Director
(Principal Executive Officer)

November 13, 2019

By: /s/ Edward Wholihan
Edward Wholihan
Chief Financial Officer
(Principal Financial and Accounting Officer)

ALLENA PHARMACEUTICALS, INC.

PACIFIC WESTERN BANK

LOAN AND SECURITY AGREEMENT

This LOAN AND SECURITY AGREEMENT (the "Agreement") is entered into as of June 29, 2018, by and between PACIFIC WESTERN BANK, a California state chartered bank ("Bank") and ALLENA PHARMACEUTICALS, INC., a Delaware corporation ("Borrower").

RECITALS

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 FAS 123R 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) 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(b)(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.

(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.

(c) 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 Twelve Million Dollars (\$12,000,000) (each a "Term Loan" and collectively the "Term Loans"). The initial Term Loan shall be in a principal amount of at least Ten Million Dollars (\$10,000,000), the first proceeds of which Borrower shall use to repay all indebtedness that Borrower owes to Silicon Valley Bank pursuant to the SVB Loan Agreement and for working capital and other general corporate purposes. Borrower may request one (1) additional Term Loan at any time from the date hereof through the Availability End Date. The proceeds of the Term Loans shall be used for general working capital and corporate purposes and for capital expenditures.

(ii) Interest shall accrue from the date of each Term Loan at the rate specified in Section 2.3(a), and prior to the Availability End Date for the applicable Term Loan shall be payable monthly in arrears 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 Availability End Date shall be payable in thirty (30) equal monthly installments of principal, plus all accrued but unpaid interest, beginning on January 1, 2020, and continuing on the same day of each month thereafter through the Maturity Date, at which time all outstanding amounts due in connection with the Term Loans and any other outstanding amounts due under this Agreement shall be immediately due and payable. Notwithstanding the foregoing, if the Availability End Date is extended to June 30, 2020, then any Term Loans outstanding on such date shall be payable in twenty four (24) equal monthly installments of principal, plus all accrued but unpaid interest, beginning on July 1, 2020, and continuing on the same day each month thereafter through the Maturity Date, at which time all outstanding amounts due in connection with the Term Loans and any other outstanding amounts due under this Agreement shall be immediately due and payable. Term Loans, once repaid, may not be reborrowed.

(iii) Borrower may prepay all but not less than all of the outstanding Term Loans, provided that Borrower shall pay a prepayment fee equal to (i) 2.0% of the amount prepaid before the first anniversary of the Closing Date, (ii) 1.0% of the amount prepaid on or after the first anniversary but before the second anniversary of the Closing Date, and 0% for any prepayment on or after the second anniversary of the Closing Date.

(iv) 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, out-of-pocket loss or reasonable documented out-of-pocket costs and expenses suffered by Bank as a result of such reliance (except to the extent such damages, losses, costs or expenses result from Bank's gross negligence or willful misconduct).

2.2 [Reserved].

2.3 Interest Rates, Payments, and Calculations

(a) Interest Rates. Except as set forth in Section 2.3(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 and (B) 5.0%.

(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 and (ii) the maximum amount permitted to be charged under applicable law. All outstanding Obligations shall, at Bank's option, 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, at its option, to 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, first, a deposit account designated by Borrower in writing, and second, if insufficient funds remain in such account, any of Borrower's other deposit accounts. 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.

(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.

2.4 Crediting Payments. Except 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.

2.5 Fees. Borrower shall pay to Bank the following:

(a) **Facility Fee.** None;

(b) **Success Fee.** Promptly upon the closing of one or more financing(s) after the Closing Date in which Borrower receives aggregate gross proceeds of at least \$25,000,000, Borrower shall pay Bank a one-time fee equal to (i) \$200,000, if such fee is paid on or before June 30, 2019 and (ii) \$300,000, if such fee is paid after June 30, 2019. Borrower's obligation to pay this fee shall survive termination of this Agreement.

(c) **Prepayment Fee.** The prepayment fee specified in Section 2.1(c)(iii), as applicable.

(d) **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.

