

**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, 2018

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38268

**ALLENA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in its Charter)

**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**

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, 2018, the registrant had 20,761,249 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:

- the design and conduct of our Phase 3 clinical program of reloxaliase (formerly referred to as ALLN-177) in enteric hyperoxaluria;
  - the number, designs, results and timing of our clinical trials 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;
  - 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;
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- 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 ability to generate revenue and become profitable; and
- our estimates regarding our capital requirements 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.

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## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements.

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

	September 30, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 70,559	\$ 94,494
Prepaid expenses and other current assets	2,178	1,539
Total current assets	72,737	96,033
Property and equipment, net	469	127
Other assets	191	89
Total assets	<u>\$ 73,397</u>	<u>\$ 96,249</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,779	\$ 1,724
Loan payable, net of discount	—	3,870
Accrued expenses and other current liabilities	3,159	1,949
Total current liabilities	4,938	7,543
Loan payable, net of current portion and discount	9,977	5,516
Other liabilities	37	320
Total liabilities	14,952	13,379
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Undesignated preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares authorized, issued or outstanding	—	—
Common stock, \$0.001 par value; 125,000,000 shares authorized; 20,756,185 and 20,694,658 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	21	20
Additional paid-in capital	166,418	164,807
Accumulated deficit	(107,994)	(81,957)
Total stockholders' equity	58,445	82,870
Total liabilities and stockholders' equity	<u>\$ 73,397</u>	<u>\$ 96,249</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>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
<b>Operating expenses:</b>				
Research and development	\$ 7,316	\$ 2,949	\$ 19,107	\$ 10,758
General and administrative	2,389	1,413	6,706	3,621
Total operating expenses	<u>9,705</u>	<u>4,362</u>	<u>25,813</u>	<u>14,379</u>
Loss from operations	(9,705)	(4,362)	(25,813)	(14,379)
<b>Other income (expense):</b>				
Interest income (expense), net	180	(146)	398	(401)
Other income (expense), net	15	(162)	(5)	(193)
Loss on extinguishment of debt	—	—	(617)	—
Other income (expense), net	<u>195</u>	<u>(308)</u>	<u>(224)</u>	<u>(594)</u>
Net loss	<u>\$ (9,510)</u>	<u>\$ (4,670)</u>	<u>\$ (26,037)</u>	<u>\$ (14,973)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.46)</u>	<u>\$ (3.49)</u>	<u>\$ (1.26)</u>	<u>\$ (11.19)</u>
Weighted-average common shares outstanding—basic and diluted	<u>20,753,215</u>	<u>1,343,429</u>	<u>20,727,426</u>	<u>1,342,898</u>
Net loss	\$ (9,510)	\$ (4,670)	\$ (26,037)	\$ (14,973)
<b>Other comprehensive income (loss):</b>				
Unrealized gain on investments	—	—	—	2
Total other comprehensive income	<u>—</u>	<u>—</u>	<u>—</u>	<u>2</u>
Comprehensive loss	<u>\$ (9,510)</u>	<u>\$ (4,670)</u>	<u>\$ (26,037)</u>	<u>\$ (14,971)</u>

*See accompanying notes.*

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

	<b>Nine Months Ended September 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (26,037)	\$ (14,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,512	295
Depreciation expense	44	53
Non-cash interest expense	159	264
Loss on extinguishment of debt	617	—
Amortization of premium on investments	—	33
Change in fair value of warrant liability	—	193
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(639)	(22)
Other assets	(102)	(89)
Accounts payable	(1)	150
Accrued expenses	1,300	(132)
Other liabilities	18	—
Net cash used in operating activities	(23,129)	(14,228)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(156)	(56)
Purchases of investments	—	(1,247)
Maturities of investments	—	24,721
Net cash (used in) provided by investing activities	(156)	23,418
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	87	5
Payments of initial public offering costs	(186)	(571)
Proceeds from loan payable	10,000	—
Repayment of loan payable	(10,492)	—
Debt issuance costs paid	(33)	—
Capital lease payments	(26)	—
Net cash used in financing activities	(650)	(566)
Net (decrease) increase in cash and cash equivalents	(23,935)	8,624
Cash and cash equivalents, beginning of period	94,494	25,250
Cash and cash equivalents, end of period	\$ 70,559	\$ 33,874
<b>Supplemental disclosure of non-cash activities:</b>		
Accretion of convertible preferred stock to redemption value	\$ —	\$ 52

*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, relaxaliase (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.

The Company has an accumulated deficit of \$108.0 million at September 30, 2018, 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, 2018, the Company had \$70.6 million of cash and cash equivalents. The Company believes that its cash and cash equivalents as of September 30, 2018 will be sufficient to fund the Company’s operating plan into 2020.

**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, 2017 and notes thereto, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 27, 2018. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited financial statements. 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, 2018, the results of its operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017. Such adjustments are of a normal and recurring nature. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results for the year ending December 31, 2018, 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.

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, 2017 that was filed with the United States Securities and Exchange Commission on March 27, 2018.

### **Recently Adopted Accounting Pronouncements**

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* (“ASU No. 2016-15”). This guidance addresses the presentation and classification of certain cash receipts and cash payments in the statement of cash flows. The Company adopted ASU No. 2016-15 effective January 1, 2018. The adoption of ASU No. 2016-15 did not have a material impact on the Company’s financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* (“ASU No. 2017-09”). This update clarifies the changes to terms or conditions of a share-based payment award that require an entity to apply modification accounting. The Company adopted ASU No. 2017-09 effective January 1, 2018. The adoption of ASU No. 2017-09 did not have a material impact on the Company’s financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The Company adopted ASC 606 on January 1, 2018 under the modified retrospective method. The modified retrospective method requires that the cumulative effect of initially applying ASC 606 be recognized as an adjustment to the opening balance of retained earnings or accumulated deficit of the annual period that includes the date of initial application. The Company did not have any arrangements that were in the scope of ASC 606 and thus there was no impact to the condensed consolidated financial statements as a result of the adoption.

### **Recently Issued Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (“ASU No. 2016-02”). The new standard aims to increase transparency and comparability among organizations by requiring lessees to recognize lease assets and lease liabilities on the balance sheet and requiring disclosure of key information about leasing arrangements. ASU No. 2016-02 is effective for public entities for annual periods beginning after December 15, 2018 and for interim periods within those fiscal years. The Company is currently evaluating the potential impact that ASU No. 2016-02 will have on its financial position and results of operations. The Company has reviewed its portfolio of existing leases and current accounting policies to identify and assess the potential differences that would result from applying the requirements of the new standard. The Company anticipates that the amended guidance will result in the recognition of operating lease assets and corresponding liabilities on its condensed consolidated balance sheets primarily related to its real estate leases.

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 new guidance will be effective for the Company on January 1, 2019. The Company is currently evaluating the potential impact that ASU No. 2018-07 may have on its financial position and results of operations.

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 currently is evaluating the impact the adoption of ASU 2018-15 will have on its condensed 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 currently is evaluating the impact the adoption of ASU 2018-13 will have on its disclosures.

### 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 (that were converted into warrants to purchase common stock in connection with the Company’s IPO in November 2017), 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,	
	2018	2017	2018	2017
<b>Numerator:</b>				
Net loss	\$ (9,510)	\$ (4,670)	\$ (26,037)	\$ (14,973)
Accretion of convertible preferred stock	—	(17)	—	(52)
Net loss attributable to common stockholders	\$ (9,510)	\$ (4,687)	\$ (26,037)	\$ (15,025)
<b>Denominator:</b>				
Weighted-average common shares—basic and diluted	20,753,215	1,343,429	20,727,426	1,342,898
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.46)	\$ (3.49)	\$ (1.26)	\$ (11.19)

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,	
	2018	2017
Series A convertible preferred stock	—	4,400,410
Series B convertible preferred stock	—	4,753,536
Series C convertible preferred stock	—	4,791,563
Warrants	9,040	43,265
Stock options	2,134,904	1,528,370
Total	2,143,944	15,517,144

#### 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, 2018 and December 31, 2017, and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

Description	September 30, 2018	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds, included in cash and cash equivalents	\$ 63,782	\$ 63,782	\$ —	\$ —
Total assets	<u>\$ 63,782</u>	<u>\$ 63,782</u>	<u>\$ —</u>	<u>\$ —</u>

Description	December 31, 2017	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market funds, included in cash and cash equivalents	\$ 93,745	\$ 93,745	\$ —	\$ —
Total assets	<u>\$ 93,745</u>	<u>\$ 93,745</u>	<u>\$ —</u>	<u>\$ —</u>

At September 30, 2018 and December 31, 2017, 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, 2018 and the year ended December 31, 2017. There were no transfers within the fair value hierarchy during the three and nine months ended September 30, 2018 and the year ended December 31, 2017.

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 and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Payroll and employee-related expenses	\$ 1,422	\$ 1,132
Professional fees	237	420
Third-party research and development expenses	1,400	135
IPO-related services	—	111
Other	100	151
Total accrued expenses and other current liabilities	<u>\$ 3,159</u>	<u>\$ 1,949</u>

#### 6. 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 of 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, accordingly.

On June 29, 2018 the Company also entered into a loan agreement with Pacific Western Bank (“PWB Loan Agreement”) 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 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 will be paid to the Lender. If the gross proceeds are received on or before June 30, 2019, the Success Fee is \$200,000, and if the gross proceeds are received after June 30, 2019, the Success Fee is \$300,000. 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, 2018.

## 7. Stockholders’ Equity

### Common Stock

Common stockholders are not entitled to receive dividends, unless declared by the Board of Directors.

At September 30, 2018, warrants to purchase up to 9,040 shares of common stock at an exercise price of \$11.06 were outstanding. These warrants expire on May 1, 2026.

The Company has reserved for future issuances the following shares of common stock as of September 30, 2018 and December 31, 2017:

	September 30, 2018	December 31, 2017
Warrants	9,040	9,040
Stock options	4,307,693	3,538,345
Employee stock purchase plan	413,230	206,284
Total	<u>4,729,963</u>	<u>3,753,669</u>

## 8. 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.

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, 2018, 2,172,789 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 157	\$ 30	\$ 391	\$ 87
General and administrative	438	69	1,121	208
Total	\$ 595	\$ 99	\$ 1,512	\$ 295

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 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Risk-free interest rate	2.8%	1.9%-2.0%	2.3%-2.8%	1.9%-2.0%
Expected dividend yield	—%	—%	—%	—%
Expected term (in years)	5.6-6.1	5.9-6.3	5.5-6.1	5.6-6.3
Expected volatility	84%-85%	82%	81%-89%	82%-87%

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, 2017	1,508,124	1.89	7.9	\$ 12,328
Granted	743,674	8.50		
Exercised	(61,527)	1.42		
Cancelled	(55,367)	5.69		
Outstanding at September 30, 2018	2,134,904	\$ 4.11	7.9	\$ 14,554
Exercisable at September 30, 2018	1,101,412	\$ 1.91	7.0	\$ 9,721

As of September 30, 2018, total unrecognized stock-based compensation expense relating to unvested stock options was \$4.6 million. This amount is expected to be recognized over a weighted-average period of 2.9 years.

## **9. Commitments and Contingencies**

The Company has operating leases for office space in Newton, MA (“Newton Lease”) and for laboratory space in Sudbury, MA (“Sudbury Lease”). The Newton lease expires in December 2020 and base rent is \$0.3 million annually.

In March 2018, the Company amended the Sudbury Lease to reduce the square footage and to extend the term to February 28, 2021. In August 2018, the Company amended the amended Sudbury Lease, adding approximately 2,928 square feet of office space. Base rent for the Sudbury Lease is approximately \$0.2 million annually.

## 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, 2017 that was filed with the United States Securities and Exchange Commission, or the SEC, on March 27, 2018.*

*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 the 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, and are in discussions with the U.S. Food and Drug Administration, or the FDA, to finalize the design of our planned pivotal Phase 3 program in enteric hyperoxaluria. In March 2018, we initiated URIROX-1™ (URIROX-1) (formerly Study 301), the first of two anticipated Phase 3 clinical trials in support of our planned Biologic License Application, or BLA, for reloxaliase in patients with enteric hyperoxaluria. We expect to announce topline data from this trial in the second half of 2019. We continue to engage with the FDA to finalize the design of URIROX-2™ (URIROX-2) (formerly Study 302), the larger and second of two planned Phase 3 clinical trials, and to discuss suitability for an accelerated approval pathway for our planned BLA submission for reloxaliase in patients with enteric hyperoxaluria. In the third quarter, we submitted to the FDA the second draft of our protocol for URIROX-2 and the planned statistical approach to support a BLA filing using the Subpart E accelerated approval pathway. The FDA subsequently provided guidance on two elements for the post-approval outcome phase of the trial. We amended and resubmitted the URIROX-2 protocol and statistical approach to the FDA to address this feedback. In preparation for implementing this protocol, we have also entered into an agreement with our clinical research organization, or CRO, for start-up activities for URIROX-2, including site identification and development of the operational plan to collect data for the confirmatory clinical benefit elements of the trial. Pending ongoing interactions with the FDA, we continue to expect to initiate URIROX-2 in 2018. 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 expect to announce interim data from Study 206 in the first half of 2019 and topline data from this trial in the second half of 2019.

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 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 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.

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, conducting preclinical studies of our product candidates and conducting 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, 2018, we had cash and cash equivalents totaling \$70.6 million.

