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: 001-38443

UNUM THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-5308248**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
200 Cambridge Park Drive, Suite 3100 Cambridge, Massachusetts	**02140**
(Address of principal executive offices)	**(Zip code)**

(617) 945-5576
(Registrant's telephone number, including area code)

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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☐
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2018, the registrant had 29,989,472 shares of common stock, $0.001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plan, objectives of management and expected market growth are forward-looking statements. You can identify these forward-looking statements by the use of words such as “outlook,” “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seeks,” “approximately,” “predicts,” “intends,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under “Risk Factors” and include, among other things:

- the success, cost, and timing of our product development activities and clinical trials;
- our ability to obtain and maintain regulatory approval for our ACTR087 and ACTR707 product candidates and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the potential for our identified research priorities to advance our ACTR and BOXR platform;
- the ability to license additional intellectual property relating to our product candidates from third-parties and to comply with our existing license agreements and collaboration agreements;
- the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates;
- our ability to commercialize our products in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the scalability and commercial viability of our manufacturing methods and processes;
- the commercialization of our product candidates, if approved;
- our plans to research, develop, and commercialize our product candidates;
- the potential benefits of our existing collaboration with Seattle Genetics and our ability to attract other collaborators with development, regulatory, and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our use of the proceeds from the initial public offering and the concurrent private placement; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Quarterly Report on Form 10-Q. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.

Unum Therapeutics Inc.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

UNUM THERAPEUTICS INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 49,296	$ 28,270
Marketable securities	37,824	12,691
Accounts receivable	1,419	830
Prepaid expenses and other current assets	960	513
Restricted cash	—	75
Total current assets	89,499	42,379
Property and equipment, net	3,613	4,108
Restricted cash	1,255	1,255
Deferred offering costs	—	1,373
Other assets	419	—
Total assets	$ 94,786	$ 49,115
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 803	$ 1,346
Accrued expenses and other current liabilities	5,495	2,953
Deferred revenue	20,086	6,891
Total current liabilities	26,384	11,190
Deferred rent	871	906
Deferred revenue, net of current portion	—	8,714
Total liabilities	27,255	20,810
Commitments and contingencies (Note 11)		
Redeemable convertible preferred stock (Series A and B), $0.001 par value; no shares and 20,791,407 shares authorized at September 30, 2018 and December 31, 2017, respectively; no shares and 20,771,850 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively; liquidation preference of $77,297 at December 31, 2017	—	77,151
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 10,000,000 shares and no shares authorized at September 30, 2018 and December 31, 2017, respectively; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 150,000,000 shares and 60,040,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 29,924,589 shares and 10,201,690 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	30	10
Additional paid-in capital	150,978	2,499
Accumulated other comprehensive loss	(24)	(16)
Accumulated deficit	(83,453)	(51,339)
Total stockholders' equity (deficit)	67,531	(48,846)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 94,786	$ 49,115

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

UNUM THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$ 2,043	$ 2,331	$ 5,929	$ 6,237
Operating expenses:				
Research and development	10,252	8,177	27,520	22,270
General and administrative	2,367	1,324	5,410	3,239
Total operating expenses	12,619	9,501	32,930	25,509
Loss from operations	(10,576)	(7,170)	(27,001)	(19,272)
Other income (expense):				
Interest income	405	100	745	287
Other income, net	3	70	330	183
Total other income, net	408	170	1,075	470
Net loss	(10,168)	(7,000)	(25,926)	(18,802)
Accretion of redeemable convertible preferred stock to redemption value	—	(16)	(16)	(49)
Net loss attributable to common stockholders	$ (10,168)	$ (7,016)	$ (25,942)	$ (18,851)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.69)	$ (1.12)	$ (1.85)
Weighted average common shares outstanding, basic and diluted	29,879,476	10,192,189	23,169,348	10,190,889
Comprehensive loss:				
Net loss	$ (10,168)	$ (7,000)	$ (25,926)	$ (18,802)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities, net of tax of $0	(11)	19	(8)	—
Total other comprehensive income (loss)	(11)	19	(8)	—
Comprehensive loss	$ (10,179)	$ (6,981)	$ (25,934)	$ (18,802)

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

UNUM THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (25,926)	$ (18,802)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	969	864
Stock-based compensation expense	2,186	881
Premiums paid on marketable securities	—	(13)
Net amortization (accretion) of premiums (discounts) on marketable securities	(159)	10
Non-cash interest expense	16	14
Changes in operating assets and liabilities:		
Accounts receivable	(589)	(583)
Prepaid expenses and other current assets	(463)	(568)
Other assets	(419)	—
Accounts payable	(349)	743
Accrued expenses and other current liabilities	3,007	714
Deferred rent	(35)	3
Deferred revenue	(1,707)	(2,582)
Net cash used in operating activities	(23,469)	(19,319)
Cash flows from investing activities:		
Purchases of property and equipment	(549)	(812)
Purchases of marketable securities	(47,682)	(6,500)
Maturities and sales of marketable securities	22,700	16,000
Net cash provided by (used in) investing activities	(25,531)	8,688
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriting discounts and commissions	66,793	—
Proceeds from private placement concurrent with initial public offering	5,000	—
Proceeds from issuance of common stock upon stock option exercises	214	15
Payments of initial public offering costs	(2,056)	(10)
Net cash provided by financing activities	69,951	5
Net increase (decrease) in cash, cash equivalents and restricted cash	20,951	(10,626)
Cash, cash equivalents and restricted cash at beginning of period	29,600	42,576
Cash, cash equivalents and restricted cash at end of period	$ 50,551	$ 31,950
Supplemental disclosure of noncash investing and financing information:		
Conversion of convertible redeemable preferred stock into common stock	$ 77,154	$ —
Purchases of property and equipment included in accounts payable	$ —	$ 15
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 127
Accretion of redeemable convertible preferred stock to redemption value	$ 16	$ 49

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

1. Nature of the Business and Basis of Presentation

Unum Therapeutics Inc. ("Unum" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel immunotherapy products designed to harness the power of a patient's immune system to cure cancer. The Company's proprietary technologies include Antibody-Coupled T cell Receptor ("ACTR"), a universal, engineered cell therapy that is intended to be used in combination with a wide range of tumor-specific antibodies to target different tumor types, and Bolt-On Chimeric Receptor ("BOXR"), a novel approach to engineered T cell therapy designed specifically for solid tumor applications. Unum was incorporated in March 2014 under the laws of the State of Delaware.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

On March 16, 2018, the Company effected a one-for-1.5701314513884 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock (see Note 7). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the redeemable convertible preferred stock conversion ratios.

On April 3, 2018, the Company completed an initial public offering ("IPO") of its common stock and issued and sold 5,770,000 shares of common stock at a public offering price of $12.00 per share, resulting in net proceeds of $61.5 million after deducting underwriting discounts and commissions and other offering costs. In addition, Seattle Genetics, Inc. ("Seattle Genetics") purchased from the Company, concurrently with the IPO in a private placement, $5.0 million of shares of common stock at a price per share equal to the initial public offering price, or 416,666 shares (the "concurrent private placement").

Upon closing of the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into shares of common stock (see Note 7). Upon conversion of the redeemable convertible preferred stock, the Company reclassified the carrying value of the redeemable convertible preferred stock to common stock and additional paid-in capital.

On April 25, 2018, the Company issued and sold an additional 215,000 shares of its common stock at the IPO price of $12.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $2.4 million after deducting underwriting discounts and commissions.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has funded its operations with the sales of redeemable convertible preferred stock, payments received in connection with a collaboration agreement, and most recently, with proceeds from the IPO and concurrent private placement completed in April 2018. The Company has incurred recurring losses since inception, including net losses attributable to the Company of $25.9 million for the nine months ended September 30, 2018. As of September 30, 2018, the Company had an accumulated deficit of $83.5 million. The Company expects to continue to generate operating losses in the foreseeable future. As of November 13, 2018, the issuance date of the interim consolidated financial statements, the Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance date of the interim consolidated financial statements, without considering available borrowings under the Company's loan and security agreement.

The Company will ultimately need to seek additional funding through equity offerings, debt financings, collaborations, licensing arrangements and other marketing and distribution arrangements, partnerships, joint ventures, combinations or divestitures of one or more of its businesses. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborative arrangements or divest its assets. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. Arrangements with collaborators or others may require the Company to relinquish rights to certain of its technologies or product candidates. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs or commercialization efforts, which could adversely affect its business prospects.

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The consolidated balance sheet at December 31, 2017 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited consolidated financial statements as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2017 included in the Company's Registration Statement on Form S-1, File No. 333-223414 on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2018 and results of 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 have been made. The Company's results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2018.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains most of its cash and cash equivalents at three accredited financial institutions. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party vendors for its product candidates. In particular, the Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and process its product candidates for its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit). Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss. The Company classifies its marketable securities with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities are available for current operations.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge to the statement of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates, assumptions and judgments reflected in these condensed consolidated financial statements include, but are not limited to, revenue, the accrual of research and development expenses and the valuation of stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Classification and Accretion of Redeemable Convertible Preferred Stock

The Company classified redeemable convertible preferred stock outside of stockholders' equity (deficit) because the shares contained certain redemption features that were not solely within the control of the Company. The carrying values of the redeemable convertible preferred stock were accreted to their respective redemption values from the date of issuance through the earliest date of redemption.

Collaboration Agreements

The Company follows the accounting guidance for collaboration agreements, which requires that certain transactions between the Company and collaborators be recorded in its consolidated statements of operations and comprehensive loss on either a gross basis or net basis, depending on the characteristics of the collaborative relationship, and requires enhanced disclosure of collaborative relationships. The Company evaluates its collaboration agreements for proper classification in its consolidated statements of operations and comprehensive loss based on the nature of the underlying activity. If payments to and from collaborative partners are not within the scope of other authoritative accounting literature, the consolidated statements of operations classification for the payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. When the Company has concluded that it has a customer relationship with one of its collaborators, such as that with Seattle Genetics (see Note 5), the Company follows the guidance in Accounting Standards Codification ("ASC") Topic 606, *Revenue From Contracts With Customers* ("ASC 606").

Revenue Recognition of Collaboration Agreements

On January 1, 2018, the Company adopted the new revenue standard, discussed below under the heading "Recently Adopted Accounting Pronouncements", which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The new revenue standard provides a five-step framework whereby revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of the new revenue standard, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when collectability of the consideration to which the Company is entitled in exchange for the goods or services it transfers to the customer is determined to be probable.

At contract inception, once the contract is determined to be within the scope of the new revenue standard, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. In determining whether goods or services are distinct, management evaluates certain criteria, including whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (capable of being distinct) and (ii) the good or service is separately identifiable from other goods or services in the contract (distinct in the context of the contract).

At the inception of an arrangement that includes options for a customer to purchase additional services or products at agreed upon prices in the future, the Company evaluates whether each option provides a material right. An option that provides a material right will be accounted for as a separate performance obligation.