2.6 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 indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement) remain outstanding or Bank has any obligation to make Credit Extensions under this Agreement. Notwithstanding the foregoing, Bank shall have the right in accordance with Section 9.1 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) a financing statement (Form UCC-1) for Borrower;
- (d) payment of the fees and Bank Expenses then due specified in Section 2.5, which may be debited from any of Borrower's accounts with Bank;
- (e) current SOS Reports indicating that except for Permitted Liens, there are no other security interests or Liens of record in the Collateral;
- (f) a payoff letter from Silicon Valley Bank;
- (g) current financial statements, including audited statements 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 balance sheets and income statements for the most recently ended month in accordance with Section 6.2, and such other updated financial information as Bank may reasonably request;
- (h) current Compliance Certificate in accordance with Section 6.2;
- (i) Borrower Information Certificate;
- (j) Borrower shall have opened and funded not less than \$50,000 in deposit accounts held with Bank; and
- (k) 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 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 be in compliance with Section 6.6 hereof;
 - (c) in Bank's sole but reasonable 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 immediately 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.
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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, upon the filing of a financing statement in the jurisdiction of Borrower's incorporation, 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. 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 indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement) are outstanding. Upon request by Borrower and payment in full in cash of the Obligations (other than inchoate indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement) and at such time as Bank's obligation to make Credit Extensions has terminated, Bank shall release its liens and interests in the Collateral and, at such time and from time to time thereafter, Bank shall take such actions as reasonably requested by Borrower in order to evidence the termination of such Liens (including filing UCC-3 or similar termination statements with respect to such Liens).

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. Where Collateral is in possession of a third party bailee, Borrower shall take such commercially reasonable steps as Bank reasonably requests for Bank to (i) subject to Section 7.10 below, obtain an acknowledgment, in form and substance reasonably satisfactory to Bank, of the bailee that the bailee holds such Collateral for the benefit of Bank, and (ii) subject to Section 6.6, 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 depository institution or issuing bank to execute a control agreement in form and substance reasonably satisfactory to Bank. No Borrower will create any chattel paper without placing a legend on the chattel paper reasonably 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 reasonably 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, 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 and inventory in transit, all tangible Collateral having an aggregate book value in excess of \$500,000, is located solely in the Collateral States or such other locations disclosed to Bank by Borrower in writing from time to time. 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 or as permitted under Section 6.6, none of 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 of the intellectual property owned by Borrower, except for licenses granted to its customers in the ordinary course of business and over-the-counter software that is commercially available to the public. To Borrower's knowledge, each of the copyrights, trademarks and patents owned by Borrower and material to Borrower's business is valid and enforceable, and no part of the intellectual property owned by Borrower and material to Borrower's business has been judged invalid or unenforceable, in whole or in part, and no claim has been made in writing alleging to Borrower that any part of the intellectual property owned 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 or such other location disclosed to Bank pursuant to Section 7.2.

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, if applicable, financial statements related to Borrower and any Subsidiary that are delivered to Bank fairly present in all material respects Borrower's consolidated and consolidating, if applicable, financial condition as of the date thereof and Borrower's consolidated and consolidating, if applicable, results of operations for the period then ended (subject, in the case of unaudited financials to the absence of footnotes and year-end audit adjustments). There has not been a material adverse change in the consolidated or in the consolidating, if applicable, financial condition of Borrower since the date of the most recent of such financial statements submitted to Bank by Borrower.

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 would reasonably be expected to result in Borrower's incurring any liability that could have a Material Adverse Effect. No Borrower is an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940. No Borrower is 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). No Borrower has 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 by Borrower or such Subsidiary, 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 Investments. No Borrower owns 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 or as disclosed to Bank pursuant to Section 6.9, Borrower is not a party to, nor is bound by, any material license or other similar agreement material to the conduct of Borrower's business that prohibits Borrower from granting a security interest in Borrower's interest in such license or agreement or any other property important for the conduct of Borrower's business, other than this Agreement or the other Loan Documents or commercial off-the-shelf software.

5.13 Full Disclosure. No representation, warranty or other statement made by Borrower in any certificate or written statement furnished to Bank in connection with the Loan Documents 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 materially 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 materially differ from the projected or forecasted results.