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 \$9.5 million and \$4.7 million for the three months ended September 30, 2018 and 2017, respectively, and \$26.0 million and \$15.0 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$108.0 million. We anticipate that our expenses will increase significantly as we:

- conduct ongoing and future clinical trials of our lead product candidate, reloxaliase;
- manufacture additional material for our planned pivotal Phase 3 clinical program, Phase 2 clinical basket trial 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 our second product candidate, ALLN-346;
- 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 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. Furthermore, we expect to incur additional costs associated with operating as a public company. 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):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Reloxaliase external costs	\$ 4,488	\$ 1,485	\$ 12,158	\$ 6,653
ALLN-346 external costs	378	208	747	331
Employee compensation and benefits	1,836	1,019	5,023	3,100
Other	614	237	1,179	674
Total research and development expenses	<u>\$ 7,316</u>	<u>\$ 2,949</u>	<u>\$ 19,107</u>	<u>\$ 10,758</u>

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 \$61.5 million of external research and development costs for reloxaliase. 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 expense incurred on our credit facilities, amortized debt discount related to the fair value of the warrants issued in conjunction with the advances under our former credit facility with Silicon Valley Bank, or SVB, debt issuance costs, and interest income earned on our cash, cash equivalents and investments.

#### ***Other Income (Expense), Net***

Other income (expense), net, primarily consists of gain (loss) on foreign currency transactions and non-cash changes in the fair value of warrants issued in connection with our former credit facility with SVB. The preferred warrants converted upon the closing of our IPO and therefore became exercisable into common stock instead of convertible preferred stock. The warrants for the purchase of common stock met the criteria to be classified in stockholders' equity and the fair value of the warrant liability as of the IPO date was reclassified to stockholders' equity (deficit). As a result, we will no longer recognize any changes to the fair value of the warrants through other income (expense).

#### **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.

Our significant accounting policies are described in detail in the notes to our consolidated financial statements appearing the Annual Report filed on Form 10-K for the year ended December 31, 2017. There have been no changes to our significant accounting policies.

## Results of Operations

### Comparison of the three months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Dollar Change
	2018	2017	
Operating expenses:			
Research and development	\$ 7,316	\$ 2,949	\$ 4,367
General and administrative	2,389	1,413	976
Total operating expenses	9,705	4,362	5,343
Loss from operations	(9,705)	(4,362)	(5,343)
Other income (expense):			
Interest income (expense), net	180	(146)	326
Other income (expense), net	15	(162)	177
Other income (expense), net	195	(308)	503
Net loss	\$ (9,510)	\$ (4,670)	\$ (4,840)

### Research and Development Expense

Research and development expense increased by \$4.4 million from \$2.9 million for the three months ended September 30, 2017 to \$7.3 million for the three months ended September 30, 2018. The following table summarizes our research and development expenses for the three months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Dollar Change
	2018	2017	
Clinical development external costs	\$ 2,954	\$ 458	\$ 2,496
Manufacturing external costs	1,906	543	1,363
Employee compensation and benefits	1,836	1,019	817
Other	620	929	(309)
Total research and development expenses	\$ 7,316	\$ 2,949	\$ 4,367

The \$4.4 million increase in research and development expense was primarily attributable to the following:

- Our clinical development external costs increased by \$2.5 million from \$0.5 million for the three months ended September 30, 2017 to \$3.0 million for the three months ended September 30, 2018:
  - We incurred \$2.0 million of costs for our URIROX-1 Study during the three months ended September 30, 2018. This study was initiated during the first quarter of 2018;
  - We incurred \$0.4 million of costs for start-up activities for our URIROX-2 Study during the three months ended September 30, 2018;
  - We also incurred \$0.4 million of costs for our 206 Study during the three months ended September 30, 2018, which was initiated during the first quarter of 2018; and

- o The increase in costs due to our URIROX-1 Study, our URIROX-2 Study and our 206 Study was partially offset by \$0.1 million of costs incurred during the three months ended September 30, 2017 as we completed the closeout of our 713 Study, for which there were no comparable costs for the three months ended September 30, 2018.
- Our manufacturing external costs increased by \$1.4 million from \$0.5 million for the three months ended September 30, 2017 to \$1.9 million for the three months ended September 30, 2018. Included in manufacturing costs for the three months ended September 30, 2018 was \$0.4 million of costs incurred at our CMOs for the production of engineering batches of drug substance for our Phase 3 clinical program and \$0.9 million of drug product costs for our Phase 3 clinical program. We also incurred \$0.2 million of drug development and formulation costs related to ALLN-346. We incurred no similar costs for the three months ended September 30, 2017; and
- Our employee compensation and benefits costs increased by \$0.8 million for the three months ended September 30, 2018, primarily due to an increase headcount from 20 employees at September 30, 2017 to 32 employees at September 30, 2018 as we grew our clinical and technical operations teams in preparation for our planned Phase 3 program.

#### *General and Administrative Expenses*

General and administrative expense increased by \$1.0 million from \$1.4 million for the three months ended September 30, 2017 to \$2.4 million for the three months ended September 30, 2018. The following table summarizes our general and administrative expenses for the three months ended September 30, 2018 and 2017 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Dollar Change</u>
	<u>2018</u>	<u>2017</u>	
Employee compensation and benefits	\$ 1,128	\$ 623	\$ 505
Consulting and professional services	796	525	271
Market research and commercialization planning	109	108	1
Other	356	157	199
<b>Total general and administrative expenses</b>	<b>\$ 2,389</b>	<b>\$ 1,413</b>	<b>\$ 976</b>

The \$1.0 million increase in general and administrative expense was primarily attributable to the following:

- Our employee compensation and benefits costs increased by \$0.5 million for the three months ended September 30, 2018, primarily due to an increase in employee salaries, wages, benefit costs and stock-based compensation. Our stock-based compensation increased from \$0.1 million for the three months ended September 30, 2017 to \$0.4 million for the three months ended September 30, 2018;
- Our consulting and professional services costs increased by \$0.3 million. The increase was primarily related to increased consulting costs, recruiting costs, accounting and tax costs and other costs incurred as a public company, partially offset by a decrease in legal costs; and
- Our other costs increased by \$0.2 million for the three months ended September 30, 2018, due primarily to a \$0.2 million increase in corporate insurance premiums. Our insurance premiums increased as a result of being a public company.

#### *Interest Income (Expense), net*

Interest income (expense), net consists of interest income earned on our cash and cash equivalents, interest expense on our outstanding debt, and amortization of our debt discount. We had net interest income of \$0.2 million for the three months ended September 30, 2018 and net interest expense of \$0.1 million for the three months ended September 30, 2017. The increase was attributable to interest earned from higher average balances of cash and cash equivalents for the three months ended September 30, 2018 due to the net proceeds received from our IPO in November 2017.

### Comparison of the Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,		Dollar Change
	2018	2017	
Operating expenses:			
Research and development	\$ 19,107	\$ 10,758	\$ 8,349
General and administrative	6,706	3,621	3,085
Total operating expenses	25,813	14,379	11,434
Loss from operations	(25,813)	(14,379)	(11,434)
Other income (expense):			
Interest income (expense), net	398	(401)	799
Other income (expense), net	(5)	(193)	188
Loss on extinguishment of debt	(617)	—	(617)
Other income (expense), net	(224)	(594)	370
Net loss	<u>\$ (26,037)</u>	<u>\$ (14,973)</u>	<u>\$ (11,064)</u>

#### Research and Development Expenses

Research and development expense increased by \$8.3 million from \$10.8 million for the nine months ended September 30, 2017 to \$19.1 million for the nine months ended September 30, 2018. The following table summarizes our research and development expenses for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,		Dollar Change
	2018	2017	
Clinical development external costs	\$ 7,639	\$ 2,940	\$ 4,699
Manufacturing external costs	4,278	2,372	1,906
Employee compensation and benefits	5,023	3,100	1,923
Other	2,167	2,346	(179)
Total research and development expenses	<u>\$ 19,107</u>	<u>\$ 10,758</u>	<u>\$ 8,349</u>

The \$8.3 million increase in research and development expense was primarily attributable to the following:

- Our clinical development external costs increased by \$4.7 million from \$2.9 million for the nine months ended September 30, 2017 to \$7.6 million for the nine months ended September 30, 2018:
  - We initiated our URIROX-1 Study during the first quarter of 2018. Expenses for this study were \$5.2 million for the nine months ended September 30, 2018;
  - We also initiated our 206 Study during the first quarter of 2018 and incurred \$1.0 million of costs for this study during the nine months ended September 30, 2018;
  - We also initiated preparation and start-up activities for our planned URIROX-2 Study during the second quarter of 2018 and incurred \$0.7 million of costs for this study during the nine months ended September 30, 2018; and
  - The increase in costs due to our URIROX-1 Study, URIROX-2 Study and 206 Study was partially offset by costs incurred during the nine months ended September 30, 2017, for which there were no comparable costs during the nine months ended September 30, 2018. We incurred \$1.6 million of costs during the nine months ended September 30, 2017 on the closeout of our 713 Study and \$0.3 million of costs as we completed our 204 Study.
- Our manufacturing external costs increased by \$1.9 million from \$2.4 million for the nine months ended September 30, 2017 to \$4.3 million for the nine months ended September 30, 2018.
  - Included in manufacturing costs for the nine months ended September 30, 2018 was \$2.0 million of costs incurred at our CMOs for the production of engineering and clinical batches of drug substance for our Phase 3 clinical program and \$1.1 million of drug product costs for our Phase 3 clinical program; and

- o Included in manufacturing costs for the nine months ended September 30, 2017 was \$0.8 million of costs incurred at our CMO for the production of engineering batches, \$0.2 of costs for modifications of equipment at our CMO and \$0.4 million of drug product costs.
- Our employee compensation and benefits costs increased by \$1.9 million for the nine months ended September 30, 2018, primarily due to an increase in headcount from 20 employees at September 30, 2017 to 32 employees at September 30, 2018 as we grew our clinical and technical operations teams in preparation for our Phase 3 program.

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 \$3.1 million from \$3.6 million for the nine months ended September 30, 2017 to \$6.7 million for the nine months ended September 30, 2018. The following table summarizes our general and administrative expenses for the nine months ended September 30, 2018 and 2017 (in thousands):

	<u>Nine Months Ended September 30,</u>		<u>Dollar Change</u>
	<u>2018</u>	<u>2017</u>	
Employee compensation and benefits	\$ 3,196	\$ 1,832	\$ 1,364
Consulting and professional services	1,972	967	1,005
Market research and commercialization planning	490	379	111
Other	1,048	443	605
<b>Total general and administrative expenses</b>	<b><u>\$ 6,706</u></b>	<b><u>\$ 3,621</u></b>	<b><u>\$ 3,085</u></b>

The \$3.1 million increase in general and administrative expense was primarily attributable to the following:

- Our employee compensation and benefits costs increased by \$1.4 million for the nine months ended September 30, 2018, primarily due an increase in employee salaries, wages, benefit costs and stock-based compensation. Our stock-based compensation increased from \$0.2 million for the nine months ended September 30, 2017 to \$1.1 million for the nine months ended September 30, 2018;
- Our consulting and professional services costs increased by \$1.0 million for the nine months ended September 30, 2018. The increase was primarily related to increased consulting costs, recruiting costs, accounting and tax costs and other costs incurred as a public company, partially offset by a decrease in legal costs;
- Our market research and commercialization planning costs increased by \$0.1 million for the nine months ended September 30, 2018. During the nine months ended September 30, 2018 we incurred costs of \$0.2 million as we engaged an independent third party to conduct a study to assess the market opportunities 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. During the nine months ended September 30, 2017, we incurred \$0.1 million of costs as we engaged another independent third party to conduct for a study to assess the enteric hyperoxaluria market opportunity for reloxaliase in the United States; and
- Our other costs increased by \$0.6 million for the nine months ended September 30, 2018, due primarily to \$0.4 million increase in corporate insurance premiums. Our insurance premiums increased as a result of being a public company.

We expect that our general and administrative expense will increase in future periods as we expand our operations and incur additional costs in connection with being a public company.

#### *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 \$0.4 million for the nine months ended September 30, 2018 and net interest expense of \$0.4 million for the nine months ended September 30, 2017. The increase was primarily attributable to interest earned from higher average balances of cash and cash equivalents for the nine months ended September 30, 2018 due to the net proceeds received from our IPO in November 2017.

#### *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 debt discount and the final payment fee associated with the loan.

## Liquidity and Capital Resources

### Sources of Liquidity

We have funded our operations from inception through September 30, 2018 through gross proceeds of \$96.0 million from sales of our convertible preferred stock, borrowings of \$10.0 million under our credit facilities and net proceeds from our IPO of \$67.0 million which was completed in November 2017. Our total cash and cash equivalents was \$70.6 million and \$94.5 million at September 30, 2018 and December 31, 2017, respectively.

On June 29, 2018, we entered into a loan and security agreement with Pacific Western Bank, or the PWB Loan Agreement. The PWB Loan Agreement provides up to \$12.0 million principal in term loans, \$10.0 million of which was funded at the time we entered into the agreement, of which we utilized approximately \$8.5 million to repay the outstanding indebtedness under our existing loan and security agreement with SVB. The borrowings under the PWB Loan Agreement have an interest rate equal to the greater of 5.0% or the prime rate then in effect.

The repayment schedule provides for interest only payments for 18 months, beginning in July 2018, pursuant to the terms of the PWB Loan Agreement. The PWB Loan Agreement provides for extension of the aforementioned 18 month period to 24 months following receipt by us of at least \$50 million in gross proceeds from the sale of equity securities or an upfront payment from a strategic partnership by December 31, 2019. Following the interest only period, the loan repayment schedule provides for 30 or 24 equal monthly payments of principal plus interest, as the case may be. We have the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee of 0% to 2% depending upon when the prepayment occurs. In addition, in the event we close one or more financings pursuant to which we receive aggregate gross proceeds in the amount of at least \$25.0 million, the PWB Loan Agreement requires us to pay to Pacific Western Bank, or PWB, a one-time fee equal to (a) \$200,000, if such fee is paid on or before June 30, 2019 or (b) \$300,000, if such fee is paid after June 30, 2019. This obligation survives the termination of the PWB Loan Agreement. The term loan facility matures on June 29, 2022.