The Company then determines the transaction price, which is the amount of consideration it expects to be entitled from a customer in exchange for the promised goods or services, for each performance obligation and recognizes the associated revenue as each performance obligation is satisfied. The Company's estimate of the transaction price for each contract includes all variable consideration to which it expects to be entitled. Variable consideration includes payments in the form of collaboration payments, regulatory milestone payments, commercial milestone payments, and royalty payments. For collaboration, regulatory milestone, and commercial milestone payments the Company evaluates whether it is probable that the consideration associated with each milestone will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are considered constrained and excluded from the transaction price until they meet this threshold. At the end of each subsequent reporting period, the Company re-evaluates the probability of a significant reversal of the cumulative revenue recognized for its milestones, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis. The Company excludes sales-based royalties until the sale occurs.

The new revenue standard requires the Company to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in the new revenue standard as the price at which an entity would sell a promised good or service separately to a customer. If other observable transactions in which the Company has sold the same performance obligation separately are not available, the Company is required to estimate the standalone selling price of each performance obligation. Key assumptions to determine the standalone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. A performance obligation is satisfied and revenue is recognized when "control" of the promised good or service is transferred, either over time or at a point in time, to the customer. A customer obtains control of a good or service if it has the ability to (1) direct its use and (2) obtain substantially all of the remaining benefits from it.

If a contract should be accounted for as a combined performance obligation, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. The Company will recognize revenue using the cost-to-cost method, which it believes best depicts the transfer of control to the customer. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation. Under this method, revenue will be recorded as a percentage of the estimated transaction price based on the extent of progress towards completion. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement. The estimate of the Company's measure of progress and estimate of variable consideration to be included in the transaction price will be updated at each reporting date as a change in estimate. The amount of transaction price allocated to the satisfied portion of the performance obligation, based on the Company's measure of progress, will be recognized immediately on a cumulative catch-up basis, resulting in an adjustment to revenue in the period of change. The amount related to the unsatisfied portion will be recognized as that portion is satisfied over time.

Amounts received prior to satisfying the revenue recognition criteria listed above are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts expected to be recognized as revenue within 12 months of the balance sheet date are classified as current deferred revenue. Amounts not expected to be recognized as revenue within the following 12 months of the balance sheet date are classified as deferred revenue, net of current portion. At September 30, 2018, the Company had deferred revenue of $20.1 million related to its collaboration. The Company recognized revenue of $2.0 million and $5.9 million during the three and nine months ended September 30, 2018, respectively, from the deferred revenue balance at January 1, 2018. The Company recognizes deferred revenue by first allocating from the beginning deferred revenue balance to the extent that the beginning deferred revenue balance exceeds the revenue to be recognized. Billings during the period are added to the deferred revenue balance to be recognized in future periods. To the extent that the beginning deferred revenue balance is less than revenue to be recognized during the period, billings during the period are allocated to revenue. In the event that a collaboration agreement was to be terminated and the Company had no further performance obligations, the Company would recognize as revenue any portion of the upfront payment and other payments that had not previously been recorded as revenue and were classified as deferred revenue at the date of such termination.

Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less or the amount is immaterial. At September 30, 2018, the Company has not capitalized any costs to obtain its contract.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The standard outlines a five-step process to achieve this principle, and requires companies to use more judgment and make more estimates than under the previous guidance. The Company determined that these judgments and estimates include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of ASU 2014-09 such that the standard became effective for public entities for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. The FASB subsequently issued amendments to ASU No. 2014-09 that had the same effective dates and transition requirements as ASU 2014-09, all of which collectively are herein referred to as "ASC 606".

On January 1, 2018, the Company adopted the new revenue standard by applying the modified retrospective method to its collaboration agreement with Seattle Genetics (see Note 5) which was not completed as of January 1, 2018. As a result, while reporting periods beginning on the Company's adoption of the new revenue standard are presented under the new revenue standard, prior period amounts have not been adjusted and continue to be presented under the revenue standard in effect prior to January 1, 2018.

The following table summarizes the cumulative effect to the Company's consolidated balance sheet upon the adoption of the new revenue standard on January 1, 2018 (in thousands):

	Balance at December 31, 2017	Adjustments	Balance at January 1, 2018
Deferred revenue, current and net of current portion	$ 15,605	$ 6,188	$ 21,793
Accumulated deficit	$ (51,339)	$ (6,188)	$ (57,527)

The adjustment is the result of the application of the new revenue standard regarding how entities should measure progress in satisfying performance obligations and the contract's transaction price. Under ASC 606, the Company will recognize revenue using the cost-to-cost method, which it believes best depicts the transfer of control to the customer. In contrast, under the previous revenue standard, the Company recognized revenue on a straight-line basis over the estimated period of performance. In addition, under ASC 606, the estimated transaction price will include variable consideration for payments expected to be earned for preclinical research and clinical development activities through Phase I, which, under the previous standard, the Company was precluded from including in the estimated transaction price until such payments were determinable and due.

The Company will account for the license, research and development services, and steering committee services under ASC 606 as a single performance obligation under the collaboration agreement, just as it accounted for those items as a single unit of accounting under the previous standard. The options held by Seattle Genetics are expected to continue to be accounted for separately as they do not represent material rights based on the criteria of ASC 606. Further, ASC 606 will not have an impact on the Company's current accounting for milestone or royalty payments.

In accordance with the new revenue standard requirements, the following tables summarize the impact of adoption on the Company's consolidated balance sheets, consolidated statements of operations and comprehensive loss, and consolidated statements of cash flows (in thousands):

Consolidated Balance Sheet

	At September 30, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Deferred revenue, current portion	$ 20,086	$ 7,764	$ 12,322
Deferred revenue, net of current portion	$ —	$ 3,983	$ (3,983)
Accumulated deficit	$ (83,453)	$ (75,114)	$ (8,339)

Consolidated Statements of Operations and Comprehensive Loss

	Three Months Ended September 30, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Collaboration revenue	$ 2,043	$ 2,847	$ (804)
Net loss	$ (10,168)	$ (9,364)	$ (804)
Net loss attributable to common stockholders	$ (10,168)	$ (9,364)	$ (804)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.31)	$ (0.03)
Comprehensive loss	$ (10,179)	$ (9,375)	$ (804)

	Nine Months Ended September 30, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Collaboration revenue	$ 5,929	$ 8,080	$ (2,151)
Net loss	$ (25,926)	$ (23,775)	$ (2,151)
Net loss attributable to common stockholders	$ (25,942)	$ (23,791)	$ (2,151)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.12)	$ (1.03)	$ (0.09)
Comprehensive loss	$ (25,934)	$ (23,783)	$ (2,151)

Consolidated Statement of Cash Flows

	Nine Months Ended September 30, 2018		
	Under Topic 606	Under Topic 605	Effect of Change
Net loss	$ (25,926)	$ (23,775)	$ (2,151)
Change in deferred revenue	$ (1,707)	$ (3,858)	$ 2,151

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted the standard retrospectively for all periods presented on the required effective date of January 1, 2018, and its adoption had no impact on the Company's financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows, Restricted Cash*, requiring restricted cash and restricted cash equivalents to be included with cash and cash equivalents on the statement of cash flows when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted this standard during the first quarter of 2018. Restricted cash is now included as a component of cash, cash equivalents, and restricted cash on the Company's unaudited consolidated statements of cash flows. The inclusion of restricted cash increased the beginning and ending balances of the unaudited consolidated statement of cash flows by $1.3 million for the nine months ended September 30, 2017 and increased the beginning balance of the unaudited consolidated statement of cash flows by $1.3 million for the nine months ended September 30, 2018.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted the standard prospectively beginning on the required effective date of January 1, 2018, and its adoption did not have a material impact on the Company's financial position, results of operations or cash flows.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. The guidance is effective for public entities for annual reporting periods beginning after December 15, 2018 and for interim periods within those fiscal years, and early adoption is permitted. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating the method of adoption and the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements. The Company expects that the adoption of the new leasing standards will result in the recognition of material right-of-use assets and liabilities on its consolidated balance sheet.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. ASU 2017-11 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. While the Company continues to evaluate the impact of the adoption of ASU 2017-11, it does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. ASU 2018-07 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. While the Company continues to evaluate the impact of the adoption of ASU 2018-07, it does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

3. Marketable Securities and Fair Value of Financial Assets and Liabilities

Marketable securities by security type consisted of the following (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills and notes (due within one year)	$ 37,848	$ —	$ (24)	$37,824
	$ 37,848	$ —	$ (24)	$37,824

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills and notes (due within one year)	$ 5,007	$ —	$ (10)	$ 4,997
U.S. government agency bonds (due within one year)	7,700	—	(6)	7,694
	$ 12,707	$ —	$ (16)	$12,691

The following tables present information about the Company's assets that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 44,706	$ —	$ 44,706
Marketable securities:				
U.S. Treasury bills and notes	37,824	—	—	37,824
	$ 37,824	$ 44,706	$ —	$ 82,530

	Fair Value Measurements at December 31, 2017 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 24,196	$ —	$ 24,196
Marketable securities:				
U.S. Treasury bills and notes	4,997	—	—	4,997
U.S. government agency bonds	—	7,694	—	7,694
	$ 4,997	$ 31,890	$ —	$ 36,887

During the three and nine months ended September 30, 2018 and 2017, there were no transfers between Level 1, Level 2 and Level 3.

4. Accrued Expenses and Other Current Liabilities

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

	September 30, 2018	December 31, 2017
Accrued employee compensation and benefits	$ 1,271	$ 1,315
Accrued professional fees	670	980
Accrued external research and development expense	1,538	478
Accrued other	2,016	180
	$ 5,495	$ 2,953

5. Collaboration Agreement

The Company has a collaboration agreement with Seattle Genetics, entered into in 2015, whereby the parties agreed to jointly develop two product candidates incorporating the Company's ACTR platform and Seattle Genetics' antibodies. Under the collaboration agreement, the Company conducts preclinical research and clinical development activities related to the two specified product candidates through Phase I clinical development, and Seattle Genetics provides the funding for those activities. Under the collaboration agreement, the Company recognized revenue of $2.0 million and $5.9 million for the three and nine months ended September 30, 2018, respectively, related to research and clinical development activities performed. The Company recognized $2.3 million and $6.2 million for the three and nine months ended September 30, 2017, respectively, related to research and clinical

development activities performed. As of September 30, 2018 and December 31, 2017, deferred revenue of $20.1 million and $15.6 million, respectively, was recorded related to this agreement. As noted in Note 2 above, deferred revenue was increased by $6.2 million as of January 1, 2018 upon adoption of ASC 606. As of September 30, 2018, the aggregate amount of the transaction price allocated to the remaining performance obligation for preclinical research and clinical development activities related to the two specified product candidates through Phase I is estimated to be approximately $71.3 million, which is expected to be recognized as revenue through December 31, 2022.