6. AFFIRMATIVE COVENANTS.

Borrower shall do all of the following:

6.1 Good Standing and Government Compliance. Borrower shall maintain its and (except as permitted under Section 7.3) 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, in each case, 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 balance sheet, income statement, and agings covering Borrower's operations during such period, 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 consolidated financial statements of Borrower prepared in accordance with GAAP, consistently applied, together with an opinion which is either unqualified, qualified only for going concern related to Borrower's liquidity position or otherwise consented to in writing by Bank on such financial statements of Ernst & Young, any "Big Four" accounting firm or any other 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 the earlier to occur of (a) 90 days after the end of each fiscal year and (b) 15 days after approval by the Board of Directors; (iv) 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 with the Securities and Exchange Commission, including Borrower's quarterly financial statements in connection with Form 10-Q (documents filed with the SEC and required to be delivered pursuant to the terms of this clause may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower

provides a link thereto, on Borrower's website on the internet at Borrower's website address); (v) promptly upon receipt of notice thereof, a report of any legal actions pending or threatened in writing against Borrower or any Subsidiary in which a likely adverse decision would reasonably be expected to have a Material Adverse Effect; (vi) within 45 days after the end of each calendar quarter, strategic business updates, (vii) promptly upon receipt by Borrower, each management letter prepared by Borrower's independent certified public accounting firm regarding Borrower's management control systems; (viii) such budgets, sales projections, operating plans or other financial information generally prepared by Borrower in the ordinary course of its business 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 3 Business 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) Bank (through any of its officers, employees, or agents) shall have the right, upon reasonable prior notice, from time to time at reasonable times during Borrower's usual business hours but no more than once 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 (ordinary wear and tear and casualty damage excepted), 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, or as is standard in the industry. Borrower shall promptly notify Bank of all returns and recoveries and of all written disputes and claims involving inventory having a book value of more than \$500,000.

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 reasonably 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 customarily insured against by other owners in businesses similar to Borrower's. Not later than thirty (30) days after the Closing Date, Borrower shall cause all such policies of insurance to be in such form, with such companies, and in such amounts as reasonably satisfactory to Bank, with all policies of property insurance containing a lender's loss payable endorsement, in a form reasonably satisfactory to Bank, showing Bank as lender's loss payee and all liability insurance policies to show, or have endorsements showing, Bank as an additional insured. Any such insurance policies shall specify that the insurer must give at least 20 days notice to Bank before canceling its policy for any reason (or 10 days notice in the event of cancellation for non-payment). Within 30 days of the Closing Date, Borrower shall cause to be furnished to Bank

certificates of insurance and a copy of its policies including any endorsements covering Bank or showing Bank as an additional insured. Upon Bank's reasonable 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 repair or replace the property subject to the claim, provided that any such repaired or replacement property shall be deemed Collateral in which Bank has been granted a first priority security interest (subject to Permitted Liens), 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 3.1(j), within 30 days 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 reasonably satisfactory to Bank. Notwithstanding the above, Borrower and its Subsidiaries shall be permitted to maintain an aggregate amount of cash in one or more accounts outside of Bank or its affiliates, without an account control agreement, as follows: (i) up to \$10,000,000 from the date that is 31 days after the Closing Date through the date that is 60 days after the Closing Date; (ii) up to \$5,000,000 from the date that is 61 days after the Closing Date through the date that is 90 days after the Closing Date; and (iii) up to \$100,000 at all times thereafter.

6.7 Massachusetts Security Corporation. As long as (i) APSC remains a Massachusetts Security Corporation, (ii) Borrower maintains Cash in accounts with Bank with a balance not less than 120% of the outstanding principal owing under this Agreement, and (iii) APSC maintains all its investment and depository accounts with Bank, Borrower may invest cash in excess of that 120% minimum in APSC.

6.8 Financial Covenants. None.

6.9 Consent of Inbound Licensors. Within thirty (30) days of 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) at Bank's reasonable request, 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 would reasonably be expected to 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; provided, further, however, that, for the avoidance of doubt and notwithstanding anything in this Section 6.9 or in this Agreement to contrary, Borrower shall not be required to take any efforts to obtain consents or waivers from licensors in connection with licenses existing on the Closing Date and disclosed to Bank.

6.10 Creation/Acquisition of Subsidiaries. In the event Borrower creates or acquires any Subsidiary (other than APSC), Borrower shall promptly notify Bank of such creation or acquisition, and Borrower 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 will not do any of the following:

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 10 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 Business 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 60 consecutive days; 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 \$500,000 during any fiscal year, (ii) no Event of Default has occurred, is continuing or would exist immediately after giving effect to such transactions, (iii) such transactions do not result in a Change in Control, and (iv) in transactions involving Borrower, Borrower is the surviving entity; or (b) the outstanding Obligations (other than inchoate indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement) 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) [Reserved], (ii) [Reserved], and (iii) Borrower notifies Bank within thirty 30 days 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, in each case, 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 current or former employees or directors pursuant to stock repurchase agreements in an aggregate amount not to exceed \$350,000 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, (ii) repurchase the stock of current or 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, (iii) convert any of its convertible securities or Subordinated Debt into other securities in accordance with the terms of such convertible securities or Subordinated Debt, (iv) pay dividends solely in capital stock, (v) purchase fractional shares of capital stock arising out of stock dividends, splits or combinations.