The borrowings under the PWB Loan Agreement are secured by a lien on all of our assets except intellectual property. The PWB Loan Agreement contains customary representations, warranties and covenants by us, including negative covenants restricting our activities, such as disposing of our business or certain assets, incurring additional debt or liens or making payments on other debt, making certain investments and declaring dividends, acquiring or merging with another entity, engaging in transactions with affiliates or encumbering intellectual property, among others. The obligations under the PWB Loan Agreement are subject to acceleration upon occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition.

### Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2018 and 2017 (in thousands):

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operations	\$ (23,129)	\$ (14,228)
Net cash (used in) provided by investing activities	(156)	23,418
Net cash used in financing activities	(650)	(566)
Net (decrease) increase in cash and cash equivalents	\$ (23,935)	\$ 8,624

### Net Cash Used in Operating Activities

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

Net cash used in operating activities was \$23.1 million for the nine months ended September 30, 2018 compared to \$14.2 million for the nine months ended September 30, 2017. The increase in cash used in operating activities of \$8.9 million was attributable to:

- an increase in net loss of \$11.1 million, partially offset by;
- an increase in non-cash items of \$1.5 million resulting primarily from increases in stock-based compensation expense and our loss on extinguishment of debt; and
- an increase of \$0.7 million in changes in the components of working capital, including increases in accounts payable and accrued expenses partially offset by decreases in prepaid expenses and other current assets.

### *Net Cash (Used in) Provided by Investing Activities*

Net cash used by investing activities was \$0.2 million for the nine months ended September 30, 2018 compared to net cash provided by investing activities of \$23.4 million for nine months ended September 30, 2017. The decrease in cash flows from investing activities of \$23.6 million was attributable to maturities of short term investments of \$24.7 million for the nine months ended September 30, 2017, partially offset by \$1.2 million of purchases of investments during the period, as we converted short-term investments to cash and cash equivalents to fund our operations. We did not have any maturities or purchases of short term investments during the nine months ended September 30, 2018.

### *Net Cash (Used in) Provided by Financing Activities*

Net cash used in financing activities was \$0.7 million for the nine months ended September 30, 2018 compared to \$0.6 million for the nine months ended September 30, 2017. The net cash used in financing activities for the nine months ended September 30, 2018 included \$10.5 million used to pay off our credit facility with SVB 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 PWB and \$0.1 million received from the exercises of stock options. The net cash used in financing activities for the nine months ended September 30, 2017 included \$0.6 million for payments of initial public offering costs incurred during the period.

### **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. Furthermore, we expect to incur additional costs associated with operating as a public company. 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.

We believe that our cash and cash equivalents as of September 30, 2018 will enable us to fund our operating expenses and capital requirements into 2020. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the costs of conducting ongoing and future clinical trials of reloxaliase;
- the costs of manufacturing additional material for our planned 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 with PWB, 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, 2018, our cash equivalents consisted of primarily 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, 2018 and 2017.

### **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.

**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 27, 2018.*

**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 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, the first country in which we intend to make reloxaliase available for sale, 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 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 of a generic or biosimilar 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 may not be predictive of future clinical trial results, and planned 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 other product candidates that we may pursue may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Data, our interpretation of data and results from our Phase 2 clinical trials of reloxaliase in adults with enteric hyperoxaluria do not ensure that we will achieve similar results in a pivotal Phase 3 clinical trial in enteric hyperoxaluria or in clinical trials of reloxaliase in other patient populations. 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 initial clinical trials.

In particular, as is common with Phase 2 clinical trials, particularly with the first clinical trials to be 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 registration trials will have to demonstrate statistically significant improvement in the pre-specified primary endpoint in the applicable registration trial. To date, two of our Phase 2 clinical trials of reloxaliase (Study 713 and Study 649) have not demonstrated statistically significant results in the pre-specified primary endpoints. Our later-stage clinical trials will differ in significant ways from our Phase 2 clinical trials of reloxaliase, which may cause the outcome of these later-stage trials to differ from our earlier stage clinical trials. These differences may include changes to inclusion and exclusion criteria, efficacy endpoints and statistical design. We are still finalizing the design of our planned pivotal Phase 3 clinical program for reloxaliase, including the primary and secondary endpoints and statistical analysis plan for these trials.

Product candidates in Phase 3 clinical trials, such as reloxaliase in our planned 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 trends toward efficacy. Some of the data we present on the use of reloxaliase for the treatment of enteric hyperoxaluria is drawn from post-hoc analyses. While we believe these data are useful in informing the design of future clinical trials for reloxaliase, these 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 proposed indication for our planned pivotal Phase 3 program, enrolled in the trial. Thus, we have limited data on the activity of reloxaliase in the target population for our planned Phase 3 clinical program.

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, 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 assure you 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 a time-weighted average of daily urinary oxalate excretion 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.

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.

**\* We have not yet finalized the design of our pivotal Phase 3 clinical program for reloxaliase, including the primary and secondary endpoints and the statistical analyses for our second of two planned Phase 3 clinical trials (the URIROX-2 trial), and whether reloxaliase may be eligible for the accelerated approval pathway remains subject to further discussion with the FDA. The FDA and comparable foreign regulators may not agree with our proposed Phase 3 clinical program, in which case we may be required to modify our planned clinical trials, or run additional clinical trials, before we can submit a BLA and comparable foreign applications for this product candidate.**

In March 2018, we initiated URIROX-1™ (formerly Study 301), the first of two anticipated Phase 3 clinical trials in support of our planned Biologic License Application (BLA) for reloxaliase in patients with enteric hyperoxaluria. However, we remain in active discussions with the FDA to finalize the design of our pivotal Phase 3 program for reloxaliase, including the primary and secondary endpoints and the statistical analyses for the second of our two planned Phase 3 clinical trials (the URIROX-2 trial) and the potential for reloxaliase to be eligible for the accelerated development approval pathway. There can be no assurance that we will reach agreement with the FDA on our Phase 3 clinical program as currently proposed.

For our URIROX-2 trial, we have proposed as a primary endpoint the percent change from baseline in 24-hour UOx excretion averaged during Weeks 1-4, comparing reloxaliase to placebo. The FDA has advised us that it may be willing to accept a substantial change in 24 hour UOx excretion as a surrogate endpoint in patients with secondary hyperoxaluria, especially patients with enteric hyperoxaluria, a prior history of kidney stones and very high baseline levels of UOx excretion. However, the FDA has also 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 have 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. However, the FDA has preliminarily agreed with our proposal to help validate the analyses presented to date with data collected from the planned URIROX-2 trial. 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 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. The data generated from the URIROX-1 and URIROX-2 trials could thus potentially form the basis of an accelerated approval BLA for 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. In addition, we 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. We remain in active dialogue with the FDA, and the design of the URIROX-2 trial, including the endpoints and statistical analysis plan for this study, and whether reloxaliase may be eligible for the accelerated approval pathway, remains subject to further discussion with the FDA.

If the FDA agrees to accept a change in TWA 24 hour UOx excretion as surrogate endpoint for our pivotal Phase 3 program under the accelerated approval pathway, we will be required to provide study data on longer term clinical follow up from trial patients, or conduct a separate clinical outcomes trial, to confirm the clinical benefit predicted by the biochemical therapeutic response demonstrated in our Phase 3 clinical trials. The clinical data we have proposed to collect in URIROX-2 may include serial assessments for kidney stone disease progression and other measures of kidney function. 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. 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. Moreover, the FDA may require us to make other changes to our proposed design of our Phase 3 clinical program for reloxaliase, including expanding the number of patients and/or treatment period evaluated or running one or more additional clinical trials prior to the submission of a BLA. 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.

Similarly, our planned 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 planned 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 planned 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.

**\* We may attempt to secure approval from the FDA or comparable non-U.S. regulatory authorities through the use of accelerated registration pathways. If unable to obtain approval under an accelerated pathway, 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 intend to pursue accelerated approval for reloxaliase and to continue to seek further feedback from the FDA or otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that the FDA will agree that our proposed primary endpoint for our planned pivotal Phase 3 clinical program is an appropriate surrogate endpoint. There also can be no assurance that, after our evaluation of the additional feedback from the FDA or other factors, we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback that we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we submit an application for 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, if another company receives full approval from the FDA to market a product for treatment of 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 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, 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.

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.

**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 expected for our planned pivotal Phase 3 clinical program. 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.

We have engaged in discussions with the FDA during our end of Phase 2 meeting, and subsequently, regarding the design of our planned pivotal Phase 3 clinical program for reloxaliase in adult patients with enteric hyperoxaluria. While we have received initial feedback, we do not yet have definitive feedback from the FDA on the proposed primary endpoint of our second of two planned pivotal Phase 3 clinical trials (the URIROX-2 trial), the measure of what is clinically meaningful in respect of this endpoint, secondary endpoints and the requisite data necessary to justify an approval, including use of our proposed primary endpoint as a surrogate endpoint as part of an accelerated approval. Furthermore, the FDA has discretion to reserve judgment on whether our endpoint and the results seen in our planned pivotal Phase 3 clinical program sufficiently demonstrate clinical meaningfulness until the FDA reviews our BLA several years from now.

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.

The design and conduct of clinical trials is complex, particularly where there is not an established regulatory approval pathway for a given patient population, such as enteric hyperoxaluria, or a new mechanism of action is being tested, as this may result in unpredictable results. For example, in our Phase 2 clinical trial referred to as Study 649, a “crossover” trial design was used, which is a longitudinal study in which subjects receive a sequence of different exposures during the course of the trial. Each treatment sequence consisted of two seven-day treatment periods separated by a seven-day washout period. While no clear factor was identified to account for the lack of differentiation between reloxaliase and placebo in Study 649, we believe the lack of effect may have been due to, among other things, the complexities inherent in the crossover study design.

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 planned Phase 2 trials will have elevated urinary oxalate levels, the underlying cause of their hyperoxaluria may be different. We cannot predict whether the design of our planned 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 planned pivotal Phase 3 clinical program for reloxaliase consists of two Phase 3 clinical trials of reloxaliase in adult patients with enteric hyperoxaluria. We are in discussions with the FDA and have conducted scientific advisory meetings with regulatory authorities in three countries within the European Union. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other comparable foreign regulators could disagree that we have satisfied their requirements to commence our clinical trials or 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 begin or 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 European Union, or 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 and toxicology studies, as well as Phase 1, Phase 2 and Phase 3 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 of patients in 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. 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.

**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. Alynlyam is conducting a phase 3 study and has announced that it received Breakthrough Therapy Designation by the FDA for the treatment of patients with primary hyperoxaluria Type 1. Dicerna has announced plans to initiate a phase 2/3 clinical study in primary hyperoxaluria in the first quarter of 2019. Oxthera AB (Sweden) and Captozyme (U.S.) are developing orally delivered products to degrade oxalate in the stomach and GI tract. Oxthera's oxabact, *Oxalobacter formigenes*, is in phase 3 clinical trials for the treatment of primary hyperoxaluria.

Many 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, 2018, we had 44 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 are 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, are 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 filing for 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 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.

**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 2024 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.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. In May 2017, the House of Representatives passed legislation to repeal and replace parts of the Affordable Care Act. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Thus, the full impact of the Affordable Care Act, any law repealing and/or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

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.

**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.

**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 were low and no drug-related serious or severe adverse events were observed, it is possible that our planned Phase 3 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 in our clinical trials to date, it is possible absorption could occur in our planned 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 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.

## 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 our completed Phase 2 clinical trials we relied 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 Financial Position and Need for Additional Capital**

**\* 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 \$9.5 million and \$4.7 million for the three months ended September 30, 2018 and 2017, respectively, and \$26.0 million and \$15.0 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$108.0 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 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 planned 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, 2018, we had working capital of \$67.8 million and capital resources consisting of cash and cash equivalents of \$70.6 million. We believe that 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.

We believe that our existing cash and cash equivalents as of September 30, 2018 will enable us to fund our operating plan into 2020. 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 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, 2018, 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 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 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 Alexey Margolin, Ph.D., our Chief Executive Officer, Louis Brenner, M.D., our President and Chief Operating Officer, and Edward Wholihan, our Chief Financial Officer. 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 expect to prepare and implement 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, relaxaliase. 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 relaxaliase 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, relaxaliase, 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 relaxaliase. 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, relaxaliase. 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 reloxaliate 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**

**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 will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K 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 is 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. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. 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.

**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. 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.

**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, 2018, our executive officers, directors and principal stockholders collectively controlled approximately 72.1% 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, 2018, we had 20,761,249 outstanding shares of common stock, assuming no exercise of outstanding options or warrants. In addition, the 2,134,904 shares subject to outstanding options under our stock option plans as of September 30, 2018, the 2,172,789 shares reserved for future issuance under our stock option plans, the 413,230 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, 2017, 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, 2017, we had federal net operating loss carryforwards of approximately \$77.9 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 will not be 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 will be 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.

In addition, we will be 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 by the time our annual report for the year ending December 31, 2018 is due and thereafter, which will require us to document and make significant changes to our internal controls over financial reporting. Likewise, 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, 2018, 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).