6. Loan and Security Agreement

In January 2017, the Company entered into a loan and security agreement (the "Loan Agreement") with Pacific Western Bank ("PWB"), which provides for term loan borrowings of up to $15.0 million through January 19, 2019. Borrowings under the Loan Agreement bear interest at a variable annual rate equal to the greater of (i) the prime rate plus 0.25% or (ii) 3.75%, and are payable over an interest-only period until January 19, 2019, followed by a 24-month period of equal monthly payments of principal and interest. All amounts outstanding as of the maturity date of January 19, 2021 become immediately due and payable.

In connection with the Loan Agreement, the Company agreed to enter into warrant agreements with PWB pursuant to which warrants will be issued to purchase a number of shares of the Company's capital stock equal to 1% of the amount of each term loan borrowing under the Loan Agreement, divided by the applicable exercise price.

No amounts have been borrowed as term loans under the Loan Agreement as of September 30, 2018. Borrowings under the Loan Agreement are collateralized by substantially all of the Company's assets, except for its intellectual property. Under the Loan Agreement, the Company has agreed to affirmative and negative covenants to which it will remain subject until maturity. These covenants include limitations on the Company's ability to incur additional indebtedness and engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses. There are no financial covenants associated with the Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants and material adverse effects with respect to the Company.

7. Redeemable Convertible Preferred Stock

The Company issued Series A redeemable convertible preferred stock (the "Series A preferred stock") and Series B redeemable convertible preferred stock (the "Series B preferred stock"). The Series A preferred stock and the Series B preferred stock are collectively referred to as the "Preferred Stock". The Preferred Stock converted to shares of common stock on a 1:1.5701314513884 basis upon the closing of the IPO on April 3, 2018.

As of December 31, 2017, the Preferred Stock consisted of the following (in thousands, except share amounts):

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A preferred stock	12,297,276	12,297,276	$ 12,267	$ 12,297	7,832,001
Series B preferred stock	8,494,131	8,474,574	64,884	65,000	5,397,361
	20,791,407	20,771,850	$ 77,151	$ 77,297	13,229,362

Prior to the closing of the IPO, the holders of the Preferred Stock had the following rights and preferences:

Voting

The holders of Preferred Stock were entitled to vote, together with the holders of common stock, on matters submitted to stockholders for a vote. The holders of Preferred Stock were entitled to the number of votes equal to the number of common shares into which each such share of Preferred Stock could convert. In addition, the holders of Series A preferred stock, voting exclusively and as a separate class, were entitled to elect two directors of the Company. The holders of Series B preferred stock, voting exclusively and as a separate class, were entitled to elect one director of the Company.

Conversion

Each share of Preferred Stock was convertible at the option of the holder at any time after the date of issuance. Each share of Preferred Stock would have automatically converted into shares of common stock at the applicable conversion ratio then in effect upon the closing of a firm commitment public offering with at least $50.0 million of gross proceeds to the Company. Shares of Series A preferred stock would have automatically converted into shares of common stock at the applicable conversion ratio then in effect upon written consent of the holders of at least 65% of the then-outstanding shares of Series A preferred stock. Shares of Series B preferred stock would have automatically converted into shares of common stock at the applicable conversion ratio then in effect upon written consent of the holders of at least a majority of the then-outstanding shares of Series B preferred stock.

The conversion ratio of each series of Preferred Stock was determined by dividing the Original Issue Price of each series by the Conversion Price of each series. The Original Issue Price was $1.00 per share for Series A preferred stock and $7.67 per share for Series B preferred stock. The Conversion Price at issuance was $1.570131 per share for Series A preferred stock and $12.042908 per share for Series B preferred stock, subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization and other adjustments as set forth in the Company's certificate of incorporation, as amended and restated.

Dividends

The holders of Preferred Stock were entitled to receive noncumulative dividends if and when declared by the Company's board of directors. The Company could not declare, pay or set aside any dividends on shares of any other series of capital stock of the Company, other than dividends on common stock payable in common stock, unless the holders of the Series A and Series B preferred stock first received, or simultaneously received, a dividend on each outstanding share of Series A and Series B preferred stock in an amount at least equal to the greater of (i) $0.08 per share in the case of Series A preferred stock and $0.61 per share in the case of Series B preferred stock, each subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization with respect to such shares, and (ii) (A) in the case of a dividend on common stock or any class or series of stock that was convertible into common stock, that dividend per share of Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (2) the number of shares of common stock issuable upon conversion of each share of Preferred Stock, or (B) in the case of a dividend on any class or series that was not convertible into common stock, at a rate per share of Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the Original Issue Price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination of or other similar recapitalization affecting such shares) and (2) multiplying such fraction by an amount equal to the Original Issue Price of each series of Preferred Stock. If the Company declared, paid or set aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of the Preferred Stock would have been calculated based upon the dividend on the class or series of capital stock that would have resulted in the highest Preferred Stock dividend. Stockholders were not entitled to any accruing dividends. No dividends had been declared or paid.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company or Liquidating Event (as described below), the holders of shares of Preferred Stock would have received, in preference to the common stockholders, an amount equal to the greater of (i) the Original Issue Price per share of the respective share of Preferred Stock, plus all dividends declared but unpaid on such shares, or (ii) the amount the holders would have received if the Preferred Stock were converted into common stock prior to such liquidation event. In the event that the assets available for distribution to the Company's stockholders had not been sufficient to permit payment to the holders of Preferred Stock in the full amount to which they were entitled, the assets available for distribution would have been distributed on a pro rata basis among the holders of the Series A and Series B preferred stock. After the payment of all preferential amounts to the holders of the Preferred Stock then, to the extent available, the remaining assets available for distribution would have been distributed among the holders of the common stock ratably based on the number of shares of common stock held by each holder.

Unless the holders of at least two-thirds of the then-outstanding shares of Preferred Stock, voting together as a single class on an as-converted basis, elected otherwise, a Liquidating Event would have included a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Redemption

At any time on or after June 10, 2020, shares of each of the Series A and Series B preferred stock were subject to mandatory redemption by the Company in three equal annual installments beginning 60 days after receipt of a notice of redemption from the holders of at least two-thirds of the combined voting power of the holders of outstanding shares of Series A and Series B preferred stock, voting together as a single class, in an amount equal to the Original Issue Price per share of each series of Preferred Stock plus any dividends declared but unpaid thereon.

8. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

9. Stock-Based Compensation

2015 Stock Incentive Plan

The Company's 2015 Stock Incentive Plan (the "2015 Plan") provided for the Company to grant incentive stock options or nonqualified stock options, restricted stock, restricted stock units and other equity awards to employees, directors and consultants of the Company. The 2015 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The board of directors could also delegate to one or more officers of the Company the power to grant awards to employees and certain officers of the Company. The exercise prices, vesting and other restrictions were determined at the discretion of the board of directors, or its committee if so delegated. Stock options granted under the 2015 Plan with service-based vesting conditions generally vest over four years and expire after ten years. The total number of shares of common stock that could have been issued under the 2015 Plan was 4,144,876 shares. Upon effectiveness of the Company's 2018 Stock Option and Incentive Plan, the ("2018 Plan") in March 2018, the remaining shares available under the 2015 Plan became available for issuance under the 2018 Plan and no future issuance will be made under the 2015 Plan. Additionally, outstanding options under the 2015 Plan that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future issuance under the 2018 Plan.

The exercise price for stock options granted is not less than the fair value of common shares as determined by the board of directors as of the date of grant. Prior to the Company's IPO, the Company's board of directors valued the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

2018 Stock Option and Incentive Plan

On March 16, 2018, the Company's stockholders approved the 2018 Plan, which became effective on March 27, 2018. The 2018 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights. The number of shares initially reserved for issuance under the 2018 Plan is 2,800,721 plus the shares of common stock remaining available for issuance under the 2015 Plan. The number of shares reserved shall be cumulatively increased on January 1, 2019 and each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or a lesser number of shares determined by the Company's board of directors. The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2018 Plan or the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan. As of September 30, 2018, 2,820,460 shares remained available for future issuance under the 2018 Plan.

2018 Employee Stock Purchase Plan

On March 16, 2018, the Company's stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective on March 28, 2018. A total of 314,000 shares of common stock were reserved for issuance under this plan. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2019, and each January 1 thereafter through January 1, 2027, by the least of (i) 500,000 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares as determined by the ESPP administrator.

Stock Option Issuances

During the nine months ended September 30, 2018, the Company granted options to employees, consultants and directors for the purchase of 873,528 shares of common stock with a weighted average grant-date fair value of $6.56 per share.

Stock-Based Compensation

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development expenses	$ 629	$ 261	$ 1,637	$ 767
General and administrative expenses	231	38	549	114
Total	$ 860	$ 299	$ 2,186	$ 881

As of September 30, 2018, total unrecognized compensation cost related to the unvested stock-based awards was $9.4 million, which is expected to be recognized over a weighted average period of 2.74 years.

10. Income Taxes

2017 U.S. Tax Reform

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from 34% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of the Company's deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of its deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA.

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118") which allows the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. Since the Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next 12 months, the Company considers the accounting for the effect of the TCJA to be provisional in accordance with SAB 118 at September 30, 2018. During the three and nine months ended September 30, 2018, the Company did not make any adjustments to the provisional amounts recorded as a result of the TCJA.

Income Taxes

During the three and nine months ended September 30, 2018 and 2017, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year due to its uncertainty of realizing a benefit from those items. The Company has provided a valuation allowance for the full amounts of its net deferred tax assets because, at September 30, 2018 and December 31, 2017, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

As of September 30, 2018 and December 31, 2017, the Company had not recorded any amounts for unrecognized tax benefits. The Company files income tax returns in the U.S. and Massachusetts. The statute of limitations for assessment by the Internal Revenue Service and Massachusetts tax authorities remains open for all years since 2014. No federal or state tax audits are currently in process.

11. Commitments and Contingencies

Operating Lease

The Company leases its facility under a non-cancelable operating lease that expires in April 2023. Under the terms of the lease, the Company secured a $1.3 million letter of credit as security for its leased facility. The underlying cash securing this letter of credit has been classified as non-current restricted cash in the accompanying consolidated balance sheets. The lease includes annual rent escalations, which are accrued, such that rent expense is recognized on a straight-line basis over the terms of occupancy.

The following table summarizes the future minimum payments due under the operating lease as of September 30, 2018 (in thousands):

Year Ending December 31,	
2018 (three months ending December 31)	$ 461
2019	1,878
2020	1,933
2021	1,989
2022	2,046
Thereafter	689
	$8,996

Rent expense for the three months ended September 30, 2018 and 2017 was $0.4 million and $0.4 million, respectively. Rent expense for the nine months ended September 30, 2018 and 2017 was $1.3 million and $1.3 million, respectively.