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 (other than APSC) so to do, other than Permitted Investments, or, from the date that is thirty (30) days after the Closing Date, 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 reasonably 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 (other than the Loan Documents or any documents governing Subordinated Debt).

7.8 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, (ii) the sale of Borrower's equity securities in bona fide transactions with or the incurrence of Subordinated Debt to Borrower's existing investors that do not result in a Change in Control, (iii) transactions permitted pursuant to Section 7.3, (iv) Permitted Transfers, Permitted Indebtedness and Permitted Investments, (v) reasonable and customary director, officer and employee compensation (including bonuses) and other benefits (including retirement, health, stock option and other benefit plans and indemnification arrangements approved by the relevant board of directors or equivalent corporate body), (vi) transactions with Alcresta, Inc. in the ordinary course of business or approved by the Board.

7.9 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.

7.10 Inventory and Equipment. Store the Inventory or the Equipment of a book value in excess of \$500,000 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 in the possession of Borrower's employees or agents, 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 needed to perfect its security interest or to obtain a bailee's acknowledgment of Bank's rights in the Collateral.

7.11 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 (a) make any payment of principal or interest on any Credit Extension when due or (b) pay any of the Obligations within three (3) Business Days of the date when due. During this three (3) Business Day cure period, the failure to make or pay any payment specified under clause (b) hereunder is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 Covenant Default.

(a) If Borrower fails to perform any obligation under Sections 6.2 (financial reporting), 6.4 (taxes), 6.5 (insurance), or 6.6 (primary accounts), 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 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 30 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 30 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 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 lease of real property material to the conduct of Borrower's business, if such default or failure to perform results in the right of another party to terminate such lease, or (iii) that would reasonably be expected to have a Material Adverse Effect;

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 when made or deemed made.

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, in accordance with applicable law, 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 Credit Card Services remaining undrawn, as collateral security for the repayment of any future drawings under such Credit Card Services, and (ii) pay in advance all fees scheduled to be paid or payable in connection with such Credit Card Services, 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 shall assemble the Collateral if Bank so requires, and to make the Collateral available to Bank as Bank may designate which is reasonably convenient to Borrower and Bank. 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 grants Bank a license to enter into possession of such premises and to occupy the same, without charge, by Borrower 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 of Borrower (other than any payroll, trust or escrow 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 then due 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 granted a license or other right, solely pursuant to the provisions of this Section, 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, Borrower's rights under all licenses and all franchise agreements shall inure to Bank's benefit;

(i) Dispose of 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 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 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 indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement) 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. After the occurrence and during the continuance of an Event of Default, 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 timely 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; 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 reasonably 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. 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:	ALLENA PHARMACEUTICALS, INC. One Newton Executive Park, Suite 202 Newton, MA 02462 Attn: Edward Wholihan E-Mail: ewholihan@allenapharma.com
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: loanotices@square1bank.com
with a copy to:	Pacific Western Bank 131 Oliver Street, Suite 250 Boston, MA 02110 Attn: Scott Hansen E-Mail: shansen@square1bank.com

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. Notwithstanding the foregoing, unless an Event of Default shall have occurred and be continuing, Bank shall not assign the Agreement or sell a participation therein to any vulture hedge fund or director competitor of Borrower.

12.2 Indemnification. Borrower shall defend, indemnify and hold harmless Bank and its officers, directors, employees, affiliates, advisors and agents 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 (including without limitation reasonable documented out-of-pocket attorneys fees and expenses), except, in each case, for claims, losses, obligations or liabilities caused by Bank'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 (other than inchoate indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement) 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) In handling any confidential information, Bank and all employees and agents of Bank shall exercise commercially reasonable efforts to maintain in confidence, in accordance with its customary procedures for handling confidential information, all non-public information furnished to Bank ("Confidential Information") other than any such Confidential Information that becomes generally available to the public (other than through disclosure by Bank in violation of this Section 12.8) 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 (provided that the applicable Affiliate agrees to the terms of this Section 12.8); (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 (provided that any such Person shall have entered into an agreement containing confidentiality provisions no less restrictive than the provisions of this Section 12.8 and Bank shall have delivered a copy to Borrower); (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 shall supersede and replace any other confidentiality obligations agreed to by Bank or its Affiliates.