<b>Exhibit Number</b>	<b>Description</b>
10.10*	<a href="#">Commercial Lease, by and between the Registrant and Cummings Properties, LLC, dated August 18, 2016, as amended.</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Exchange Act rules 13a-14 or 15d-14.</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Exchange Act rules 13a-14 or 15d-14.</a>
32.1+	<a href="#">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.</a>
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 7, 2018

By: /s/ Alexey Margolin  
Alexey Margolin  
*Chief Executive Officer and Director*  
*(Principal Executive Officer)*

November 7, 2018

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

**CUMMINGS PROPERTIES, LLC  
STANDARD FORM  
COMMERCIAL LEASE**

Cummings Properties, LLC (“LESSOR”) hereby leases to Allena Pharmaceuticals, Inc. (a DE corp.), One Newton Executive Park, Suite 202, Newton, MA 02462 (“LESSEE”), the following premises, approximately 7,162 square feet (including 4.7% common area) at 142-B North Road, Sudbury, MA 01776 (“premises”), for a term of one year commencing at noon on September 1, 2016 and currently scheduled to terminate at noon on August 30, 2017 unless sooner terminated or extended as herein provided. LESSOR and LESSEE now covenant and agree that the following terms, conditions, covenants, and obligations (“terms”) shall govern the lease.

**1. RENT.** LESSEE shall pay LESSOR base rent of one hundred five thousand nine hundred ninety nine (105,999) U.S. dollars per year, drawn on a U.S. bank, in monthly installments of \$8,833.25 on or before the first day of each calendar month, without offset or deduction. One monthly rental payment, plus an appropriate traction of a monthly payment for any portion of a month at the commencement of the lease term, shall be made upon LESSEE’S execution of this lease. All payments shall be made to LESSOR at 200 West Cummings Park, Woburn, Massachusetts 01801, or at such other place designated in writing by LESSOR. If the “Cost of Living” has increased as shown by the Consumer Price Index (Boston, Massachusetts, all items, all urban consumers), U.S. Bureau of Labor Statistics (“Index”), then base rent due during each calendar year of this lease and all extensions thereof shall be adjusted in proportion to any increase in the Index. The base month from which to determine the amount of each increase shall be January 2016, which figure shall be compared with the figure for November 2016, and each November thereafter to determine the increase (if any) in base rent to be paid during the following calendar year commencing each January 1.

**2. SECURITY DEPOSIT.** LESSEE shall pay LESSOR a security deposit of \$33,000, drawn on a U.S. bank, upon LESSEE’S execution of this lease, which shall be held as security for LESSEE’S performance herein and refunded to LESSEE without interest at the end of this lease, subject to LESSEE’S satisfactory compliance with the terms hereof. LESSEE shall not apply the security deposit to any payment due under this lease. In the event of any breach of this lease by LESSEE, however, LESSOR may apply the security deposit first to any outstanding invoice or other payment due to LESSOR, and then to outstanding rent, in which event LESSEE shall fully restore said deposit forthwith. LESSEE’S failure to remit or restore the security deposit shall constitute a substantial (ease default if LESSEE fails to pay the security deposit and the initial rental payment as and when required herein, LESSEE agrees that LESSOR may at its sole option, declare this lease null and void for failure of consideration.

**3. USE.** LESSEE shall use the premises only for executive and administrative offices and a laboratory.

**4. REAL ESTATE TAX INCREASES.** LESSEE shall pay LESSOR as additional rent a proportionate share (based on square footage leased by LESSEE as compared with the total leasable square footage of the building(s) of which the premises are a part (building’)) of (i) all increases in the real estate (axes levied against the land and building (“property”), whether such increase(s) is/are due to an increase in the tax rate or assessment, or a change in the method of determining real estate taxes, and (ii) all real property surcharges and special assessments levied against the property. The base from which to determine the amount of any increase in taxes shall be (he rate and the assessment in effect for the fiscal year ending June 30, 2016, net of abatements, if any.

**5. UTILITIES.** LESSOR shall provide equipment per LESSOR’S building standards to heat the premises in season and to cool all office areas between May 1 and November 1. LESSEE shall pay all charges for utilities used on the premises, including electricity, telecommunications, gas, oil, water, and sewer, and shall use whichever utility service provider LESSOR designates. LESSEE shall also pay LESSOR a proportionate share of any other fees and charges relating in any way to utility use at the building, including charges for routine maintenance of any on-site septic system. LESSEE shall pay the utility provider or LESSOR, as applicable, for all such charges as determined by separate meters serving the premises and/or as a proportionate share if not separately metered.

**6. COMPLIANCE WITH LAWS.** LESSEE and LESSEE’S employees, agents, affiliates, callers, contractors, visitors, and invitees (“LESSEE parties”) shall not use the premises in any way that may be unlawful, improper, noisy, offensive, harmful, or contrary to any applicable statute, regulation, ordinance, or bylaw. LESSEE parties shall fully comply with all applicable statutes, regulations, ordinances, and bylaws related to or arising out of their use and occupancy of the premises and any allowed alterations herein, including without limitation, maintaining Worker’s Compensation Insurance and obtaining all licenses, permits, and approvals necessary for LESSEE’S use and occupancy of the premises.

**7. FIRE, CASUALTY, EMINENT DOMAIN.** Should a substantial portion of the premises, or of the property of which the premises are a part be substantially damaged by fire or casualty, or be taken by eminent domain, LESSOR may elect to terminate this lease. When such an event is not caused or contributed to by LESSEE parties and renders the building uninhabitable, a proportionate abatement of rent shall be made, and LESSEE may elect to terminate this lease upon 30 days’ prior written notice if. (a) LESSOR fails

to give written notice within 30 days after said event of its Mention to restore the premises; or (b) LESSOR fails to restore the premises, using building standard finishes, to a condition substantially suitable for the use described above within 90 days after said event LESSOR reserves all rights for damages or injury to the premises for any taking by eminent domain, except for damage to LESSEE'S property or equipment.

**8. FIRE INSURANCE.** LESSEE parties shall not permit any use of the premises which will adversely affect or make voidable any insurance on the property, or the contents of the building, or which shall be contrary to any law, regulation, or recommendation made by the Insurance Services Office (or successor organization), state fire prevention agency, local fire department LESSOR'S insurer, or any similar entity. LESSEE shall not vacate the premises or permit same to be unoccupied other than during LESSEES customary nonbusiness days or hours, or cause or allow the utilities serving the premises to be terminated.

**9. SIGNS.** LESSOR ~~may~~<sup>\*</sup>, at its expense, identify LESSEE'S occupancy of the premises with a building standard sign at the main entry to the premises and, ~~if applicable,~~ <sup>\*\*</sup>on the building's directory. LESSEE shall obtain LESSOR'S prior written consent before erecting any sign(s), and shall erect and maintain any such sign(s) in accordance with LESSOR'S building standards for style, size, wording, design, location, etc., now or hereafter made by LESSOR. LESSOR may, at LESSEE'S expense, remove and dispose of any sign(s) not property approved, erected, or maintained.

\* shall  
\*\* LESSOR shall include LESSEE'S name

**10. MAINTENANCE.** Except as otherwise provided below, LESSOR will maintain the structure, roof, landscaping, common areas, and building standard heating and cooling equipment, sprinklers, doors, plumbing, and electrical wiring at the premises, but specifically excluding damage caused by the careless, malicious, willful, or negligent acts of LESSEE parties or others, and corrosion and chemical or water damage from any source. LESSEE agrees to maintain at its expense all other aspects of the premises in the same condition as they are when delivered to LESSEE or as they may be put in during the lease term, normal wear and tear only excepted, and whenever necessary, to replace light bulbs and glass, acknowledging that the premises ~~\*are now~~ in good order<sup>\*\*</sup>. LESSEE shall properly control and vent all chemicals, radioactive materials, smoke, moisture, odors, and other materials that may be harmful, and shall not cause the area surrounding the premises or any other common area to be in anything other than a neat and clean condition, and shall appropriately dispose of all waste. LESSEE shall be solely responsible for any damage to any equipment serving the premises or the building which relates to or arises out of the storage, discharge, or use of any substance by LESSEE. LESSEE shall not permit the premises to be overloaded, damaged, stripped, or defaced, nor suffer any waste, and will not bring or keep animals therein. If the premises include any wooden mezzanine-type space, the floor capacity of such space is suitable only for light office or storage use. LESSEE will protect any flooring with chair pads under any rolling chairs and shall maintain sufficient heat to prevent freezing of pipes or other damage. All heating, ventilating, air conditioning, plumbing, and electrical equipment serving areas of the premises used for any purpose other than general office or warehouse, and any installation or maintenance of any "non-building standard" leasehold improvements or equipment which is associated with some specific aspect of LESSEE'S use, whether installed by LESSOR, LESSEE or a prior occupant, shall be LESSEE'S sole responsibility and at LESSEE'S expense. All maintenance and other services provided by LESSOR shall occur during LESSOR'S normal business hours.

\* will be  
\*\* upon delivery by LESSOR

**11. ASSIGNMENT OR SUBLEASE.** Provided LESSEE is not in default of any term hereof, LESSEE may assign this lease or sublet or allow another entity or individual to use or occupy all or part of the premises, but only with LESSOR'S prior written consent in each instance. LESSEE shall not assign this lease or sublet any part of the premises to any other current or prospective tenant of LESSOR, or any affiliate of such current or prospective tenant. As a condition to any assignment or sublease, a security deposit increase shall be paid to and held by LESSOR. If LESSEE notifies LESSOR of its desire to assign this lease or sublet, LESSOR may elect to terminate this lease, at an effective date to be determined by LESSOR, upon notice to LESSEE. Notwithstanding LESSOR'S consent to any assignment or sublease, LESSEE and GUARANTOR shall remain liable for the payment of all rent and for the full performance of all terms of this lease and all amendments and extensions thereto.

**12. ALTERATIONS.** LESSEE parties shall not make structural alterations, additions, or improvements of any kind to the premises, but LESSEE may make nonstructural alterations, additions, or improvements with LESSOR'S prior written consent (allowed alterations"). All allowed alterations shall be at LESSEE'S expense and shall conform with LESSOR'S building standards and construction specifications or will be subject to restoration charges, If LESSOR or its agents provide(s) any services or maintenance in connection with allowed alterations and/or the review thereof, LESSEE will promptly pay any just invoice(s). LESSEE shall obtain, prior to the commencement of any work, a lien waiver from any contractor(s) performing work at the premises. LESSEE shall not permit mechanics' liens or similar liens to remain upon the premises in connection with any work performed or claimed to have been performed at the direction of LESSEE and shall cause any such lien to be released or removed forthwith without cost to LESSOR. All allowed alterations shall become part of the premises and the property of LESSOR. LESSOR shall have the right at any time to make additions to the building, to change the arrangement of parking areas, stairs, or walkways, or otherwise to alter common areas or the exterior of the building. LESSEE shall move its furniture, furnishings, equipment, inventory, and other property as required by LESSOR to enable LESSOR to carry out the above-described work.

**13. LESSOR'S ACCESS.** LESSOR, its agents or designees may at any reasonable time enter to view the premises; to show the premises to others; to make repairs and alterations as LESSOR, its agents, or designees should elect to do for the premises, the common areas, or any other portions of the building; and without creating any obligation or liability for LESSOR, but at LESSEES expense, to perform work which LESSEE is required but has failed to do.

**14. SNOW REMOVAL.** The plowing of snow from all driveways and unobstructed parking areas shall be at the sole expense of LESSOR. The control of snow and ice on all walkways, stairs, and loading areas serving the premises and all other areas not readily accessible to plows shall be the sole responsibility of LESSEE. Notwithstanding the foregoing, LESSEE shall hold LESSOR and OWNER harmless from any and all claims by LESSEE parties for personal injuries and/or property damage resulting in any way from snow or ice on any area serving the premises.

**15. ACCESS AND PARKING.** LESSEE parties may without additional charge use parking spaces provided for the building in common with others. The number of spaces used by LESSEE parties, which shall be presumed to equal the number of persons present at the premises, shall not at any time exceed LESSEE'S proportionate share of the total spaces for the building. No unattended parking (i.e., parking where the driver of a vehicle is not readily available at the premises to relocate said vehicle) will be permitted between 7:00 PM and 7:00 AM without LESSOR'S prior written approval, and any such allowed parking shall be permitted only in designated overnight parking areas. Unregistered or disabled vehicles or trailers of any type may not be parked at any time. LESSOR may tow, at LESSEES sole risk and expense, any misparked vehicle belonging to LESSEE parties, at any time. LESSEE parties shall not obstruct any portion of the building or its common areas. LESSOR may record activities at the building with monitored and/or unmonitored cameras; however, LESSEE agrees that LESSOR is not in any way providing any security services for LESSEE parties, and accepts full responsibility for protecting LESSEE parties and their property.

**16. LIABILITY.** LESSEE shall be solely responsible as between LESSOR and LESSEE parties for death or personal injuries to all persons and/or property damage, including damage by fire or casualty, arising out of the use, control, condition, or occupancy of the premises by LESSEE parties, except for death, personal injuries, and/or property damage directly resulting from the negligence of LESSOR. LESSEE agrees to indemnify and hold harmless LESSOR and OWNER from any and all liability, including but not limited to costs, expenses, damages, causes of action, claims, judgments, and attorneys' fees caused by or in any way arising out of any of the aforesaid matters. All common areas, including but not limited to any parking areas, driveways, stairs, loading areas, corridors, roofs, walkways, lobbies, atria, elevators, communications closets, community conference rooms, and outdoor areas ("common areas") shall be considered a part of the premises for purposes of Sections 16 and 17 when they are used by LESSEE parties.