In January 2017, the Company entered into a 12-month sublease agreement with a tenant for up to 2,500 square feet of general office and laboratory space at its headquarters. In December 2017, the Company entered into a new sublease agreement with a tenant for approximately 5,000 square feet of general office and laboratory space at its headquarters. The sublease ended in June 2018. The Company recognized $0 and $0.1 million received under the subleases as other income in the consolidated statements of operations and comprehensive loss for the three months ended September 30, 2018 and 2017, respectively. The Company recognized $0.3 million and $0.2 million received under the subleases as other income in the consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2018 and 2017, respectively.

License Agreement

Under its license agreement with National University of Singapore and St. Jude Children's Research Hospital, Inc. (collectively the "Licensors") entered into in 2014, the Company is obligated to pay license maintenance fees on each anniversary of the effective date of the agreement that escalate from less than $0.1 million for each of the first seven years to $0.1 million on the eighth anniversary and each year thereafter. The Company is also obligated to make aggregate milestone payments of up to 5.5 million Singapore dollars (equivalent to approximately $4.0 million as of September 30, 2018) upon the achievement of specified clinical and regulatory milestones and to pay tiered royalties ranging in the low single-digit percentages on annual net sales of licensed products sold by the Company or its sublicensees. The royalties are payable on a product-by-product and country-by-country basis and may be reduced in specified circumstances. Additionally, under certain circumstances, the Company is obligated to pay the Licensors a percentage of amounts received from sublicensees.

The license agreement will expire on a country-by-country basis until the last to expire of the patents and patent applications covering such licensed product or service. The Licensors may terminate the license agreement within 60 days after written notice in the event of a breach of contract. The Licensors may also terminate the agreement upon written notice in the event of the Company's bankruptcy, liquidation, or insolvency. In addition, the Company has the right to terminate this agreement in its entirety at will upon 90 days' advance written notice to the Licensors. However, if the Company has commenced the commercialization of licensed products, the Company can only terminate at will if it ceases all development and commercialization of licensed products.

Manufacturing Commitment

As of September 30, 2018, the Company had non-cancelable minimum purchase commitments under contract manufacturing agreements for payments totaling $1.5 million over the following 12 months.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2018 or December 31, 2017.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

12. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$ (10,168)	$ (7,000)	$ (25,926)	$ (18,802)
Accretion of redeemable convertible preferred stock to redemption value	—	(16)	(16)	(49)
Net loss attributable to common stockholders	$ (10,168)	$ (7,016)	$ (25,942)	$ (18,851)
Denominator:				
Weighted average common shares outstanding, basic and diluted	29,879,476	10,192,189	23,169,348	10,190,889
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.69)	$ (1.12)	$ (1.85)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated above because including them would have had an anti-dilutive effect:

	September 30,	
	2018	2017
Redeemable convertible preferred shares (as converted to common stock)	—	13,229,362
Stock options to purchase common stock	3,768,371	2,689,570
	3,768,371	15,918,932

13. Retirement Plan

The Company has a defined-contribution plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. As currently established, the Company is not required to make and to date has not made any contributions to the 401(k) Plan. The Company did not make any matching contributions during the three or nine months ended September 30, 2018 or 2017.

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 financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or SEC, on March 29, 2018. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel immunotherapy products designed to harness the power of a patient's immune system to cure cancer. Our proprietary technologies include a universal, engineered cell therapy, referred to as Antibody-Coupled T cell Receptor (ACTR), that is intended to be used in combination with a wide range of tumor-specific antibodies to target different tumor types. In addition, we have developed a novel technology, Bolt-On Chimeric Receptor (BOXR), for improving engineered T cell functionality to enable solid tumor cancer applications through engineering the expression of specific proteins to overcome the immunosuppressive microenvironment found in solid tumors. The BOXR technology may be combined with ACTR T cells or with engineered T cells expressing a scFv chimeric receptor designed to directly recognize cancer cells. Our vision is to use our ACTR and BOXR derived product candidates to transform cancer treatment and deliver patient cures in many different hematologic and solid tumor cancers, improving upon current cell therapies.

We have a broad product pipeline that includes four clinical stage product candidates, composed of either ACTR087 or ACTR707 T cells co-administered with approved and commercially available antibodies or antibodies in preclinical or clinical development. ACTR087 is our original ACTR construct, comprising the ectodomain of CD16, the costimulatory domain of 4-1BB, and the signaling domain of CD3-zeta. ACTR707 is a modified ACTR construct selected for improved performance across a number of dimensions, including increased proliferation, cytokine secretion, and persistence in a repeat stimulation test. ACTR707 differs from ACTR087 in terms of its costimulatory domain (CD28) and other structural components. Our most advanced product candidates are ACTR087 and ACTR707, each used in combination with rituximab, to treat adult patients with relapsed or refractory non-Hodgkin lymphoma (r/r NHL). ACTR087 and ACTR707, each used in combination with rituximab, are being tested in ongoing, multi-center, open-label Phase I clinical trials called ATTCK-20-2 and ATTCK-20-03, respectively. We completed patient enrollment and dosing in the first dose level of the ATTCK-20-03 trial and presented preliminary data from this dose level on September 30, 2018 at the Fourth Annual CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference. We recently completed enrollment in the second dose level of this trial and are currently enrolling patients at the third dose level. We expect to report additional data from the dose escalation phase of the trial at the upcoming American Society of Hematology (ASH) meeting taking place December 1-4, 2018. We plan to continue enrolling patients in this trial into 2019. In the fourth quarter of 2017, we completed patient enrollment and dosing in the dose escalation phase of the ATTCK-20-2 trial, and in the second quarter of 2018, we initiated the cohort expansion phase of the trial using an optimized dose of ACTR087. Preliminary data from the dose escalation phase of the ATTCK-20-2 trial was presented on December 11, 2017 at the 59th ASH Annual Meeting and Exposition. In both Phase I trials, we believe that we have demonstrated clinical proof of concept, as evidenced by ACTR T cell expansion and persistence, a favorable tolerability profile at the first dose level, and anti-tumor activity. Based on emerging clinical data from the Phase I ATTCK-20-03 trial, the continuing progress in that trial, and our desire to efficiently manage resources, we recently selected ACTR707 used in combination with rituximab to be the lead lymphoma product candidate for advance to further clinical development. As a result of this decision, we intend to conclude enrollment in the ATTCK-20-2 study in the first half of 2019.

Our third clinical stage product candidate, ACTR087 used in combination with SEA-BCMA, is the first product candidate resulting from our strategic collaboration with Seattle Genetics, Inc. (Seattle Genetics). We are currently enrolling and dosing adult patients with r/r multiple myeloma in a Phase I multi-center trial, ATTCK-17-01. We expect to report initial data from this trial at the ASH meeting taking place December 1-4, 2018.

Our fourth clinical stage product candidate is ACTR707 used in combination with trastuzumab. We have an active IND to evaluate ACTR707 used in combination with trastuzumab as a potential treatment for HER2+ solid tumor cancers, and we expect to initiate a Phase I multi-center trial called ATTCK-34-01 testing this product candidate in patients with HER2+ solid tumor cancers by the end of 2018.

Since our inception in 2014, we have focused significant efforts and financial resources on building our ACTR platform, establishing and protecting our intellectual property portfolio, conducting research and development of our product candidates, manufacturing drug product material for use in preclinical studies and clinical trials, staffing our company, and raising capital. We do

not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from the sales of preferred stock, our initial public offering of common stock and concurrent private placement (as further discussed below), and payments received under our collaboration agreement with Seattle Genetics. On April 3, 2018, we completed our initial public offering (IPO) of our common stock and issued and sold 5,770,000 shares of our common stock at a public offering price of $12.00 per share, resulting in net proceeds of approximately $61.5 million, after deducting underwriting discounts and commissions and other offering costs. In addition, we completed a concurrent private placement of $5.0 million of shares of common stock at the public offering price of $12.00 per share, or 416,666 shares, with Seattle Genetics (Concurrent Private Placement).

In connection with our IPO, we issued and sold an additional 215,000 shares of our common stock on April 25, 2018, pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock at the public offering price of $12.00 and received additional net proceeds of $2.4 million, after deducting underwriting discounts and commissions.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $25.9 million for the nine months ended September 30, 2018 and $25.5 million for the year ended December 31, 2017. As of September 30, 2018, we had an accumulated deficit of $83.5 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- conduct additional clinical trials for our product candidates;
- continue to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional clinical, scientific, and commercial personnel;
- establish manufacturing capabilities in-house;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain regulatory approval; and
- add operational, financial, and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution. Further, as a result of the IPO, we expect to incur additional costs associated with operating as a public company.

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

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2018, we had cash, cash equivalents, and marketable securities of $87.1 million and available borrowings under our loan and security agreement of $15.0 million. We expect that our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through at least June 2020, without considering available borrowings under our loan and security agreement. See "—Liquidity and Capital Resources".

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval or additional license or collaboration agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from additional collaboration or license agreements that we may enter into with third parties. We expect that our revenue for the next several years will be derived primarily from a collaboration we entered into with Seattle Genetics in June 2015 as well as any additional collaborations that we may enter into in the future. We cannot provide assurance as to the timing of future milestone or royalty payments or that we will receive any of these payments at all.

The Company has a collaboration agreement with Seattle Genetics whereby the parties agreed to jointly develop two product candidates incorporating our ACTR platform and Seattle Genetics' antibodies. Under the collaboration agreement, the Company conducts preclinical research and clinical development activities related to the two specified product candidates through Phase I clinical development, and Seattle Genetics provides the funding for those activities.

Effective January 1, 2018, we adopted a new revenue recognition standard, which changed the manner in which we recognize revenue from our collaboration agreement with Seattle Genetics. Under the new standard, we recognize revenue from the collaboration agreement using the cost-to-cost method, which we believe best depicts the transfer of control to the customer, in contrast to recognizing revenue on a straight-line basis over the estimated 58-month performance period under the previous standard.

Under the collaboration agreement with Seattle Genetics, we recognized revenue of $2.0 million and $2.3 million for the three months ended September 30, 2018 and 2017, respectively, related to the upfront payment received from Seattle Genetics under our collaboration agreement as well as reimbursements of research and development costs. We recognized revenue of $5.9 million and $6.2 million for the nine months ended September 30, 2018 and 2017, respectively, related to the upfront payment received from Seattle Genetics under our collaboration agreement as well as reimbursements of research and development costs.

Operating Expenses

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, related benefits, and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contractors and contract research organizations (CROs);
- the cost of manufacturing drug products for use in our preclinical studies and clinical trials, including under agreements with third parties, such as consultants and contractors and contract manufacturing organizations (CMOs);
- laboratory supplies and animal care;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Our direct external research and development expenses are tracked on a program-by-program basis and consist of costs, such as fees paid to consultants, contractors, CMOs, and CROs in connection with our preclinical and clinical development activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical and preclinical development activities in the near term and in the future. At this time, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered, or may enter, into collaboration arrangements;
- our ability to maintain our current research and development programs and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration (FDA) or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the success in establishing and operating a manufacturing facility, or securing manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor and public relations, accounting, and audit services. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Other Income (Expense)

Interest Income

Interest income consists of interest earned on our cash equivalents and marketable securities balances. Our interest income has not been significant due to low interest earned on invested balances.