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

ALLENA PHARMACEUTICALS, INC.

By: /s/ Edward Wholihan

Name: Edward Wholihan

Title: CFO

PACIFIC WESTERN BANK

By: /s/ Scott Hansen

Name: Scott Hansen

Title: Senior 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.

“APSC” means Allena Pharmaceuticals Security Corporation.

“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.

“Availability End Date” means December 31, 2019, provided that from and after the Equity Event, Availability End Date shall mean June 30, 2020.

“Bank Expenses” means all reasonable and documented costs or expenses (including reasonable and documented 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.

“Cash” means unrestricted cash and cash equivalents.

“Change in Control” shall mean a transaction other than pursuant to a public offering or 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 nonassignable 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 Massachusetts.

"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.

"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 Two Hundred Fifty Thousand Dollars (\$250,000).

"Credit Card Maturity Date" means 364 days after the Closing Date.

"Credit Extension" means each Term Loan and any other extension of credit by Bank to or for the benefit of Borrower hereunder.

"Environmental Laws" means all laws, rules, regulations, orders and the like issued by any federal state, local foreign or other governmental or quasi-governmental authority or any agency pertaining to the environment or to any hazardous materials or wastes, toxic substances, flammable, explosive or radioactive materials, asbestos or other similar materials.

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

"Equity Event" means the receipt by Borrower after the Closing Date but not later than December 31, 2019 of at least Fifty Million Dollars (\$50,000,000) of gross proceeds from the sale of its equity securities or upfront cash payment from a strategic partnership.

“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.

“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 any Copyrights, Trademarks and Patents.

“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.

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

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

“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.

“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.

“Maturity Date” means June 29, 2022.

“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.

“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.

“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 not to exceed \$250,000 in the aggregate at any time 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 as a result of endorsing negotiable instruments received in the ordinary course of business;
- (g) Indebtedness (i) owing from Borrower or any Subsidiary that is a guarantor to Borrower or any Subsidiary that is a guarantor, (ii) owing from any Subsidiary that is not a guarantor to any Subsidiary that is not a guarantor, and (iii) owing from any Subsidiary that is not a guarantor to Borrower or any Subsidiary that is a guarantor in an amount not to exceed \$100,000 outstanding;
- (h) Indebtedness that otherwise constitutes a Permitted Investment;
- (i) To the extent constituting Indebtedness obligations, Indebtedness incurred in connection with financing of insurance premiums in the ordinary course of business;
- (j) To the extent constituting Indebtedness, Indebtedness in respect of netting services or overdraft protections or otherwise in connection with deposit or securities accounts in the ordinary course of business;
- (k) Reimbursement obligations with respect to corporate credit cards;
- (l) the Standby Letter of Credit, issued by Silicon Valley Bank in the amount of \$26,500 existing as of the Closing Date;
- (m) Indebtedness not otherwise permitted hereunder not to exceed \$250,000 in the aggregate outstanding; and
- (n) 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:

- (o) Investments existing on the Closing Date disclosed in the Schedule;
 - (p) (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) certificates of deposit maturing no more than one year from the date of investment therein, and (iv) money market accounts; (v) Investments in regular
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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;

(q) Investments accepted in connection with Permitted Transfers;

(r) Investments (i) by Borrower or any Subsidiary that is a guarantor in Borrower or any Subsidiary that is a guarantor, (ii) by any Subsidiary that is not a guarantor in any Subsidiary that is not a guarantor, and (iii) by Borrower or any Subsidiary that is a guarantor in any Subsidiary that is not a guarantor in an amount not exceeding \$100,000 per year;

(s) Investments 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, which shall not exceed \$350,000 in the aggregate in any fiscal year;

(t) 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;

(u) 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;

(v) 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 \$250,000 in the aggregate in any fiscal year;

(w) Investments in APSC, to the extent permitted in Section 6.7;

(x) Investments permitted under Section 7.3; and

(y) Investments not otherwise permitted hereunder not to exceed \$250,000 in any fiscal year.