**17. INSURANCE.** LESSEE shall maintain at its expense a commercial general liability policy insuring LESSEE, LESSOR, and OWNER against all claims for personal injuries (including death) and/or property damage arising out of the use, control, condition, or occupancy of the premises, including any common areas, by LESSEE parties, including damage by fire or casualty, such policy to insure LESSEE, LESSOR, and OWNER against any claim up to \$1,000,000 for each occurrence involving personal injuries (including death), and \$1,000,000 for each occurrence involving property damage. This insurance shall be primary to and not contributory with any insurance carried by LESSOR, whose insurance shall be excess. LESSOR and OWNER shall be included in each such policy as additional insureds using ISO form CG 20 2611 85, ISO form CG 2011 01 96 (without exclusions), ISO form CG 20 11 04 13 (without exclusions), or some other form approved in writing by LESSOR, and each such policy shall be issued by a company or companies satisfactory to LESSOR. Prior to occupancy, LESSEE shall deliver to LESSOR a copy of such policy, together with the declarations page and all applicable riders and endorsements, showing that such insurance is in force, and thereafter will deliver, prior to the expiration of any such policy, notice of renewal of same. In the event any such policy or coverage changes, a copy of the policy, declarations page, and all applicable riders and endorsements shall be delivered to LESSOR within 10 days of such change. No policy shall be cancelled without at least 10 days' prior written notice to each insured. If LESSEE fails to deliver or maintain such insurance at any time during the term of this lease, LESSOR may, without further notice to LESSEE, elect to obtain such insurance, whereupon LESSEE shall pay LESSOR a reasonable charge for such insurance, plus LESSOR'S administrative expenses.

**18. BROKERAGE.** LESSEE warrants and represents that it has dealt with no broker, tenant representative, or third party in connection with this lease\*, and agrees to indemnify LESSOR against all brokerage claims arising out of this lease. LESSOR warrants and represents that it has employed no exclusive broker or agent in connection with this lease. If either LESSOR or LESSEE introduces a broker, tenant representative, or other third party on its behalf for any extension, amendment, or other modification of this lease, any fees or commissions shall be the sole responsibility of the party engaging such broker, tenant representative, or third party.

\* except for NAI Hunneman to which LESSOR shall pay a commission in accordance with a separate agreement

**19. SUBORDINATION.** This lease shall be subject and subordinate to any and all mortgages and other like instruments made at any time hereafter, and LESSEE shall, when requested, promptly execute and deliver such instruments as necessary to show the subordination of this lease to said mortgages or other such instruments.

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**20. DEFAULT AND RENT ACCELERATION.** In the event that (a) any assignment for the benefit of creditors, trust mortgage, receivership, or other insolvency proceeding shall be made or instituted with respect to LESSEE or LESSEE'S property, or (b) LESSEE shall default in the observance or performance of any term herein,

2 and such default shall not be corrected within 10 days after written notice thereof\*, then LESSOR shall have the right thereafter, while such default continues and without demand or further notice, to re-enter and take possession of the premises, to declare the term of this lease ended, and/or to remove LESSEE'S effects, without liability, including for trespass or conversion, and without prejudice to any other remedies. If LESSEE defaults in the payment of any rent and any such rental default continues for 10 days after written notice thereof, and, because both parties agree that nonpayment of said sums is a substantial breach of this lease, and, because the payment of rent in monthly installments is for the sole benefit and convenience of LESSEE, then, in addition to any other remedies, the net present value of the entire balance of rent due herein as of the date of LESSOR'S notice, using the published prime rate then in effect, shall immediately become due and payable as liquidated damages, since both parties agree that such amount is a reasonable estimate of the actual damages likely to result from such breach. No actions taken by LESSOR under this section shall terminate LESSEE'S obligation to pay rent under this lease, as liquidated damages or otherwise. Any sums received by LESSOR from or on behalf of LESSEE may at any time be applied by LESSOR in its sole discretion first to any unamortized improvements completed for LESSEE'S occupancy, then to any unpaid invoice or other payment due to LESSOR, and then to unpaid rent. LESSEE shall pay all invoices within 10 days of the date of such invoice(s). If any rent and/or other payment is not received by LESSOR when due, then LESSEE shall pay LESSOR a one-time late charge for each past due amount equal to one percent of such overdue amount or \$35 (whichever is greater) and interest at the rate of 18 percent per annum on any past due amount.

\* or, in the event such default cannot be cured within said 10-day period, LESSEE shall have not commenced to cure and be diligently proceeding to cure

**21. NOTICE.** All notices from LESSOR to LESSEE under this lease shall be given in writing and shall be deemed duly served when ~~left at the premises,~~ served by constable, sent by recognized courier service with a receipt therefor, or mailed by certified or registered mail, return receipt requested, postage prepaid to LESSEE at ~~\*the premises~~ or such other address as LESSEE may designate in writing. All notices from LESSEE to LESSOR under this lease shall be given in writing and shall be deemed duly served only when served by constable, or delivered to LESSOR by certified or registered mail, return receipt requested, postage prepaid, or by recognized courier service with a receipt therefor, addressed to LESSOR at 200 West Cummings Park, Woburn, Massachusetts 01801 or to the last address designated by LESSOR. No oral, facsimile, or electronic notice shall have any force or effect. Time is of the essence in the service of any notice.

\* Allena Pharmaceuticals, Inc., One Newton Executive Park, Suite 202, Newton, MA 02462, Attn: Chief Financial Officer,

**22. OCCUPANCY.** If LESSEE takes possession of the premises prior to the commencement of this lease, LESSEE shall perform all terms of this lease from the date it takes possession. LESSOR may require LESSEE at LESSEE'S expense to relocate to another similar premises (~~which shall be within the same municipality as the current premises, unless~~ \*LESSEE is not regularly occupying the premises) at any time upon written notice to LESSEE and on terms comparable to those herein. If any of LESSEE parties occupies, controls, or encumbers any part of the premises without LESSOR'S written permission after the termination of this lease or otherwise beyond the period specified by LESSOR in writing, LESSEE shall be liable to LESSOR for any and all loss, damages, and/or expenses incurred by LESSOR, including consequential damages, and all terms of this lease shall continue to apply, except that use and occupancy payments shall be due in full monthly installments at a rate which shall be two times the greater of the monthly rent due under this lease for the immediately preceding calendar month or LESSOR'S then-current published one-year rental rate for the premises, it being agreed that such extended occupancy is a tenancy at sufferance, solely for the benefit and convenience of LESSEE and of greater rental value. The occupancy, control, or encumbrance of any part of the premises by any of LESSEE parties beyond noon on the last day of any rental period shall constitute occupancy for an entire additional month, and increased payment as provided in this section shall be immediately due and payable. LESSOR'S acceptance of any payments shall not alter LESSEES status as a tenant at sufferance.

\* only in the event

**23. FIRE PREVENTION.** LESSEE agrees to use all reasonable precautions against fire, to provide and maintain approved, labeled fire extinguishers, emergency lighting equipment, and exit signs, and to complete all other modifications within the premises as required or recommended by the Insurance Services Office (or successor organization), OSHA, the local fire department, LESSOR'S insurer, or any similar entity.

**24. OUTSIDE AREA.** All items left or stored by LESSEE in any common area without LESSOR'S prior written consent shall be deemed abandoned and may be removed or disposed of by LESSOR at LESSEE'S expense without notice. LESSEE shall maintain a building standard size dumpster in a location approved by LESSOR, which dumpster shall be provided and serviced at LESSEE'S expense by a disposal firm designated by LESSOR. Alternatively, if a shared dumpster or compactor is provided by LESSOR, LESSEE shall pay the disposal firm or LESSOR, as applicable, LESSEE'S share of all charges associated therewith.

**25. ENVIRONMENT.** LESSEE parties shall not interfere in any way with the use and enjoyment of other portions of the same or neighboring buildings by others, in LESSOR'S discretion, by reason of odors, smoke, exhaust, vibrations, noise, moisture, pets, garbage, trash, vermin, pests, or otherwise, and will at their expense employ a professional service to eliminate such interference if determined necessary by LESSOR. No oil, hazardous material, or waste shall be used, stored, disposed of, or allowed to remain at the premises at any time without LESSOR'S prior written approval, and LESSEE shall be solely responsible for, and shall indemnify and hold harmless LESSOR and OWNER from, any and all corrosion and other damage in any way associated with the use, storage, disposal, and/or release of same by LESSEE parties. LESSEE shall provide and maintain effective devices for preventing damage to the building and property from deionized water, chemicals, and hazardous materials that may be used or present at the premises.

**26. RESPONSIBILITY.** In all events, neither LESSOR nor OWNER shall be liable to anyone for, nor shall LESSEE'S obligations under this lease be reduced because of loss, injury, or damage caused in any way by the use, leakage, Incursion, discharge, seepage, flooding, or escape of water or sewage in any form or from any source, or by the interruption or cessation of any service rendered customarily to the premises or building or agreed to by the terms of this lease, by any accident, the making of repairs, alterations or improvements, labor difficulties, weather conditions, mechanical breakdowns, trouble or scarcity in obtaining fuel, electricity, service, or supplies from the sources from which they are usually obtained, or by any change in any utility or service provider, or by any cause beyond LESSOR'S immediate control. Except as otherwise provided for in this lease, neither LESSOR nor OWNER nor LESSEE shall be liable for any special, incidental, indirect, or consequential damages, including but not limited to lost profits or loss of business, arising out of or in any manner connected with performance or nonperformance under this lease, even if any party has knowledge of the possibility of such damages.

**27. SURRENDER.** On or before the termination of this lease, LESSEE shall remove all of LESSEE parties' goods and effects from the premises, and shall deliver to LESSOR exclusive and unencumbered possession of the premises and all keys and locks thereto, all fixtures, equipment and workstations of any type connected therewith, and all allowed alterations made to or upon the premises, whether completed by LESSEE, LESSOR, or others, including but not limited to any offices, window blinds, floor coverings, computer floors, plumbing, plumbing fixtures, heating, ventilating and air conditioning equipment, ductwork, exhaust fans, chillers, security, surveillance and fire protection systems, telecommunications and data wiring, cable trays, telephone systems, racking, air and gas distribution piping, compressors, cranes, hoists, cabinets, counters, shelving, millwork, casework, electrical work, including but not limited to lighting fixtures of any type, wiring, conduit, transformers, generators, distribution panels, bus ducts, raceways, receptacles and disconnects, and all furnishings and equipment that have been bolted, welded, nailed, screwed, glued, or otherwise attached to any wall, floor, ceiling, roof, pavement, or ground, or which have been directly wired, ducted, or plumbed to any portion of any building or system serving the premises. Prior to surrender, LESSEE shall, at LESSOR'S option, remove or properly terminate and label for future use any and all wiring and cabling installed and/or used by LESSEE. LESSEE shall deliver the premises broom clean, fully sanitized from all chemicals or other contaminants, and in at least the same condition as they were at the commencement of this lease or any prior lease between the parties for the premises, or as they were modified during said term with LESSOR'S written consent, reasonable wear and tear only excepted, and LESSEE shall be deemed to be encumbering the premises until it delivers the premises to LESSOR at the time and in the condition required herein. Any and all property, including business records, that remains at the premises upon termination of this lease shall, at LESSOR'S option, be subject to Section 22 above or be deemed abandoned and be disposed of as LESSOR sees fit, without LESSOR being liable for any loss or damage thereto, and at the sole risk of LESSEE. LESSOR may remove and store any such property at LESSEE'S expense; retain same under LESSOR'S control; sell same without notice at a public or private sale and apply the net proceeds of such sale to the payment of any sum due herein; or destroy same. Notwithstanding the delivery of any keys to LESSOR, in no case shall the premises be deemed surrendered to LESSOR until the termination date provided herein or such other date as may be specified in a written agreement between the parties. The parties' rights and obligations under this section shall survive termination of this lease.

**28. GENERAL.** (a) The invalidity or unenforceability of any clause or term of this lease shall not affect or render invalid or unenforceable any other clause or term hereof. (b) No consent or waiver, express or implied, by LESSOR to or of any breach of any obligation of LESSEE is intended or shall be construed as a consent or waiver to or of any other breach of the same or any other obligation. (c) The terms of this lease shall run with the land, and this lease shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, except that LESSOR and OWNER shall be liable for obligations occurring only which each is lessor or owner of the premises. (d) This lease is made and delivered in the commonwealth of Massachusetts, and shall be interpreted, construed, and enforced in accordance with the laws thereof and only in a court therein. Any action or proceeding arising out of this lease shall be brought by LESSEE within one year after the event giving rise to the claim has occurred. (e) If LESSOR or OWNER is a trust, corporation, or other limited liability entity, the obligations of LESSOR shall be binding upon the trust, corporation, or other entity, but not upon any trustee, officer, director, shareholder, member, limited partner, or beneficiary individually. (f) LESSOR represents that the owner of the premises ("OWNER") has agreed to be bound by the terms of this lease unless LESSEE is in default hereof. (g) If LESSEE is more than one person, corporation, other legal entity, ownership, or some combination thereof, LESSEE's obligations shall be joint and several. Unless repugnant to the context, "LESSOR" and "LESSEE" mean the person or persons, natural or corporate, named above as LESSOR and as LESSEE respectively, and their respective heirs, executors, administrators, successors, and assigns. (h) This lease is the result of negotiations between parties of equal bargaining strength, and when executed by other parties shall constitute the entire agreement between the parties, superseding all prior oral and

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written agreements, representations, and statements, and LESSEE agrees to keep all financial and other terms of this lease confidential. This lease may not be amended except by written agreement signed by all parties, or as otherwise provided herein, and no oral or written representation shall have any effect hereon. (i) Notwithstanding any other statements herein, LESSOR makes no warranty, express or implied, concerning the suitability of the premises for the use described above. (j) If, for any reason, LESSOR does not deliver possession of the premises as provided herein, unless a delay is caused or contributed to in any way by any of LESSEE parties, the rent, excluding the cost of any amortized improvements, shall be proportionately abated until LESSOR delivers possession, and LESSOR shall use reasonable efforts to deliver possession at the earliest practical date. LESSEE agrees that said abatement shall be LESSEE's sole remedy for any delay in delivery of possession and that LESSOR shall not be liable for any damages to LESSEE for such delay. (k) Neither the submission of this lease form or any amendment hereof, nor the acceptance of the security deposit and/or rent shall constitute a reservation of or option for the premises, or an offer to lease, it being expressly understood and agreed that neither this lease nor any amendment shall bind either party in any manner whatsoever unless and until it has been executed by both parties. (l) LESSEE shall not be entitled to exercise any option in this lease, the attached Rider to Lease, or any subsequent amendment or extension, or to receive LESSOR's consent as provided for herein, if LESSEE is at that time in default of any term hereof. If this lease terminates pursuant to Section 20 above, LESSEE acknowledges and agrees that this lease may, at LESSOR's election, be reinstated by LESSOR with or without notice to LESSEE, and LESSOR may require one or more conditions prior to reinstatement. (m) No restriction, condition, or other endorsement by LESSEE on any payment, nor LESSOR's deposit of any full or partial payment, shall bind LESSOR in any way or limit LESSOR's rights under this lease. (n) LESSEE shall pay LESSOR for all legal and administrative fees and expenses incurred by LESSOR due to any consent requested by LESSEE or in enforcing any term of this lease. (o) LESSEE will conform to all rules and regulations now or hereafter made by LESSOR for parking, for the care, use, and/or alteration of the building, its facilities and approaches, and for the administration of this lease, and will not permit any of LESSEE parties to violate this lease or any of its terms. (p) LESSEE's covenants under this lease shall be independent of LESSOR's covenants, and LESSOR's failure to perform any of its covenants under this lease, including a covenant constituting a significant inducement to LESSEE to enter into this lease, shall not excuse the payment of rent or any other charges by LESSEE or allow LESSEE to terminate this lease. (q) LESSOR, LESSEE, OWNER, and GUARANTOR hereby waive any and all right to a jury trial in any proceeding in any way arising out of the subject matter of this lease and/or the guaranty. (r) See attached Rider to Lease for additional terms.