Other Income, Net

Other income, net consists of miscellaneous income and expense unrelated to our core operations, primarily income from subleasing a portion of our headquarters facilities.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each year or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of December 31, 2017, we had U.S. federal and state net operating loss carryforwards of $29.8 million and $31.0 million, respectively, which may be available to offset future income tax liabilities and begin to expire in 2035. As of December 31, 2017, we also had U.S. federal and state research and development tax credit carryforwards of $2.7 million and $1.0 million, respectively, which begin to expire in 2034 and 2029, respectively. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

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:

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Collaboration revenue	$ 2,043	$ 2,331	$ (288)
Operating expenses:			
Research and development	10,252	8,177	2,075
General and administrative	2,367	1,324	1,043
Total operating expenses	12,619	9,501	3,118
Loss from operations	(10,576)	(7,170)	(3,406)
Other income (expense):			
Interest income	405	100	305
Other income, net	3	70	(67)
Total other income, net	408	170	238
Net loss	$ (10,168)	$ (7,000)	$(3,168)

Collaboration Revenue

Collaboration revenue recognized during the three months ended September 30, 2018 and 2017 of $2.0 million and $2.3 million, respectively, was due to the recognition of the upfront payment received from Seattle Genetics under our collaboration agreement as well as reimbursements of research and development costs by Seattle Genetics over the performance period. Effective January 1, 2018, we adopted the new revenue recognition standard, which changed the manner in which we recognize revenue from our collaboration agreement with Seattle Genetics. Under the new standard, we recognize revenue from the collaboration agreement by applying the cost-to-cost method, in contrast to recognizing revenue on a straight-line basis over the estimated 58-month performance period under the previous standard.

Research and Development Expenses

	Three Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
ACTR087 used in combination with rituximab	$ 1,149	$ 2,788	$(1,639)
ACTR707 used in combination with rituximab	1,092	683	409
ACTR087 used in combination with SEA-BCMA	1,544	560	984
ACTR707 used in combination with trastuzumab	239	—	239
Unallocated expenses:			
Personnel related (including stock-based compensation)	3,174	2,480	694
Laboratory supplies, facility related and other	3,054	1,666	1,388
Total research and development expenses	$ 10,252	$ 8,177	$ 2,075

Research and development expenses were $10.3 million for the three months ended September 30, 2018, compared to $8.2 million for the three months ended September 30, 2017. The decrease in direct external costs related to our ACTR087 used in combination with rituximab program of $1.6 million was primarily due to a decrease in manufacturing costs as there was low production activity in the third quarter of 2018. The increase in direct external costs related to our ACTR707 used in combination with rituximab program of $0.4 million was primarily due to an increase in clinical trial costs and manufacturing costs related to our Phase I clinical trial, which commenced in the fourth quarter of 2017. The increase in direct external costs incurred for our ACTR087 used in combination with SEA-BCMA program primarily related to increased clinical trial and manufacturing costs related to our Phase I clinical trial which commenced in the first quarter of 2018. We are developing our ACTR087 used in combination with SEA-BCMA product candidate in conjunction with Seattle Genetics. We incurred costs related to our ACTR707 used in combination with trastuzumab program in connection with our IND filing.

The increase in personnel-related costs of $0.7 million included in unallocated expenses was primarily a result of an increase in stock-based compensation expense and an increase in overall compensation. Personnel-related costs for the three months ended September 30, 2018 and 2017 included stock-based compensation expense of $0.6 million and $0.3 million, respectively. The increase in stock-based compensation expense was primarily related to additional employee stock options and a higher value of our common stock. The increase in laboratory supplies, facility-related, and other costs of $1.4 million was primarily due to increased facilities costs related to scaling our manufacturing processes.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2018 were $2.4 million, compared to $1.3 million for the three months ended September 30, 2017. The increase in general and administrative expenses was primarily due to an increase in personnel-related costs of $0.3 million, increased professional and consulting fees of $0.5 million and an increase in facility related and other costs of $0.2 million. The increase in personnel-related costs was primarily due to higher stock-based compensation expense related to additional stock option grants and a higher value of our common stock. The increase in professional and consulting fees was primarily due to an increase in various advisory fees, including those related to audit, accounting and investor relations, associated with operating as a public company. The increase in facility related and other costs was primarily due to increased insurance expense associated with operating as a public company.

Interest Income

Interest income for the three months ended September 30, 2018 and 2017 was $0.4 million and $0.1 million, respectively. Interest income increased primarily as a result of higher invested balances due to cash proceeds received from our IPO and concurrent private placement.

Other Income, Net

Other income, net for the three months ended September 30, 2018 was less than $0.1 million, compared to $0.1 million for the three months ended September 30, 2017. The decrease in other income, net was primarily due to sublease income for the three months ended September 30, 2017, which we did not have in the three months ended September 30, 2018.

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:

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Collaboration revenue	$ 5,929	$ 6,237	$ (308)
Operating expenses:			
Research and development	27,520	22,270	5,250
General and administrative	5,410	3,239	2,171
Total operating expenses	32,930	25,509	7,421
Loss from operations	(27,001)	(19,272)	(7,729)
Other income (expense):			
Interest income	745	287	458
Other income, net	330	183	147
Total other income, net	1,075	470	605
Net loss	$ (25,926)	$ (18,802)	$(7,124)

Collaboration Revenue

Collaboration revenue recognized during the nine months ended September 30, 2018 and 2017 of $5.9 million and $6.2 million, respectively, was due to the recognition of the upfront payment received from Seattle Genetics under our collaboration agreement as well as reimbursements of research and development costs by Seattle Genetics over the performance period. Effective January 1, 2018, we adopted the new revenue recognition standard, which changed the manner in which we recognize revenue from our collaboration agreement with Seattle Genetics. Under the new standard, we recognize revenue from the collaboration agreement by applying the cost-to-cost method, in contrast to recognizing revenue on a straight-line basis over the estimated 58-month performance period under the previous standard.

Research and Development Expenses

	Nine Months Ended September 30,		
	2018	2017	Change
	(in thousands)		
Direct research and development expenses by program:			
ACTR087 used in combination with rituximab	$ 2,952	$ 5,711	$(2,759)
ACTR707 used in combination with rituximab	3,534	1,365	2,169
ACTR087 used in combination with SEA-BCMA	2,889	1,385	1,504
ACTR707 used in combination with trastuzumab	239	—	239
Unallocated expenses:			
Personnel related (including stock-based compensation)	8,925	7,494	1,431
Laboratory supplies, facility related and other	8,981	6,315	2,666
Total research and development expenses	$ 27,520	$ 22,270	$ 5,250

Research and development expenses were $27.5 million for the nine months ended September 30, 2018, compared to $22.3 million for the nine months ended September 30, 2017. The decrease in direct external costs related to our ACTR087 used in combination with rituximab program of $2.8 million was primarily due to a decrease in manufacturing costs as there was no production activity in the first half of 2018 and low production in the third quarter of 2018. The increase in direct external costs related to our ACTR707 used in combination with rituximab program of $2.2 million was primarily due to an increase in clinical trial costs and manufacturing costs related to our Phase I clinical trial, which commenced in the fourth quarter of 2017. The increase in direct external costs incurred for our ACTR087 used in combination with SEA-BCMA program primarily related to increased clinical trial and manufacturing costs related to our Phase I clinical trial which commenced in the first quarter of 2018, partially offset by a decrease in consulting costs related to the IND filing in 2017. We are developing our ACTR087 used in combination with SEA-BCMA product candidate in conjunction with Seattle Genetics. We incurred costs related to our ACTR707 used in combination with trastuzumab program in connection with our IND filing.

The increase in personnel-related costs of $1.4 million included in unallocated expenses was primarily a result of an increase in stock-based compensation expense. Personnel-related costs for the nine months ended September 30, 2018 and 2017 included stock-based compensation expense of $1.6 million and $0.8 million, respectively. The increase in stock-based compensation expense was primarily related to additional employee stock options and a higher value of our common stock. The increase in laboratory supplies, facility-related, and other costs of $2.7 million was primarily due to increased facilities costs related to scaling our manufacturing processes.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2018 were $5.4 million, compared to $3.2 million for the nine months ended September 30, 2017. The increase in general and administrative expenses was primarily due to an increase in personnel-related costs of $0.7 million, increased professional and consulting fees of $1.1 million, and an increase in facility related and other costs of $0.4 million. The increase in personnel-related costs was primarily due to increased stock-based compensation expense due to additional stock option grants and a higher value of our common stock as well as increased overall compensation. The increase in professional and consulting fees was primarily due to an increase in various advisory fees, including those related to audit, accounting and investor relations, associated with operating as a public company. The increase in facility related and other costs was primarily due to increased insurance expense associated with operating as a public company.

Interest Income

Interest income for the nine months ended September 30, 2018 was $0.7 million, compared to $0.3 million for the nine months ended September 30, 2017. Interest income increased primarily as a result of higher invested balances due to cash proceeds received from our IPO and concurrent private placement.

Other Income, Net

Other income, net for the nine months ended September 30, 2018 was $0.3 million, compared to $0.2 million for the nine months ended September 30, 2017. The increase in other income, net was primarily due to an increase in sublease income as the sublease in effect for the nine months ended September 30, 2018 for a portion of our facilities was for a larger amount of space compared to the prior period.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have generated limited revenue to date from funding arrangements with our collaboration partner. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. Prior to our IPO, we had funded our operations with proceeds from the sales of preferred stock and payments received under our collaboration agreement.

On April 3, 2018, we completed our IPO, and issued and sold 5,770,000 shares of common stock at a public offering price of $12.00 per share, resulting in net proceeds of $61.5 million after deducting underwriting discounts and commissions and other offering costs. We also completed the Concurrent Private Placement and sold 416,666 shares of common stock at a public offering price of $12.00 per share, resulting in proceeds of $5.0 million. On April 25, 2018, we issued and sold an additional 215,000 shares of our common stock at the IPO price of $12.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $2.4 million after deducting underwriting discounts and commissions.

As of September 30, 2018, we had cash, cash equivalents, and marketable securities of $87.1 million and available borrowings under our loan and security agreement of $15.0 million

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Cash used in operating activities	$ (23,469)	$ (19,319)
Cash provided by (used in) investing activities	(25,531)	8,688
Cash provided by financing activities	69,951	5
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 20,951	$ (10,626)

Operating Activities

During the nine months ended September 30, 2018, operating activities used $23.5 million of cash, primarily resulting from our net loss of $25.9 million and from net cash used by changes in our operating assets and liabilities of $0.6 million, partially offset by net non-cash charges of $3.0 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2018 consisted primarily of a $1.7 million decrease in deferred revenue, after the impact of the adoption of the new revenue standard (ASC 606), a $0.6 million increase in accounts receivable, a $0.5 million increase in prepaid expenses and other current assets and a $0.4 million increase in other assets, all partially offset by a $2.7 million increase in accounts payable and accrued expenses and other current liabilities.