"Permitted Liens" means the following:

(z) 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;

(aa) 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;

(bb) Liens not to exceed \$250,000 in the aggregate 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;

(cc) 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;

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

(ee) Liens securing Subordinated Debt;

(ff) Liens of carriers, warehousemen, suppliers, mechanics, materialmen, landlords or other similar persons incurred in the ordinary course of business;

(gg) Liens to secure the payment of worker's compensation, employment insurance, old age pensions, social security, bonds to secure 401k or similar retirement plans and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(hh) Subject to Section 6.6, Liens in favor of other financial institutions arising in connection with Borrower's deposit and/or securities accounts held at such institutions;

(ii) Non-exclusive licenses, partnerships and joint ventures for the use of property of Borrower or its Subsidiaries in the ordinary course of business and licenses that do not result in a legal transfer of the title of the licensed property but may be exclusive in respects other than territory and that may be exclusive as to territory only as to discrete geographical areas outside of the United States;

(jj) Leases or subleases of real property granted in the ordinary course of business and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of business, if the leases, subleases, licenses and sublicenses do not prohibit granting Bank a security interest therein;

(kk) For up to sixty (60) days after the Closing Date, a Lien on Borrower's account with Silicon Valley Bank securing obligations in connection with a Letter of Credit in the amount of \$26,500; and

(ll) Cash collateral securing corporate credit cards.

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

(mm) Inventory in the ordinary course of business;

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

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

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

(qq) Permitted Investments;

(rr) Consisting of the sale or issuance of any stock of Borrower permitted under Section 7.2;

(ss) Cash in a manner not prohibited by the terms of this Agreement; and

(tt) 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.

“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.

“Responsible Officer” means each of the Chief Executive Officer, the Chief Operating Officer, 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.

“SVB Loan Agreement” means that certain Loan and Security Agreement, dated as of August 18, 2014, by and between Silicon Valley Bank and Borrower, as amended, restated, supplemented or otherwise modified from time to time.

“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.

SCHEDULE OF EXCEPTIONS

Permitted Indebtedness (Exhibit A) – None.

Permitted Investments (Exhibit A) – None.

Permitted Liens (Exhibit A) – None.

Prior Names (Section 5.5) – None.

Litigation (Section 5.6) – None.

Inbound Licenses (Section 5.12) – that certain License Agreement, dated as of March 22, 2012, by and between Althea Technologies, Inc. and Borrower.

CORPORATE RESOLUTION

The undersigned duly elected and qualified officer of ALLENA PHARMACEUTICALS, INC. (the "Company") certifies that the following is a true and correct copy of certain resolutions adopted by the Company's Board of Directors in accordance with applicable law and the Company's bylaws, and that such resolutions are now unmodified and in full force and effect:

BE IT RESOLVED, that:

- 1) Any one (1) of the following, duly elected officers of the Company (each, an "Authorized Officer") whose genuine original signature appears next to his or her name is authorized to act for, on behalf of, and in the name of the Company in connection with the resolutions below:

<u>Title</u>	<u>Name</u>	<u>Authorized Signature</u>
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- 2) Any Authorized Officer may:

- a) Borrow money from time to time from Pacific Western Bank (the "Bank"), and may negotiate and procure loans, letters of credit, foreign exchange contracts and other financial accommodations from Bank, including without limitation, that certain Loan and Security Agreement dated as of June 29, 2018, and also to execute and deliver to Bank one or more renewals, extensions, or modifications thereof;
 - b) Give security for any liabilities of the Company to Bank by grant, security interest, assignment, lien, deed of trust or mortgage upon any real or personal property, tangible or intangible of the Company;
 - c) Purchase, sell, exchange, assign, endorse for transfer and/or deliver certificates and/or instruments representing stocks, bonds, evidences of Indebtedness or other securities owned by the Company, whether or not registered in the name of the Company;
 - d) Discount with the Bank, commercial or other business paper belonging to the Company made or drawn by or upon third parties, without limit as to amount;
 - e) Authorize and direct the Bank to pay the proceeds of any such loans or discounts as directed by the persons so authorized to sign;
 - f) [Reserved];
 - g) Execute and deliver in form and content as may be required by the Bank any and all notes, evidences of indebtedness, applications for letters of credit, guaranties, subordination agreements, loan and security agreements, financing statements, assignments, liens, deeds of trust, mortgages, trust receipts and other agreements, instruments or documents to carry out the purposes of these Resolutions, any or all of which may relate to all or to substantially all of the Company's property and assets;
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- 3) The Authorized Officers may designate additional or alternate individuals as being authorized to request loan advances, to do and perform such other acts and things, to pay any and all fees and costs, and to execute and deliver such other documents and agreements as he or she may in his or her discretion deem reasonably necessary or proper in order to carry into effect the provisions of these Resolutions.