**29. SECURITY AGREEMENT.** LESSEE hereby grants LESSOR a continuing security interest in all existing and hereafter acquired property of LESSEE kept in any of LESSOR's buildings (excluding LESSEE's intellectual property, patents and accounts receivable) to secure the performance of all LESSEE's obligations under this lease or any subsequent lease between the parties. \_\_\_\_\_ all necessary amendments in connection with this security interest. This security agreement \_\_\_\_\_ subsequent lease between the parties, and shall not negate or replace any continuing security interest of LESSOR under any prior lease between the parties. Default in the payment or performance of any of LESSEE's obligations under this lease or any subsequent lease shall be a default under this security agreement and shall entitle LESSOR to immediately exercise all of the rights and remedies of a secured party under the Uniform Commercial Code as adopted in Massachusetts. In the event of default, LESSEE shall assist and facilitate LESSOR's exercise of its rights under this section.

**30. AUTOMATIC LEASE EXTENSIONS.** This lease, including all terms and escalations, etc. shall be automatically extended for additional successive periods of one year each unless LESSOR \_\_\_\_\_ whereupon it will be of no further force or effect. The time for serving such written notice shall be not more than 12 months or less than six months prior to the expiration of the then current lease term. Time is of the essence.

In witness whereof, LESSOR and LESSEE, intending to be legally bound, have caused this lease to be executed this 18th day of August, 2016.

**LESSOR: CUMMINGS PROPERTIES, LLC**

**LESSEE: ALLENA PHARMACEUTICALS, INC.**

By: /s/ Eric S. Anderson  
Duly authorized

By: /s/ Edward Wholihan  
Duly authorized

Edward Wholihan  
Print name

CFO  
Title



**GUARANTY**

In consideration of LESSOR making this lease with LESSEE, GUARANTOR hereby personally and unconditionally guarantees the prompt payment of rent by LESSEE and the performance by LESSEE of all financial and nonfinancial obligations arising out of (i) this lease (and all amendments, extensions, and/or assignments thereof) with respect to the premises herein and any new premises that may become subject to this lease, and (ii) LESSEE's use and/or occupancy of any premises managed by LESSOR. The undersigned \_\_\_\_\_ enforcing this guaranty. LESSOR's consent to any assignments, subleases, amendments, and extensions by LESSEE or to any compromise or release of LESSEE's liability under this lease, with or without notice to the undersigned, or LESSOR's failure to notify the undersigned of any default and/or reinstatement of this lease, shall not relieve GUARANTOR from personal liability.

In witness whereof, the undersigned GUARANTOR, intending to be legally bound, has caused this guaranty to be executed this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_.

\_\_\_\_\_  
Address: \_\_\_\_\_  
*Signature*

Print name: \_\_\_\_\_

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**CUMMINGS PROPERTIES, LLC  
STANDARD FORM  
RIDER TO LEASE**

The following additional terms are incorporated into and made a part of the attached lease and in the event of any conflict between any term of this Rider to Lease and the attached lease, the terms of this rider shall govern:

A. **SOUTH ESSEX SEWERAGE DISTRICT.** With respect to leases at Cummings Center and Dunham Road in Beverly (only), LESSEE shall fully comply with all regulations of the South Essex Sewerage District (SESD) now or hereafter in effect including prompt filing with LESSOR of any documents required by the SESD. LESSEE agrees to indemnify and hold harmless LESSOR and OWNER from any and all liability arising out of any noncompliance of LESSEE with such regulations.

B. **ACTIVITY AND USE LIMITATION.** Except as provided below, with respect to leases at Cummings Center in Beverly and leases at 10 and 18 Commerce Way in Wobum (only), the following activities and uses are expressly prohibited at the property of which the premises are a part: residential uses (except for facilities for adult congregate care or assisted living, senior housing, nursing home uses and other adult residential facilities in certain designated areas of the property); child care, day care, or public or private elementary or secondary schools; a public park, playground or playing field, or other activities involving more than casual contact with the ground; cultivation out-of-doors of fruits and vegetables destined for human consumption; and fishing or swimming in the ponds and other waterways on or adjacent to the property. In addition, implementation of a health and safety plan is required for construction, utilities maintenance and other intrusive activities which are likely to involve extensive exposure to or contact with subsurface soils at the property. Notwithstanding the foregoing, residential, school, child care, day care and children's learning center uses (and associated outside recreational activities and/or associated playground) are authorized in specific locations at Cummings Center and/or 10 and 18 Commerce Way. As to Cummings Center, the Notice of Activity and Use Limitation dated April 26, 1996 was recorded at the Essex (South) Registry of Deeds at Book 13533, Page 559, and amended on September 2, 1997 (Book 14299, Page 257), June 19, 2003 (Book 21871, Page 314), March 10, 2005 (Book 24047, Page 1), August 11, 2006 (Book 25994, Page 425), September 17, 2008 (Book 28043, Page 576), and June 20, 2016 (Book 35016, Page 348). As to 10 and 18 Commerce Way, the Notice of Activity and Use Limitation dated December 12, 1996 was recorded at the Middlesex (South) Registry of Deeds at Book 26901, Page 293 and registered with the Middlesex Registry District of the Land Court as Document No. 1231513, and amended on September 24, 2002 (Book 36592, Page 499) and September 19, 2007 (Book 50124, Page 578 and Land Court Document No. 01454912).

C. **CHANGE IN CORPORATE FORM.** If LESSEE is a trust, corporation, partnership or other limited liability entity, LESSEE shall serve written notice to LESSOR within 30 days following the date LESSEE: (a) changes its legal name, (b) merges into or consolidates with a third party, (c) files articles of entity conversion, (d) changes its state of organization/registration or domestication, (e) voluntarily or involuntarily dissolves or revokes its articles of organization, articles of incorporation or other charter documents, or (f) changes any trustee(s).

D. LESSOR, at LESSOR'S cost, shall, at the premises, repair and repaint all drywall partitions, replace glass and light bulbs as needed, change all primary lock cylinders on exterior entry doors, clean all flooring, replace all damaged and missing ceiling tiles, broom-clean the premises, and connect gas and electric services. LESSOR agrees to deliver the premises in good working condition as of the commencement date of this lease, including all systems serving the premises, three fume hoods, one emergency shower with eyewash station, and two backflow preventers.

E. Notwithstanding anything to the contrary in Section 25 of this lease, LESSEE may use and store hazardous material, as that term is defined in M.G.L. c. 21E, §2, within the premises, in an amount not to exceed LESSEE'S proportionate share of the total hazardous material storage capacity allowed by applicable building code(s) and governmental authorities, which proportionate share is currently 10.22%, provided LESSEE fully complies with all applicable local, state, and federal laws, regulations, ordinances, and bylaws (collectively, "applicable laws"). In the event of any future changes in the size of the premises or the total leasable square footage of the building, there shall be a further corresponding adjustment of LESSEE'S proportionate share of the total hazardous materials storage capacity. In the event that any hazardous material and/or hazardous waste remains in the premises after the termination of this lease or, if applicable, the date LESSEE otherwise vacates the premises, including but not limited to relocating to a new premises pursuant to an amendment to this lease (in either case, the "Vacate Date"), or in the event that any manifest(s) need to be prepared for the delivery, transport, removal, and/or disposal of any hazardous material and/or hazardous waste to or from the premises (e.g., EPA Form 8700-22) and LESSEE'S authorized representative is unavailable for any reason, LESSEE hereby authorizes LESSOR to execute any and all manifests and related documents necessary to properly effectuate such delivery, transport, removal, and/or disposal on LESSEE'S behalf and at LESSEE'S sole expense using LESSEE'S Hazardous Waste Generator Identification Number. LESSEE shall be solely responsible for and shall indemnify and hold LESSOR and OWNER harmless from any and all liability, damage, and personal injury in any way relating to or arising out of the use, storage, disposal, transport, and/or release of such hazardous material or hazardous waste.

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F. Notwithstanding anything in Section 10 of this lease to the contrary, LESSEE'S maintenance and repair obligations shall specifically include, without limitation, quarterly (or more frequent if necessary) inspection, repair, and replacement as needed of (i) all acid neutralization, pH adjustment, and other wastewater treatment tanks and equipment and drain lines into which said tanks and equipment discharge, (ii) backflow preventers and back-up generators that serve the premises, and (iii) all HVAC equipment not exclusively serving office areas, as well as all exhaust and intake fan components, including belts and air filters. LESSOR agrees to deliver to LESSEE a list of HVAC equipment not exclusively serving office areas, as well as exhaust fans serving the premises as of the commencement date of this lease. LESSEE shall be responsible for semiannual (or more frequent if necessary) cleaning and replenishment of neutralizing materials in all tanks, ensuring that all wastewater discharged from the premises is neutralized to a pH range between 6 and 9, or, in the case of deionized water, is appropriately diluted or treated, and fully complying with all applicable laws. Notwithstanding anything in Section 10 of this lease to the contrary, LESSEE acknowledges and agrees that the plumbing, electrical, and heating, and cooling systems serving the premises shall be maintained by LESSEE, at its sole expense, except that LESSOR shall maintain the restrooms and any of the above systems that exclusively serve(s) the office areas of the premises. Throughout the term of this lease, within 30 days following LESSOR'S request, and on or before the Vacate Date, LESSEE shall provide LESSOR with written evidence from a qualified third party documenting LESSEE'S compliance with the foregoing inspection, repair, and maintenance obligations, and certifying that all such equipment and systems required to be maintained by LESSEE are in good working condition (the "Condition Statement"). Time is of the essence.

G.\* On or before the Vacate Date, LESSEE shall, at its sole expense, have the entire premises, including all extensions thereof (e.g. shafts, ducts, etc.) used in any way by LESSEE, cleaned, sanitized, and tested, and shall provide LESSOR with a written certification from a licensed, independent, and certified industrial hygienist ("CIH") stating that as of the Vacate Date, the entire premises have been cleaned, sanitized, and tested and are free from all harmful chemical, biological, radioactive, and other contamination arising out of LESSEE'S tenancy, that there are no restrictions on future use or occupation by others, including any demolition, modification, and/or disposal of any materials as non-hazardous waste, and that the indoor air quality at the premises is satisfactory. Said cleaning, testing, and certification shall be completed in accordance with all CIH professional standards and all applicable laws and shall include, but not be limited to, all cabinetry, countertops, walls, ceilings, floors, casework, and all other surfaces, all mechanical and HVAC equipment, ductwork, diffusers, return air grilles, filters, make-up air units, exhaust fans, hoods, plumbing lines and fixtures, drains, septic systems (if any), and all acid neutralization, pH adjustment, and other wastewater treatment tanks, piping, and equipment. If LESSEE used, stored, and/or disposed of any radioactive materials at, in, on, or near the premises, LESSEE shall provide LESSOR with a written statement from all applicable governmental authorities that the premises have been fully decommissioned in accordance with all applicable laws on or before the Vacate Date.

H.\* The premises shall be deemed occupied by LESSEE in accordance with Sections 22 and 27 of this lease unless and until LESSEE has provided, to LESSOR'S satisfaction and/or the satisfaction of LESSOR'S CIH, the required CIH certification, all applicable decommissioning statements, and the Condition Statement, all in accordance with the terms of the three preceding paragraphs.