During the nine months ended September 30, 2017, operating activities used $19.3 million of cash, primarily resulting from our net loss of $18.8 million and net cash used by changes in our operating assets and liabilities of $2.3 million, partially offset by net non-cash charges of $1.8 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2017 consisted primarily of a $2.6 million decrease in deferred revenue and increases of $0.6 million in both accounts receivable and prepaid expenses and other current assets, all partially offset by a $1.5 million increase in accounts payable and accrued expenses and other current liabilities.

In June 2015, we received an upfront payment of $25.0 million from Seattle Genetics under our collaboration agreement. At that time, we recorded the $25.0 million as deferred revenue, to be subsequently recognized as revenue over our period of performance. Changes in deferred revenue in all periods were due to the initial recording of and increases to the amount of deferred revenue from payments from Seattle Genetics for reimbursements of research and development costs as well as the subsequent recognition as revenue of a portion of the deferred revenue.

Changes in accounts payable, accrued expenses, and prepaid expenses and other current assets and other assets in all periods were generally due to growth in our business, the advancement of our product candidates, and the timing of vendor invoicing and payments.

Investing Activities

During the nine months ended September 30, 2018, net cash used in investing activities was $25.5 million, consisting of net purchases of marketable securities of $25.0 million and purchases of property and equipment of $0.5 million.

During the nine months ended September 30, 2017, net cash provided by investing activities was $8.7 million, consisting primarily of net maturities of marketable securities of $9.5 million, partially offset by purchases of property and equipment of $0.8 million.

Financing Activities

During the nine months ended September 30, 2018, net cash provided by financing activities was $70.0 million, consisting primarily of proceeds from our IPO in April 2018, net of underwriting discounts and commissions, of $66.8 million and proceeds from our concurrent private placement of $5.0 million, partially offset by payments of offering costs related to our IPO of $2.1 million.

Loan and Security Agreement

In January 2017, we entered into a loan and security agreement (the Loan Agreement) with Pacific West Bank (PWB), which provides for term loan borrowings of up to $15.0 million through January 19, 2019. Borrowings under the Loan Agreement bear interest at a variable annual rate equal to the greater of (i) the prime rate plus 0.25% or (ii) 3.75%, and are payable over an interest-only period until January 19, 2019, followed by a 24-month period of equal monthly payments of principal and interest. All amounts outstanding as of the maturity date of January 19, 2021 become immediately due and payable.

In connection with the Loan Agreement, we agreed to enter into warrant agreements with PWB pursuant to which warrants will be issued to purchase a number of shares of our capital stock equal to 1% of the amount of each term loan borrowing under the Loan Agreement, divided by the applicable exercise price.

No amounts had been borrowed as term loans under the Loan Agreement as of September 30, 2018.

Borrowings under the Loan Agreement are collateralized by substantially all of our assets, except for our intellectual property. Under the Loan Agreement, we have agreed to affirmative and negative covenants to which we will remain subject until maturity. These covenants include limitations on our ability to incur additional indebtedness and engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses. There are no financial covenants associated with the Loan Agreement. Events of default under the Loan Agreement include failure to make payments when due, insolvency events, failure to comply with covenants, and material adverse effects with respect to us.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. In addition, as a result of the IPO, we are incurring additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- the commencement, enrollment, or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel; and
- unanticipated serious safety concerns related to the use of our product candidates.

As of September 30, 2018, we had cash, cash equivalents, and marketable securities of $87.1 million and available borrowings under our Loan Agreement of $15.0 million. We expect that our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through at least June 2020, without considering available borrowings under our Loan Agreement. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams,

research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce, or terminate our research, product development, or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

During the nine months ended September 30, 2018, there were no material changes to our contractual obligations and commitments from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on March 29, 2018 other than the increase to our manufacturing commitment. As of September 30, 2018, our manufacturing commitment is with two external CMOs and includes non-cancelable minimum quantities to be purchased over the next twelve months of $1.5 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that of our critical accounting policies described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on March 29, 2018, the following involve the most judgment and complexity:

- revenue recognition of collaboration agreements;
- accrued research and development expenses; and
- stock-based compensation.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no significant changes to our critical accounting policies from those described in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on March 29, 2018.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

As of September 30, 2018, we had cash, cash equivalents, and marketable securities of $87.1 million, which consisted of cash, money market funds and U.S. Treasury bills and notes and agency bonds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

As of September 30, 2018, we had no debt outstanding and are therefore are not subject to interest rate risk related to debt.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 (JOBS Act) permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our President and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our Chief Executive Officer and President and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page i of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Business and Industry

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are a clinical-stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in March 2014. Our net loss was $25.9 million for the nine months ended September 30, 2018 and $25.5 million for the year ended December 31, 2017. As of September 30, 2018, we had an accumulated deficit of $83.5 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, product candidates.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our ACTR T cell product candidates represent a novel approach to cancer treatment, which creates significant challenges for us.

Our ACTR T cell product candidates involve (1) harvesting T cells from the patient's blood via leukapheresis, (2) genetically engineering the T cells to incorporate the ACTR transgene, (3) expanding the number of engineered T cells to the desired dose level and (4) infusing the engineered ACTR T cells back into the patient with or following the administration of the antibody. Advancing this novel and personalized investigational therapy creates significant challenges for us, including:

- educating medical personnel about the administration of the ACTR-combination therapy;
- educating medical personnel regarding the potential side effect profile of our product candidates, such as the potential adverse side effects related to cytokine release syndrome, neurotoxicity or autoimmune or rheumatologic disorders;
- administering chemotherapy to patients in advance of administering our product candidates, which may increase the risk of adverse side effects;
- sourcing clinical and, if approved, commercial, supplies for the materials used to manufacture and process our product candidates;
- manufacturing viral vectors to deliver ACTR to T cells;
- developing a robust and reliable ACTR T cell manufacturing process, including efficiently managing shipment of patient cells from and to clinical sites, minimizing potential contamination to the cell product and effectively scaling manufacturing capacity to meet demand;
- managing costs of inputs and other supplies while scaling production;
- using medicines to manage adverse side effects of our product candidates, which may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;

- obtaining and maintaining regulatory approval from the U.S. Food and Drug Administration (FDA); and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

In developing our product candidates we have not exhaustively explored different options in the design of the ACTR construct and in the method for manufacturing ACTR T cells. We may find our existing ACTR T cells and manufacturing process may be substantially improved with future design or process changes, necessitating development of new backup ACTR constructs and further clinical testing and delaying launch of our first products. For example:

- We have made a large number of ACTR constructs and used preclinical tests to select product candidates to advance into clinical testing. The preclinical tests are limited in their ability to predict behavior in patients. As we gain clinical experience with ACTR, new learnings may prompt us to select other ACTR constructs for clinical development.
- We have used a retroviral vector to deliver ACTR to T cells. In the future, we may find that a lentiviral vector offers advantages. Switching from retroviral to lentiviral delivery would necessitate additional process development and clinical testing and delay existing product candidates.
- The process by which patient cells are converted into an ACTR T cell has many steps that can influence quality and activity. We have explored a subset of variables and expect to continue to improve and optimize the manufacturing process. Depending upon the nature of the process changes, we may be compelled to perform bridging studies and/or to re-start clinical development, causing delays in time to market and potentially introducing a risk of failure if new processes do not perform as expected.

Our business is highly dependent on the success of our lead lymphoma product candidate, ACTR707 used in combination with rituximab, our other ACTR-antibody combination that we develop, and other ACTR-antibody combinations that we may develop.

Our business and future success depend on our ability to obtain regulatory approval of and then successfully commercialize our lead product candidate, ACTR707 used in combination with rituximab, and other product combinations that we develop using antibodies in combination with ACTR087 or ACTR707. All of our product candidates, including ACTR707 used in combination with rituximab, are in the early stages of development and will require additional clinical and non-clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because all our product candidates are based on our ACTR platform, if both ACTR087 and ACTR707 constructs encounter safety, efficacy, or manufacturing problems, developmental delays, regulatory, or commercialization difficulties or other problems, our development plans and business would be significantly harmed. For example, our Phase I clinical trial for ACTR087 used in combination with rituximab was placed on clinical hold in December 2017 pending submission of certain information relating to the trial. The clinical hold was removed in February 2018, following review of this information by the FDA.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, including for our lead lymphoma product candidate ACTR707 used in combination with rituximab or any ACTR T cell product candidates used in combination with other antibodies, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy, or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

Any clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

We designed our Phase I clinical trials of ACTR087 and ACTR707, each used in combination with rituximab, called ATTCK-20-2 and ATTCK-20-03, respectively, primarily to assess safety and efficacy in adult patients with r/r NHL. We recently selected ACTR707 used in combination with rituximab to be the lead lymphoma product candidate to advance to further clinical development. However, the preliminary results from the ATTCK-02-03 Phase I clinical trial may not be indicative of the final analysis of this Phase I clinical trial, especially given the small number of patients that have dosed in this trial. In addition, the Phase I results may not predict results for any further clinical testing of either ACTR087 or ACTR707 used in combination with rituximab or other product candidates that we have developed, such as ACTR087 used in combination with SEA-BCMA and ACTR T cells in combination with trastuzumab for the treatment of patients with HER2+ advanced cancers, or may develop in the future, using antibodies in combination with ACTR087 and ACTR707 or in different indications.

Additionally, as of the most recent data cutoff date for the ATTCK-20-2 trial of March 7, 2018, approximately 12% (two out of 17) of ACTR087 treated patients in ATTCK-20-2 experienced ACTR087-related severe cytokine release syndrome (CRS) and 6% (one out of 17) of patients experienced ACTR087-related neurotoxicity, which was fatal. Of the two events of CRS, one patient subsequently experienced a fatal case of enterococcal sepsis considered related to ACTR087 and one patient subsequently experienced a fatal case of sepsis considered not related to ACTR087. These events resulted in the FDA placing this trial on clinical hold in December 2017 pending submission of certain information relating to the ATTCK-20-2 clinical trial. The clinical hold was removed in February 2018, following review of this information by the FDA. Several protocol and dosing changes were made in early 2018, which we expect to reduce the incidence of severe adverse events and better manage those events that do occur. We recently selected ACTR707 used in combination with rituximab to be the lead lymphoma product candidate for further clinical development, and, as a result, we intend to conclude enrollment in the ATTCK-20-2 study in the first half of 2019. However, if severe safety events are observed in patients treated in spite of the modifications outlined above, the FDA may determine, at any time, that there is an unacceptable safety risk for patients and we may be required to stop the trial prior to the conclusion of the planned enrollment.