- 4) Any and all acts authorized pursuant to these resolutions and performed prior to the passage of these resolutions are hereby ratified and approved, and the authority conferred herein may be exercised singly by any such officer, and these resolutions shall continue in full force and effect until written notice of modification or revocation is received and accepted by Bank (such notice to have no effect on any action previously taken by the Bank in reliance on these Resolutions). Bank may rely upon any form of notice, which it in good faith believes to be genuine or what it purports to be.

- 5) The Resolutions are in full force and effect as of the date of this Certificate and are intended to replace, as of this date, any Resolutions previously given by the Company to Bank in connection with the matters described herein; these Resolutions and any borrowings or financial accommodations under these Resolutions have been properly noted in the corporate books and records, and have not been rescinded, revoked or modified; neither the foregoing Resolutions nor any actions to be taken pursuant to them are or will be in contravention of any provision of the articles of incorporation or bylaws of the Company or of any agreement, indenture or other instrument to which the Company is a party or by which it is bound; and to the extent the articles of incorporation or bylaws of the Company or any agreement, indenture or other instrument to which the Company is a party or by which it is bound require the vote or consent of shareholders of the Company to authorize any act, matter or thing described in the foregoing Resolutions, such vote or consent has been obtained.

In Witness Whereof, I have affixed my name as _____ (title) on June 29, 2018.

**USA PATRIOT ACT
NOTICE
OF
CUSTOMER IDENTIFICATION**

IMPORTANT INFORMATION ABOUT PROCEDURES FOR OPENING A NEW ACCOUNT

To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify, and record information that identifies each person who opens an account.

WHAT THIS MEANS FOR YOU: when you open an account, we will ask your name, address, date of birth, and other information that will allow us to identify you. We may also ask to see your driver's license or other identifying documents.

PACIFIC WESTERN BANK

AUTOMATIC DEBIT AUTHORIZATION

Member FDIC

To: **PACIFIC WESTERN BANK**

Re: **Loan #** _____

You are hereby authorized and instructed to charge account No. _____ in the name of
ALLENA PHARMACEUTICALS, INC.

for facility fees, principal, interest and other payments due on above referenced loan as set forth below and credit the loan referenced above.

_____ Debit the Facility Fee as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

_____ Debit each interest payment as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

_____ Debit each principal payment as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

_____ Debit each payment for Bank Expenses as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

This Authorization is to remain in full force and effect until revoked in writing.

Borrower Signature

Date

We are excited to have you as a client of Square 1 Bank, a division of Pacific Western Bank! We'd love to spread the word about your success!

From press releases to mentions on social media sites, and all points in between, Square 1's marketing and communications team is constantly seeking new opportunities to promote our clients and to connect them to prospects, existing customers and the larger entrepreneurial/venture capital community.

If you complete the authorization below and return it to us, you are authorizing us to reference and/or include your company as part of our marketing and advertising efforts without further review or advance approval by you. Please select all areas that you approve.

- All items listed below
- List company as a Square 1 customer on social media sites, including Twitter, LinkedIn, Facebook, Square 1's corporate blog, or any other social media site
- Press release including your company as a client of Square 1 Bank, a division of Pacific Western Bank (to include company name and description only ; may appear alongside other clients)
- Press release including your company as a client of Square 1 Bank, a division of Pacific Western Bank (**general** press release not focused on your company, but referring to your company as a client, and including your company's name, description, and editorial comments; may appear alongside other clients)
- Provide quote for inclusion in a Square 1-issued press release
- Use of company name and logo in Square 1 marketing materials including corporate marketing collateral, website, social media sites, and other advertising campaigns
- Provide quotes for inclusion in Square 1 marketing materials including corporate marketing collateral, website, social media sites, and other advertising campaigns
- Customer case study/application brief (success story to be posted on website, included in press kits and/or pitched to publications as potential articles)
- Willing to participate in a video testimonial highlighting your banking relationship and experiences with Square 1's team, products and services.
- Other (please describe):

If you have questions, please contact your banker or our Marketing + Communications team at marketing@square1bank.com.