I.\* LESSEE shall provide to LESSOR and maintain throughout the entire lease term an Irrevocable Standby Letter of Credit negotiable on sight in the amount of \$26,500 as security for LESSEE'S performance under the preceding four paragraphs and all other obligations under this lease. Said letter of credit shall be issued by a bank acceptable to LESSOR; provide for payment to LESSOR immediately and on sight upon LESSOR'S delivery to the bank of a statement that the drawing represents amounts due to LESSOR from LESSEE under this lease or is otherwise permitted under this lease; terminate no earlier than two months after the termination of this lease; and shall otherwise be in a form acceptable to LESSOR'S counsel. In addition, LESSOR shall be entitled to draw on said letter of credit and hold the proceeds as a cash security deposit in the event that LESSOR feels insecure about the continuing solvency of the issuing bank. Said letter of credit or the amount of the letter of credit in cash shall be delivered to LESSOR upon LESSEE'S execution of this lease. If cash is paid, LESSOR shall then refund it to LESSEE upon delivery to LESSOR of a letter of credit that fully complies with this paragraph. LESSEE shall pay LESSOR for all legal and administrative expenses incurred by LESSOR in connection with said letter of credit. The security required to be delivered to LESSOR pursuant to this paragraph shall be in addition to the cash security deposit provided for in Section 2 above.

J.\* The preceding five paragraphs are key considerations of this lease.

K. Notwithstanding anything in Paragraph F above to the contrary, if at any time during the initial term of this lease (only), any of the HVAC equipment serving the laboratory portion of the premises (only) ceases to operate notwithstanding LESSEE'S maintenance of said equipment, then, provided LESSEE is not then in arrears of any rent or invoice payment or otherwise in default of this lease, and provided an independent, licensed, arm's length third-party HVAC technician certifies to LESSOR in writing that (a) LESSEE used, operated, and maintained said equipment throughout the term of this lease in accordance with the manufacturer's recommendations and all terms of this lease, and (b) said HVAC equipment ceases to operate solely as a result of reasonable wear and tear, then LESSOR or LESSOR'S contractor (only) shall, at LESSOR'S sole discretion, repair and/or replace said equipment, and LESSOR shall be responsible for the payment of all charges to repair and/or replace said equipment, except that LESSEE shall in each

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instance of repair and/or replacement, be responsible for said charges not to exceed the first \$3,500 incurred by LESSOR to effectuate each such repair and/or replacement (said charge in each such instance, the "Initial Charge"). In each such instance, LESSEE shall pay the initial Charge to LESSOR within 10 days following receipt of LESSOR'S invoice therefor. All work performed by LESSOR and/or LESSOR'S contractor under this Paragraph K shall be performed during LESSOR's normal business hours (only). Time is of the essence. All other terms of Paragraph F above shall continue to apply.

L.\* LESSOR consents to LESSEE'S limited non-exclusive access to the roof of the building to perform LESSEE'S maintenance obligations as set forth above (only). LESSEE agrees that the roof is a common area of the building and that no other work shall be carried on or any other equipment installed on the roof without the prior written consent of LESSOR. LESSEE shall be fully responsible for, and agrees to indemnify and hold LESSOR and OWNER harmless from, all property damage and personal injury, including death, associated in any way with the activities of LESSEE parties on the roof and/or the location, installation, or maintenance of said equipment on the roof, including, but not limited to, damage to the watertight integrity of the roof and the roof membrane, from whatever cause.

M The annual base rent as provided in Section J above does not include any charge for use of approximately 3,272 square feet (including 4.7% common area) shown as the hatched area on the mutually agreed upon plan attached hereto (the "Hatched Area") because LESSEE has represented that LESSEE (i) will not use the Hatched Area and (ii) intends only to use the approximately 3,890 square feet (including 4.7% common area) of unhatched area. LESSEE may, however, elect at any time to use the Hatched Area or any portion thereof, and if LESSEE does use the Hatched Area or any portion thereof in any way other than to occasionally pass through the Hatched Area, then the annual base rent shall be immediately increased by \$111,084 for the balance of the lease term.

N.\* if LESSEE has not previously elected to use the Hatched Area or any portion thereof, LESSOR may, at LESSOR's sole expense, remove the Hatched Area from the premises at any time during the lease term by serving LESSEE with five days' prior written notice to that effect. LESSEE shall move its furniture, furnishings, equipment, inventory, and other property as requested by LESSOR to enable LESSOR to carry out any modifications required to remove the Hatched Area from the premises, and LESSEE shall indemnify and hold harmless LESSOR and LESSOR'S agents, employees and contractors from any and all injury or damage arising out of this work. In the event LESSOR removes the Hatched Area from the premises, the size of the premises shall be decreased by 3,272 square feet (including 4.7% common area) and the base rent set forth in Section 1 above shall remain the same.

O. The parties acknowledge and agree that the utilities serving the Hatched Area, are not separated from the utilities serving the remainder of Suite B, and that LESSEE shall pay all utility charges for the entire suite. If LESSOR leases the Hatched Area to a third party for any use other than storage, LESSEE'S monthly rent shall be reduced by \$409 throughout the third party's occupancy in order to compensate LESSEE for such third party's utility usage. Alternatively, LESSOR may, at its election and expense, separate (the utilities serving the Hatched Area and the remainder of Suite B, in which case, LESSEE will not receive a reduction in base rent.

P. LESSOR may elect to cancel this lease for any reason or no reason at all, to be effective on or after December 30, 2016, by serving LESSEE with not less than 90 days' prior written notice to that effect.

Q.\* Sudbury Research Center, LLC, OWNER of the premises referred to in Section 28 above, hereby consents to this lease, and, provided LESSEE is not then in default of this lease, agrees to recognize all rights of LESSEE hereunder.

**LESSOR: CUMMINGS PROPERTIES, LLC**

**LESSEE: ALLENA PHARMACEUTICALS, INC.**

By: /s/ Eric S. Anderson  
Duly authorized

By: /s/ Edward Wholihan  
Duly authorized

Date: 8/8/16

Print name Edward Wholihan

Title: CFO



**CUMMINGS PROPERTIES, LLC  
STANDARD FORM  
LEASE EXTENSION #1**

In connection with a lease in the effect between Cummings Properties, LLC, LESSOR, and Allena Pharmaceuticals, Inc., LESSEE, at 142-B North Road, Sudbury, Massachusetts ("premises" or "leased premises"), fully executed on August 18, 2016 and currently scheduled to terminate on August 30, 2017, and in consideration of the mutual benefits to be derived herefrom, the parties hereby agree to amend said lease, including its terms, conditions, covenants, and obligations ("terms"), as follows:

1. The lease is hereby extended for an additional term of one year and six months and is now currently schedule to terminate at noon on February 28, 2019, unless otherwise terminated or extended as provided in the lease, as amended.
  2. Effective March 1, 2017, base rent shall be changed to one hundred forty two thousand two hundred sixty (142,260) dollars per year of \$11,855 per month.
  3. Effective March 1, 2017, the base month from which to determine the amount of each annual increase in the "Cost of Living" shall be November 2016, which figure shall be compared with the figure for November 2017, and each November thereafter to determine the increase (if any) in the base rent to be paid during the following calendar year.
  - 4.\* LESSOR, at a total charge to LESSEE of \$4,000 to be paid by LESSEE upon LESSEE's execution of this extension, shall modify the premises according to the mutually agreed upon plan attached hereto within 30 days following full execution of this extension, approval of final plans and specifications (if any), and LESSOR's receipt of a building permit for said modifications.
  5. Notwithstanding monthly rent as provided in Section 2 above, LESSEE may deduct \$1,434.50 from the monthly rental payment due for the month of March 2017 (only), provided LESSEE is not then in arrears of any rent or invoice payment or otherwise in default of the lease.
  6. Paragraph M of the Rider to Lease is hereby deleted and the following shall not apply. The annual base rent as provided in Section 2 above does not include any charge for use of approximately 2,029 square feet (including 4.7% common area) shown as the hatched area on the attached plan (the "Hatched Area") because LESSEE has represented that LESSEE (i) will not use the Hatched Area and (ii) intends only to use the approximately 3,890 square feet (including 4.7% common area) of unhatched area and the approximately 1,243 square feet (including 4.7% common area) shows as the cross-hatched area on the attached plan (the "Cross-Hatched Area). LESSEE may, however, elect at any time to use the Hatched Area or any portion thereof, and if LESSEE does use the Hatched Area or any portion thereof in any way other than to pass through the Hatched Area, then the annual based rent shall be immediately increased by \$56,272 for the balance of the lease term.
  7. Paragraph N of the Rider to Lease is hereby deleted and the following shall now apply. If LESSEE has not previously elected to use the Hatched Area or any portion thereof, LESSOR may, at LESSOR's sole expense, remove the Hatched Area or portion(s) thereof from the premises from time to time during the lease term by serving LESSEE with at least five days' prior written notice to that effect. LESSEE shall move its furniture, furnishings, equipment, inventory, and other property as requested by LESSOR to enable LESSOR to carry out any modifications required for such removal, and LESSEE shall indemnify and hold harmless LESSOR and LESSOR's agents, employees and contractors from any and all injury or damage arising out of this work. In the event LESSOR removes the Hatched Area or portion(s) thereof from the premises, the size of the premises shall be decreased by the number of square feet so removed (including 4.7% common area) and the then-current annual base rent shall remain the same.
  8. Paragraph O of the Rider to Lease is hereby deleted and the following shall now apply. The parties acknowledge and agree that the utilities serving the Hatched Area are not separated from the utilities serving the remainder of Suite B, and that LESSEE shall pay all utility charges for the entire suite. If LESSOR leases all or any portion of the Hatched Area to a third party for any use other than storage, LESSEE's then-current annual rent shall be reduced by the product of the number of square feet so removed and \$1.50 throughout the third party's occupancy (to be apportioned on a monthly basis) in order to compensate LESSEE for such third party's utility usage. Alternatively, LESSOR may, at its election and expense, separate the utilities serving the Hatched Area or the applicable portion thereof, as the case may be, and the remainder of Suite B, in which case, LESSEE will not receive a reduction in base rent.
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9. If LESSEE has not elected to use the Hatched Area or any portion thereof as provided in Section 6 above, and LESSOR has not removed the Hatched Area or any portion thereof as provided in Section 7 above, LESSOR may elect to remove the Cross-Hatched Area or any portion thereof from the premises at any time during the lease term by serving LESSEE with at least 60 days' prior written notice to that effect. LESSOR's notice shall specify (i) the configuration of the Cross-Hatched Area to be removed, (ii) the effective date of such removal (the "Recapture Area"). The square footage of the Relocation Area shall not be less than the square footage of the Cross-Hatched Area removed by LESSOR. Effective on the Recapture Date, (a) the square footage of the Cross-Hatched Area shall be reduced in accordance with the reconfiguration in subsection (i) above, and (b) the square footage of the Hatched Area shall be reduced by the number of square feet in the Relocation Area, in accordance with subsection (iii) above without any increase or decrease in base rent. LESSEE shall move its furniture, furnishings, equipment, inventory, and other property as requested by LESSOR to enable LESSOR carry out any modifications required to remove the Cross-Hatched Area or the applicable portion thereof, as the case may be, from the premises, and LESSEE shall indemnify and hold harmless LESSOR and LESSOR's agents, employees, and contractors from any and all injury or damage arising out of this work. LESSEE shall vacate the Cross-Hatched Area or the applicable portion thereof, as the case may be, on or before 12:00 PM on the Recapture Date, and any extended occupancy of the Cross-Hatched Area or the applicable portion thereof, as the case may be, shall be governed by Section 22 of the lease. All other terms of Section 6 above shall continue to apply. Time is of the essence.
10. In consideration of this extension, Paragraph P of the Rider to Lease is hereby deleted and of no further force or effect.

This extension shall not bind any party in any manner whatsoever until it has been executed by all parties. All other terms of the lease shall continue to apply, and to the extent any inconsistency exists between this extension and the lease, including any prior amendments and extensions, the terms herein shall control and supersede any earlier provisions. In witness whereof, LESSOR and LESSEE, intending to be legally bound, have caused this extension to be executed this 28th day of February, 2017.

**LESSOR: CUMMINGS PROPERTIES, LLC**

**LESSEE: ALLENA PHARMACEUTICALS, INC.**

By: /s/ Ernest Agresti, Jr.  
*Duly authorized*

By: /s/ Edward Wholihan  
*Duly authorized*

Print Name: Edward Wholihan

Title: CFO

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**CUMMINGS PROPERTIES, LLC  
STANDARD FORM  
LEASE EXTENSION #2**

In connection with a lease in effect between Cummings Properties, LLC, LESSOR, and Allena Pharmaceuticals Inc. LESSEE, at 142-B North Road

Sudbury, Massachusetts ("premises" or 'leased premises, ") fully executed on August 18, 2016 and currently scheduled to terminate on

February 28, 2019 , and in consideration of the mutual benefits to be derived herefrom, the parties hereby agree to amend said lease, including its terms, conditions, covenants, and obligations ("terms") as follows:

1. The lease is hereby extended for an additional term of two years and is now currently scheduled to terminate at noon on February 28, 2021, unless otherwise terminated or extended as provided in the lease, as amended.
  2. Effective upon the RA Vacate Date (defined below) base rent shall be changed to one hundred thirty two thousand one hundred twenty six (132,126) dollars per year or \$11,050.00 per month.
  3. Effective upon the RA Vacate Date (defined below), the base month from which to determine the amount of each annual increase in the "Cost of Living" shall be November 2017, which figure shall be compared with the figure for November 2018, and each November thereafter to determine the increase (if any) in the base rent to be paid during the following calendar year.
  4. THIS PARAGRAPH DOES NOT APPLY
  5. Effective upon the S-175 Delivery Date (defined below), the size of the premises shall be decreased to a new total of approximately 4,636 square feet with the relinquishment of a portion of 142-B North Road shown as the hatched area on the mutually agreed upon plan attached hereto (the " Relinquishment Area") and the addition of 142-F North Road, Suite 175. The premises shall then consist of approximately 2,558 square feet (including 4.7% common area) at 142- B, and approximately 2,078 square feet (including 12% common area) at Suite 175. Notwithstanding anything to the contrary in this section, LESSEE may continue to occupy the Relinquishment Area until 12:00 PM on the tenth day following the S- 175 Delivery Date without any obligation to pay additional rent beyond that set forth in Sections 2 and 3 of Lease Extension #1, on account of LESSEE's concurrent occupancy of the Relinquishment Area, 142-8 , and Suite 175. Any occupancy of the Relinquishment Area beyond 12 : 00 PM on the tenth day following the S-175 Delivery Date, or any earlier date upon which LESSOR's Work (defined below) would have been substantially completed but for any LESSEE delays(s) (defined below), shall be governed by Section 22 of the lease. The date upon which LESSEE fully vacates the Relinquishment Area as provided herein shall be known as the "RA Vacate Date." LESSEE shall, upon vacating, be responsible for all damage to the Relinquishment Area in accordance with the lease, and shall promptly pay all just invoice(s) therefor. Time is of the essence.
  6. LESSOR, at LESSOR's cost, shall, with the exception of infilling one opening between the Relinquishment Area and the remainder of 14 2-B, substantially complete, except for punch list items, modifications to the premises according to the mutually agreed upon plan attached hereto ("LESSOR's Work ") within 45 days following full execution of this extension, approval of final plans and specifications (if any), and LESSOR's receipt of a building permit for LESSOR's Work. The first business day following the date upon which LESSOR substantially completes LESSOR's Work at Suite 175 (only) shall be known as the "S-175 Delivery Date." LESSOR shall endeavor to advise LESSEE at least seven days prior to the anticipated S-175 Delivery Date. LESSOR shall substantially complete infilling the excepted opening referenced above within five days following the RA Vacate Date.
  7. LESSEE shall move its furniture, furnishings, equipment, inventory, and other property as reasonably requested by LESSOR to enable LESSOR to carry out LESSOR's Work, which shall be performed during LESSOR's normal business hours (only). in the event LESSEE in any way delays LESSOR's substantial completion of LESSOR' s Work (which shall include without limitation any additions and/or changes requested by LESSEE to the scope of LESSOR's Work , any delay in LESSEE making payment to LESSOR under the lease, any delay in LESSEE providing information to LESSOR for any permits and/or plans, any delay in LESSEE providing prompt and timely access to the premises to LESSOR including moving its property for LESSOR's Work as provided for herein , and/or any interference by LESSEE parties with LESSOR's Work) (any such delay, a " LESSEE delay"), there shall be no abatement of rent for the number of days of LESSEE delay(s), and the above time frame for substantial completion shall be extended by the number of days of LESSEE delay(s). Time is of the essence.
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8. Notwithstanding monthly rent as provided in Section 2 above, LESSEE may deduct \$ 10,000 from the monthly rental payment due on the first day of the first calendar month following the RA Vacate Date (only), provided LESSEE is not then in arrears of any rent or invoice payment or otherwise in default of the Lease.
9. In consideration of this extension, effective upon the RA Vacate Date, Sections 6, 7, 8, and 9 of Lease Extension #1 shall be deleted and of no further force or effect, except that Paragraphs M, N, and O of the Rider to Lease shall remain deleted and of no force or effect.

This extension shall not bind any party in any manner whatsoever until it has been executed by all parties. All other terms of the lease shall continue to apply, and to the extent any inconsistency exists between this extension and the lease, including any prior amendments and extensions, the terms herein shall control and supersede earlier provisions. In witness whereof LESSOR and LESSEE, intending to be legally bound, have caused this extension to be executed this 30th day of March, 2018.

**LESSOR: CUMMINGS PROPERTIES, LLC**

**LESSEE: ALLENA PHARMACEUTICALS, INC.**

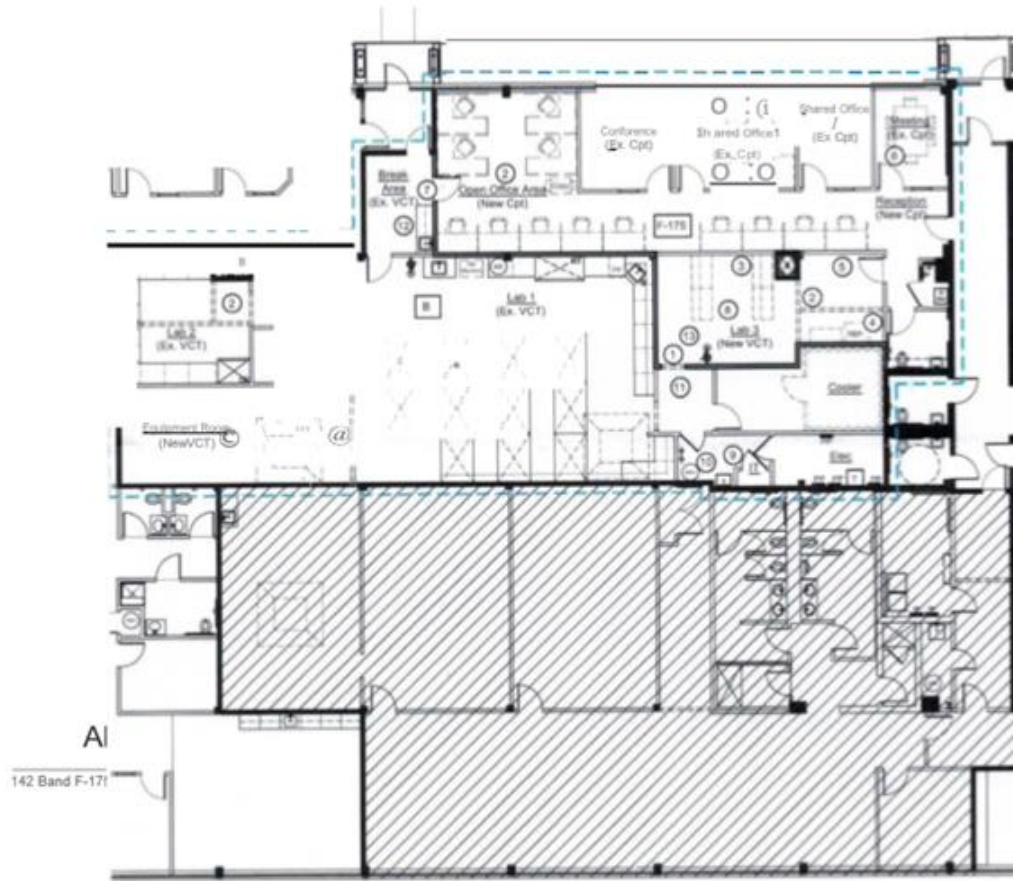
By: /s/ Ernest Agresti, Jr.  
*Duly authorized*

By: /s/ Edward Wholihan  
*Duly authorized*

Print Name: Edward Wholihan

Title: CFO

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Allena Pharmaceuticals, Inc.

Relinquishment

142 Band F-175 North Road, Sudbury, MA

Area= 4.617±LSF

**CUMMINGS PROPERTIES, LLC  
STANDARD FORM  
AMENDMENT TO LEASE #1**

In connection with a lease in effect between Cummings Properties, LLC, LESSOR and Allena Pharmaceuticals, Inc., LESSEE at 142•B North Road and 142-F North Road, Suite 175

Sudbury Massachusetts ("premises" or "leased premises") fully executed on August 18, 2016 and currently scheduled to terminate on February 28, 2021, unless otherwise terminated or extended as provided in the lease as amended and in consideration of the mutual benefits to be derived herefrom the parties hereby agree to amend said lease, including its terms, conditions, covenants, and obligations ("terms") as follows:

1. Effective September 15, 2018 base rent shall be changed to One hundred eighty four thousand six hundred eighty three (184,683) dollars per year or \$ 15,390.25 per month.
2. Effective September 15, 2018 the base month from which to determine the amount of each annual increase in the "Cost of Living" shall be November 2017, which figure shall be compared with the figure for November 2018, and each November thereafter to determine the increase (if any) in the base rent to be paid during the following calendar year.  
\*remain
3. Effective September 15, 2018, the size of the premises shall be increased with the addition of approximately 2,928 square feet (including 13% common area) at 144 North Road, Suite I 000. The premises shall then consist of approximately 2,558 square feet (including 4.7% common area) at 142-B North Road, approximately 2,078 square feet (including 12% common area) at 142-F North Road, Suite 175, and approximately 1,928 square feet (including 13% common area) at Suite 1000.
4. LESSOR, at LESSOR's cost, shall modify Suite 1000 according to the mutually agreed upon plan attached hereto within 15 days following full execution of this extension and approval of final plans and specifications (if any).
5. \* Notwithstanding the monthly rental payment amount provided in Sections 1 and 2 above, LESSEE may deduct \$1,129.35 per month (to be apportioned for any partial month) from each monthly rental payment due from September 15, 2018 through February 28, 2021 (only), provided, at the time each such payment is due, LESSEE is not then in arrears of any rent (excluding the monthly rental payment then due) or invoice payment or otherwise in default of the lease.

This amendment shall not bind any party in any manner whatsoever until it has been executed by all parties. All other terms of the lease shall continue to apply, and to the extent any inconsistency exists between this amendment and the lease, including any prior amendments and extensions, the terms herein shall control and supersede any earlier provisions. In witness hereof, LESSOR and LESSEE, intending to be legally bound, have caused this amendment to be executed this 31st day of August, 2018.

**LESSOR: CUMMINGS PROPERTIES, LLC**

**LESSEE: ALLENA PHARMACEUTICALS, INC.**

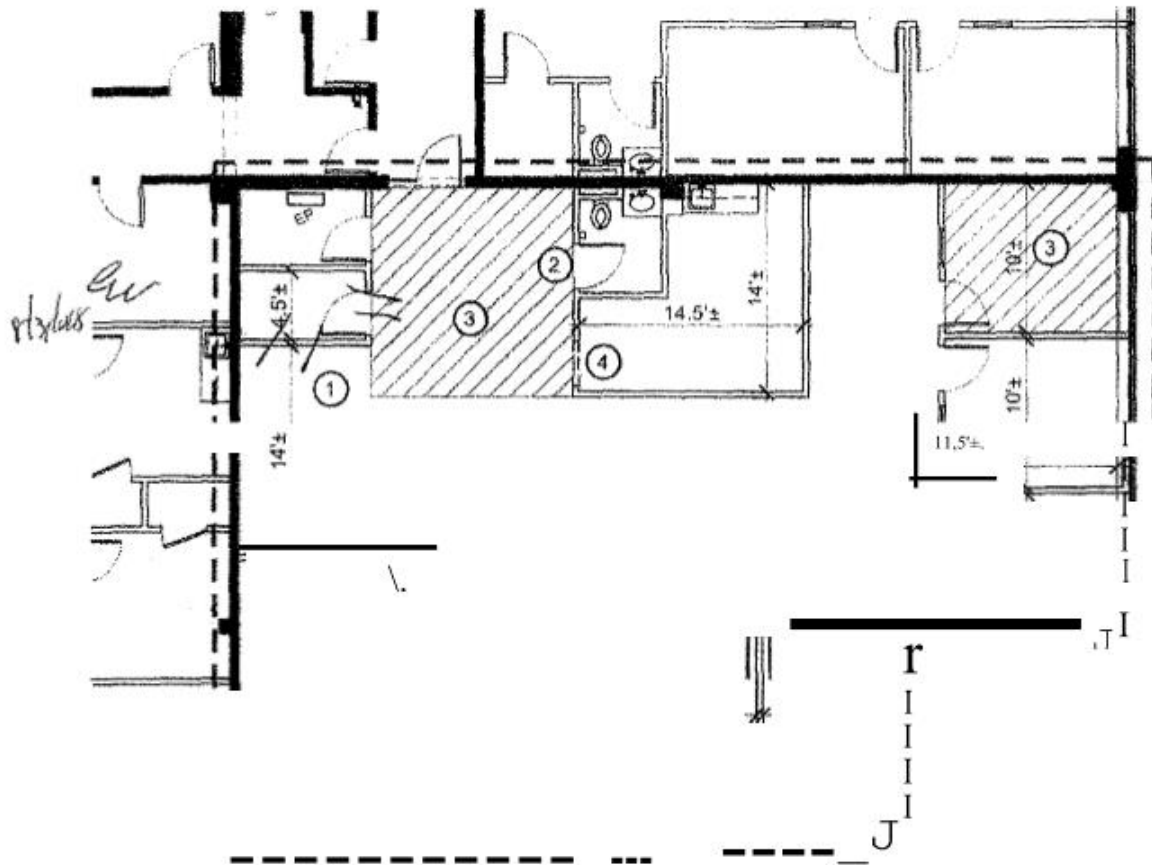
By: /s/ Ernest Agresti, Jr.  
Duly authorized

By: /s/ Edward Wholihan  
Duly authorized

Print Name: Edward Wholihan

Title: CFO

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**Limit of Work:**

- 1- Remove partition.
- 2- Remove wood paneling. Enlarge bathroom and relocate door.
- 3- Remove carpet and install 'Fortune' carpet with 4" black vinyl base.
- 4- Remove door and infill opening. Construct opening.
- 5- Complete a standard rehab including the following work: professionally clean flooring as needed, repair and repaint all drywall partitions with CPL standard paint, replace glass and light bulbs as needed, replace broken ceiling tiles as needed, and change exterior lock cylinders.

**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, Alexey Margolin, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2018 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)) 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - 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 7, 2018

By: /s/ Alexey Margolin  
Alexey Margolin  
Chief Executive Officer 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, 2018 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)) 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. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
  - 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 7, 2018

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, 2018, 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 7, 2018

By: /s/ Alexey Margolin  
Alexey Margolin  
*Chief Executive Officer and Director*  
*(Principal Executive Officer)*

November 7, 2018

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