In addition, even if the ATTCK-20-03 trial and other currently ongoing or planned trials, such as ATTCK-17-01 Phase I clinical trial or ATTCK-34-01, are successfully initiated and/or completed, as applicable, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. For instance, although our lead product candidates will be dosed in refractory patients with antibodies that the patients have already received, we plan to test future product candidates in patients that have never received the co-administered antibody in prior treatment and with antibodies that have never been independently evaluated for safety or efficacy. As a result, it may be difficult to demonstrate that the ACTR construct, rather than the antibody alone, is causing an observed effect. We cannot guarantee that the FDA will view the ACTR construct as having efficacy even if positive results are observed in these clinical trials. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We cannot guarantee that our ACTR product candidates or BOXR technology will show any functionality in the solid tumor environment.

While we plan to develop product candidates for use in solid tumor cancers, including ACTR707 used in combination with trastuzumab for HER2+ cancers, we cannot guarantee that our product candidates will show any functionality in the solid tumor environment. The cellular environment in which solid tumor cancers exist is inimical to T cells due to several factors including: (1) immunosuppressive cells (e.g., regulatory T cells (Tregs), myeloid derived suppressor cells (MDSCs)), (2) immunosuppressive enzymes and signaling molecules (e.g., IDO1, TGF-beta), (3) limited nutrients (e.g., oxygen, glucose), and (4) toxic metabolites (e.g., reactive oxygen species, lactic acid). Together, these factors can limit the ability of T cells, including ACTR T cells, both to penetrate into the solid tumor and to function properly once there. As a result of these and other solid tumor challenges, our product candidates may not demonstrate efficacy in solid tumors. For example, our ACTR-based product candidates may not be able to access the solid tumor, and even if they do, they may not be able to exert anti-tumor effects in an immunosuppressive tumor microenvironment. In addition, the safety profile of our product candidates may differ in a solid tumor setting. If we are unable to make our product candidates function in solid tumor cancers, our development plans and business may be significantly harmed. We have preliminary pre-clinical data on a new technology platform called “BOXR,” or Bolt-on Chimeric Receptor, that we believe improves the

functionality of T cells, enabling them to be more efficient in solid tumor cancers. However, the pre-clinical data we have is very new and requires additional development to determine the viability of the construct. Additionally, we have not yet chosen a nominee within the BOXR platform and may not be able to choose a nominee or further develop BOXR technology unless we obtain additional financing.

Since the number of patients that we have dosed, or plan to dose, in our ongoing or planned Phase I clinical trials is small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates.

A study design that is considered appropriate for regulatory approval includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of trials with smaller sample sizes can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we may have seen in prior clinical trials. Additionally, our inability to dose a sufficient number of patients in our clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

We may not be able to file investigational new drug applications (INDs) or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We expect to leverage the ACTR platform by submitting additional INDs in the future for ACTR T cell product candidates used in combination with other monoclonal antibodies. In addition, however, our timing of filing on future product candidates is dependent on further research. We cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

We have limited experience as a company conducting clinical trials or managing a manufacturing facility for our product candidates.

We have limited experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing clinical trials will be completed on time or if the planned clinical trials will begin or be completed on time, if at all. Large-scale trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations (CROs), or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays that are outside of our control.

In the future, we also intend to operate our own manufacturing facility, which will require significant resources, and we have limited experience as a company in expanding or managing a manufacturing facility. In part because of this lack of experience, we cannot be certain that our manufacturing facility will be completed on time, if at all, or if the planned clinical trials will begin or be completed on time, if at all. In part because of our inexperience, we may have unacceptable or inconsistent product quality success rates and yields, and we may be unable to maintain adequate quality control, quality assurance and qualified personnel. In addition, if we switch from one manufacturing facility to our own manufacturing facility for one or more of our product candidates in the future, we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Failure to successfully create and operate our proposed manufacturing facility could adversely affect the commercial viability of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, require expansion of the trial size, limit their commercial potential, or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities, including institutional review boards (IRBs), 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 regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects 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 drug. Because of our dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

In certain trials of CAR-based products, which also use an engineered T cell, side effects, such as CRS and neurotoxicity, arose that resulted in risk, injury, or death to the patients. We observed some of these side effects in the second dose level of our Phase I clinical trial of ACTR087 used in combination with rituximab, called ATTCK-20-2. These events resulted in the FDA placing the trial on clinical hold pending submission of certain information relating to the ATTCK-20-2 clinical trial. The clinical hold was removed in February 2018, following review of this information by the FDA. We will likely continue to observe some or all of these side effects in our clinical trials at additional dosage levels. We have established safety management and monitoring guidelines for clinical investigators to detect and treat potential side effects. However, there is no guarantee that these medical interventions will be effective in preventing negative effects to the patient. Additionally, if we do continue to observe severe side effects in our clinical trials, our ongoing clinical trials may be halted or put on an additional clinical hold prior to completion if there is an unacceptable safety risk for patients.

Autoimmune reaction triggered by an interaction between a patient's naturally occurring antibodies and ACTR T cells is a theoretical safety risk unique to the ACTR approach. If a patient's self-generated antibodies were directed to a target expressed on the surface of cells in normal tissue (i.e., autoantibodies), ACTR would be directed to attack these tissues, potentially resulting in off-tumor effects. These autoantibodies may be present whether or not the patient has an active autoimmune disease. In our clinical testing, we have taken steps to minimize the likelihood of this happening (e.g., excluding patients with a history of autoimmune disease from our trials and screening for the presence of certain autoantibodies). To date, we have not observed any autoimmune adverse effects in clinical testing of ACTR. There is no guarantee, however, that we will not observe autoimmune reactions in the future and no guarantee that if we do, that we will be able to implement interventions to address the risk.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities, or local regulatory authorities such as IRBs, could order us to cease clinical trials. Competent national health authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using ACTR to understand the side effect profile of ACTR for all clinical trials and upon any commercialization of any product candidates, if approved. Inadequate training in recognizing or managing the potential side effects of ACTR could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the perceived risks and benefits of our product candidate in the trial;
- reporting of the preliminary results of any of our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Additionally, because some of our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of the disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the trial and requiring additional enrollment.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

Clinical trials are expensive, time-consuming, and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technology and engineered on a patient-by-patient basis, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with relapsed or refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than those for more conventional therapeutic technologies or drug product candidates. In addition, our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments, and may be small, and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules, or a combination of these. Third line therapies can include hematopoietic stem cell transplantation in certain cancers, chemotherapy, antibody drugs, and small molecule tumor-targeted therapies, more invasive forms of surgery, and new revolutionary technologies. We expect to initially seek approval of our product candidates in most instances at least as a third line therapy, for use in patients with relapsed or refractory metastatic cancer. Subsequently, for those products that prove to be sufficiently safe and beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved as a third or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we expect ACTR087 and ACTR707, each used in combination with rituximab, to initially target a small patient population that suffers from r/r NHL. Even if we obtain significant market share for our product candidates within our addressable patient population, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as first or second line therapy.

We may choose not to develop a potential product candidate, or we may suspend, deprioritize or terminate one or more discovery programs or pre-clinical or clinical product candidates or programs.

At any time and for any reason, we may determine that one or more of our discovery programs or pre-clinical or clinical product candidates or programs does not have sufficient potential to warrant the allocation of resources toward such program or product candidate. Accordingly, we may choose not to develop a potential product candidate or elect to suspend, deprioritize or terminate one or more of our discovery programs or pre-clinical or clinical product candidates or programs. For example, we have determined to conclude enrollment in our ATTCK-20-2 study in the first half of 2019 as a result of emerging clinical data from our

Phase I ATTCK-20-03 trial, the continuing progress in our ATTCK-20-03 trial, and our desire to efficiently manage resources for our clinical programs. If we suspend, deprioritize or terminate a program or product candidate in which we have invested significant resources, we will have expended resources on a program or product candidate that will not provide a full return on our investment and may have missed the opportunity to have allocated those resources to potentially more productive uses, including existing or future programs or product candidates.

If we fail to develop additional product candidates, our commercial opportunity will be limited.

We have developed a pipeline of product candidates and intend to pursue clinical development of additional product candidates that combine ACTR T cells with different antibodies and target different tumor types. Developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding beyond the net proceeds from our initial public offering (IPO) and concurrent private placement with Seattle Genetics, Inc. (Concurrent Private Placement), and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA approval to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved product candidate.

ACTR therapies rely on the use of antibodies to target specific cancers, which are developed by third parties. We are limited in our ability to apply ACTR to a wider range of potential target cancers by our ability to partner for or acquire these antibodies on commercially reasonable terms.

ACTR therapies require the use of tumor-specific antibodies, which guide the ACTR and bind to the antigens on the surface of a tumor, to target specific types of cancers. Many of our current and proposed clinical trials rely on the use of commercially available and well-understood antibodies, such as rituximab and trastuzumab. Our ability to develop and commercialize our ACTR T cells used in combination with rituximab, trastuzumab, or any other FDA-approved antibody will depend on our ability to purchase such antibodies on commercially reasonable terms for the clinical trials and their availability for the commercialized product, if approved.

We also plan to expand the use of our ACTR platform in combination with one or more other antibodies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States, as planned with our product candidate ACTR087 used in combination with SEA-BCMA in adult patients with r/r multiple myeloma. Our ability to develop product candidates using unapproved antibodies will rely on our ability to acquire such antibodies through partnerships or collaborations on commercially reasonable terms. However, we cannot be certain that potential future collaborations will provide us with a steady supply of antibodies that we can utilize in combination with ACTR to develop future product candidates. If we are unable to enter into such strategic collaborations on commercially reasonable terms or fail to realize the benefits of any such collaboration, we may be limited to using approved antibodies in combination with ACTR087, ACTR707, or any other future ACTR construct we may develop.

We have entered into a collaboration agreement with Seattle Genetics, Inc. (Seattle Genetics), pursuant to which Seattle Genetics will generate antibodies against two target antigens to use in combination with ACTR T cells to develop future product candidates. Under the agreement, Seattle Genetics had the option to elect a third target antigen, but its option expired unexercised in June 2017. We cannot be certain that the collaboration agreement with Seattle Genetics will provide us with antibodies that we can successfully combine with ACTR T cells.

The failure to enter into a successful collaboration or the expense of purchasing an approved antibody may delay our development timelines, increase our costs and jeopardize our ability to develop ACTR087, ACTR707, or any other future ACTR construct we may develop as a commercially viable drug, which could result in delays in product development and harm our business.

ACTR therapies rely on the use of antibodies to target specific cancers, which the FDA may revoke approval for or may not approve, independent of the safety or efficacy of our ACTR T cells.

We have developed, are developing, and intend to develop product candidates using ACTR087 or ACTR707 used in combination with one or more currently approved antibodies, such as rituximab for r/r NHL and trastuzumab for HER2+ cancers. If the FDA or similar regulatory authorities outside of the United States revoke approval of any antibodies we use in combination with ACTR087, ACTR707 or any ACTR T cell product, we will not be able to market any products made in combination with such revoked antibodies.