Please acknowledge your authorization by signing below:

Company Name: _____

Authorized Signer: _____

Name: _____

Title: _____

Date: _____

INSURANCE CHECKLIST¹

In connection with the closing of your credit facility with Pacific Western Bank (the "Bank"), the following conditions related to insurance must be satisfied:

1. Insurance Company Requirements - All insurance required pursuant to the loan documents shall be issued by insurance companies in good standing with a current rating of A- or better by A.M. Best Company and a Financial Size Category of VIII or higher.
2. Property Insurance.
 - a. Pre-Closing: The Borrower must provide an Acord Form 28 showing evidence of property insurance, naming Pacific Western Bank as a certificate holder.
 - b. Post-Closing: Within thirty days following closing, Borrower must provide Bank with a Lender's Loss Payable endorsement showing Pacific Western Bank as a lender's loss payee.
3. Liability Insurance.
 - a. Pre-Closing: The Borrower must provide an Acord Form 25 showing Pacific Western Bank as a certificate holder.
 - b. Post-Closing: Within thirty days following closing, Borrower must provide Bank with an endorsement to Borrower's liability insurance policy showing Pacific Western Bank as an additional insured.
4. Name and Address – The Bank name and address format on all insurance related documentation should be as follows:

**Pacific Western Bank, its successors and assigns,
406 Blackwell Street, Suite 240 Durham, NC 27701
Attn: Loan Operations Department**

Please email copies of any documentation related to insurance to insurance@square1bank.com, and if you have any questions related to the insurance requirements associated with the closing of your credit facility please contact Lisa Stansell at (919) 597-7487 or via email at lstansell@square1bank.com.

**FIRST AMENDMENT
TO
LOAN AND SECURITY AGREEMENT**

This First Amendment to Loan and Security Agreement (this "*Amendment*") is entered into as of August 1, 2019, by and between PACIFIC WESTERN BANK, a California state chartered bank ("*Bank*"), and ALLENA PHARMACEUTICALS, INC. ("*Borrower*").

RECITALS

Borrower and Bank are parties to that certain Loan and Security Agreement dated as of June 29, 2018 (as amended from time to time, the "*Agreement*"). The parties desire to amend the Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

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

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

with a copy to: Pacific Western Bank
131 Oliver Street, Suite 250
Boston, Massachusetts 02110
Attn: Scott Hansen
E-Mail: shansen@pacwest.com

- 2) The following defined term in Exhibit A to the Agreement is hereby amended and restated, as follows:

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

- 3) Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Agreement. The Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of the Bank under the Agreement, as in effect prior to the date hereof. Borrower ratifies and reaffirms the continuing effectiveness of all agreements entered into in connection with the Agreement.
- 4) Borrower represents and warrants that the representations and warranties contained in the Agreement are true and correct in all material respects as of the date of this Amendment.
-

- 5) This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.
- 6) As a condition to the effectiveness of this Amendment, Bank shall have received, in form and substance satisfactory to Bank, the following:
 - a) this Amendment, duly executed by Borrower;
 - b) payment of all Bank Expenses, including Bank's expenses for the documentation of this Amendment and any related documents, and any UCC, good standing or intellectual property search or filing fees, which Bank may debit from any of Borrower's accounts at Bank; and
 - c) such other documents and completion of such other matters, as Bank may reasonably deem necessary or appropriate.

[Signatures Page Follows]

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

ALLENA PHARMACEUTICALS, INC.

PACIFIC WESTERN BANK

By: /s/ Edward Wholihan

Name: Edward Wholihan
Title: CFO

By: /s/ Joseph Holmes Dague

Name: Joseph Holmes Dague
Title: Senior Vice President

[Signature Page to First Amendment to Loan and Security Agreement]

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Louis Brenner, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2019 of Allena Pharmaceuticals, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on my 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.

November 13, 2019

By: /s/ Louis Brenner

Louis Brenner, M.D.
Chief Executive Officer, President and Director
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Edward Wholihan, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2019 of Allena Pharmaceuticals, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on my 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.

November 13, 2019

By: /s/ Edward Wholihan
Edward Wholihan
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report on Form 10-Q of Allena Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to his knowledge:

- 1) the Report which this statement accompanies 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.

November 13, 2019

By: /s/ Louis Brenner
Louis Brenner, M.D.
Chief Executive Officer, President and Director
(Principal Executive Officer)

November 13, 2019

By: /s/ Edward Wholihan
Edward Wholihan
Chief Financial Officer
(Principal Financial and Accounting Officer)