If safety or efficacy issues arise with any of these antibodies, we could experience significant regulatory delays, and the FDA or similar regulatory authorities outside of the United States may require us to redesign or terminate the applicable clinical trials. In addition, the approval of ACTR in combination with an antibody may require clinical trials to demonstrate the safety and efficacy of the therapeutic antibody on its own. If the antibodies we use in combination with ACTR087, ACTR707, or any other future ACTR construct we may develop are replaced as the standard of care for the indications we choose to target, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. In addition, if manufacturing or other issues result in a shortage of supply of the antibodies with which we determine to combine with ACTR087, ACTR707, or any other future ACTR construct we may develop, we may not be able to complete clinical development of ACTR087, ACTR707, or any other future ACTR construct we may develop on our current timeline or at all.

Even if ACTR087, ACTR707, or any other future ACTR construct we may develop were to receive marketing approval or be commercialized for use in combination with other existing antibodies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of an antibody used in combination with ACTR087, ACTR707, or any other future ACTR construct we may develop, or that safety, efficacy, manufacturing or supply issues could arise with these existing antibodies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks, such as revocation of regulatory approval for one part of the combination therapy, if we develop any of our other product candidates for use in combination with other antibodies. This could result in our own products being removed from the market or being less successful commercially.

We also plan to consider ACTR087, ACTR707 or any other future ACTR product in combination with one or more other antibodies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States, as planned with our product candidate ACTR087 used in combination with SEA-BCMA in adult patients with r/r multiple myeloma. We will not be able to market and sell ACTR087, ACTR707 or any other future ACTR product in combination with any such unapproved antibodies that do not ultimately obtain marketing approval, either as a standalone or used in combination with our ACTR T cells. If the FDA or similar regulatory authorities outside of the United States determines that we need to demonstrate the separate safety or efficacy of the applicable antibodies, or if safety, efficacy, manufacturing, or supply issues arise with the antibodies we choose to evaluate in combination with ACTR087, ACTR707 or any other future ACTR construct we may develop, we may be unable to obtain approval of or market ACTR087, ACTR707 or any other future ACTR construct we may develop.

If the FDA or similar regulatory authorities outside of the United States revoke their approval or do not approve these other antibodies, or if safety, efficacy, manufacturing, or supply issues arise with the antibodies we choose to evaluate in combination with ACTR087, ACTR707 or any other future ACTR construct we may develop, we may be unable to obtain approval of or market ACTR087, ACTR707 or any other future ACTR construct we may develop.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, if approved. For instance, if any co-developed products under our collaboration with Seattle Genetics are approved, we plan to co-commercialize them with Seattle Genetics in the United States, and Seattle Genetics will commercialize them outside of the United States. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Specifically, by genetically engineering T cell products, we face significant competition in both the CAR technology and TCR space from multiple companies, including Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Juno Therapeutics, Inc. (a Celgene Corporation company), Novartis AG, and bluebird bio, Inc. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer, our President and Chief Financial Officer, our Chief Scientific Officer, our Chief Medical Officer, and our Chief Technical Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our operations at our facility in Cambridge, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We maintain a “key man” insurance policy on the life of our Chief Executive Officer, but do not maintain “key man” insurance on the lives of our other management personnel or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2018, we had 56 employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We have entered into a strategic collaboration with Seattle Genetics and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. In particular, we may seek to enter into collaborations to give us access to antibodies to use in combination with our ACTR platform. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. For example, we entered into a collaboration agreement with Seattle Genetics pursuant to which Seattle Genetics has agreed to generate antibodies against two target antigens and we are responsible for creating ACTR T cells to pair with these antibodies to create combination product candidates. However, there are ways in which Seattle Genetics may elect to opt-out from further development and commercialization of the resulting product candidates. If Seattle Genetics elects to exercise one of these options our timelines could be delayed and our business otherwise adversely affected, and we cannot be certain that we will achieve the revenue or specific net income that we anticipate.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2018, we had working capital of $63.1 million and capital resources consisting of cash and cash equivalents and marketable securities of $87.1 million. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates, including our current and planned clinical trials for ACTR087 and ACTR707, each used in combination with rituximab. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

Our operating plan includes our efforts to advance our lead lymphoma product candidate ACTR707 used in combination with rituximab for adult patients with r/r B cell non-Hodgkin lymphoma through the completion of the dose escalation and the cohort expansion parts of the Phase I clinical trial; to advance our second lymphoma product candidate, ACTR087 used in combination with rituximab for adult patients with r/r non-Hodgkin lymphoma, through the conclusion of the Phase I clinical trial in the first half of 2019; to fund a Phase I clinical trial of ACTR707 used in combination with trastuzumab for patients with HER2+ cancers; and to develop product candidates in earlier stages of development and any additional product candidates that we select, to expand headcount and internal capabilities, and for working capital and other general corporate purposes. However, we know that our existing cash, cash equivalents, and marketable securities, and our available borrowings under our loan and security agreement will not be sufficient to complete our planned Phase I clinical trial of ACTR707 used in combination with trastuzumab for patients with HER2+ cancers and we will need to raise additional funds to complete this trial, or to progress into clinical development any additional product candidates that we may select. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable programs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result 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 and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, commercial manufacturing organizations (CMOs), and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services (HHS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Upon the closing of the IPO, we adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. 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, disgorgement, 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. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”. The tax rate change resulted in (i) a reduction in the gross amount of our deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of our deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the TCJA on us and our affiliates, whether adverse or favorable, is uncertain and may not become evident for some period of time. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

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

Under Sections 382 and 383 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 its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income may be limited. As a result of our most recent private placements, IPO, and other transactions that have occurred over the past three years, we may have experienced, an “ownership change.” We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2017, we had U.S. federal net operating loss carryforwards of $29.8 million and U.S. federal research and development tax credit carryforwards of $2.7 million, which could be limited if we experience an “ownership change.” 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 the us. Under the TCJA, net operating losses generated after December 31, 2017 will not be subject to expiration.

The terms of our loan and security agreement may restrict our ability to engage in certain transactions and subject our assets to collateralization.

In January 2017, we entered into a loan and security agreement with Pacific Western Bank (PWB). Pursuant to the terms of the loan and security agreement, subject to certain exceptions, we cannot engage in certain transactions without PWB’s prior written consent, which shall not be unreasonably withheld. Such transactions include:

- disposing of our business or certain assets;
- changing our business, management, ownership or business locations;
- 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.

If PWB does not provide its consent to such actions, we could be prohibited from engaging in transactions that could be beneficial to our business and our stockholders unless we were to repay the loans, which may not be desirable or possible. The loan and security agreement is collateralized by a pledge of substantially all of our assets, except for our intellectual property. If we were to default under the loan and security agreement, including for an inability to repay amounts as they become due, and we were unable to obtain a waiver for such a default, PWB would have a right to accelerate our obligation to repay the entire loan and foreclose on these assets in order to satisfy our obligations under the loan and security agreement. In addition, PWB would also have the right to place a hold on our accounts maintained at PWB and refuse to fund any then unfunded commitments under the loan and security agreement. Any such action on the part of PWB against us could have a materially adverse impact on our business, financial condition and results of operations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

As of September 30, 2018, we had cash, cash equivalents, and marketable securities of $87.1 million and available borrowings under our loan and security agreement of $15.0 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents and marketable securities since September 30, 2018, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Risks Related to Our Reliance On Third Parties

We rely and will rely on third parties to conduct our clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to conduct our preclinical studies and clinical trials under agreements with us. We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices (GCPs), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these 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 GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices (cGMP) regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We expect to rely on third parties to manufacture our clinical product supplies, and we may rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of clinical product supplies or product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture supplies and process our product candidates, which is and will need to be done on a patient-by-patient basis. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

Although in the future we do intend to develop our own manufacturing facility, we also intend to use third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must inspect any manufacturers for current cGMP compliance as part of our marketing application. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, the production of our product candidates.
- In order to utilize an additional manufacturer of our product candidates, we will be required to demonstrate comparability of the drug product produced by such a manufacturer to the FDA's satisfaction before releasing the product for clinical use.
- Our manufacturers may have little or no experience with autologous cell products, which are products made from a patient's own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates.
- Our third-party manufacturers might be unable to timely manufacture our product candidates, to produce comparable products or conduct consistent testing across sites, or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Our third-party suppliers or collaborators from whom we receive our antibodies used in combination with our ACTR T cells may be unable to timely manufacture or provide the applicable antibody or produce the quantity and quality required to meet our clinical and commercial needs.
- Contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately.
- Our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products, if any.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.

- Our third-party manufacturers could breach or terminate their agreements with us.
- Raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects.
- Our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.
- Our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future.

We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping the product candidate back to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to patient material as it moves to the manufacturing facility, through the manufacturing process and back to the patient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

In addition, because our product candidates are all based upon the ACTR construct, any problems we encounter with manufacturing the ACTR construct would likely affect all of our products, if approved, and product candidates, increasing the impact of any manufacturing issues we encounter and potentially adversely affecting our ability to attain or maintain profitable operations.

ACTR therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

ACTR requires many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. In addition, those suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some of our raw materials are currently available from a single supplier, or a small number of suppliers. The type of cell culture media and cryopreservation buffer that we currently use in our manufacturing process for ACTR087 and ACTR707 are each only available from a single supplier. In addition, the cell processing equipment and tubing that we use in our current manufacturing process is only available from a single supplier. We also use certain biologic materials, including certain activating antibodies, that are available from multiple suppliers, but each version may perform differently, requiring us to characterize them and potentially modify some of our protocols if we change suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. Accordingly, if we no longer have access to these suppliers, we may experience delays in our clinical or commercial manufacturing which could harm our business or results of operations.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Government Regulation

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a Biologics License Application (BLA) to the FDA or similar approval applications to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has no experience with commercial development of ACTR therapies for cancer. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB or ethics committee;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Securing regulatory approval also requires the submission of information about the biologic manufacturing process and inspection of manufacturing facilities by the relevant regulatory authority. FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities, whether run by us or our CMOs. In addition, if we make manufacturing changes to our product candidates in the future, we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.

We plan to advance our lead lymphoma product candidate, ACTR707 used in combination with rituximab, for the treatment of adult patients with r/r NHL through Phase I clinical trial. If we believe the Phase I data is compelling, we plan to advance that product candidate in further clinical development for the treatment of adult patients with r/r NHL and to discuss with the FDA the potential to move to a registration trial in r/r NHL upon completion of the current Phase I clinical trial of that product candidate. However, the general approach for FDA approval of a new biologic or drug is dispositive data from two well-controlled, Phase III clinical trials of the relevant biologic or drug in the relevant patient population. Phase III clinical trials typically involve hundreds of patients, have significant costs and take years to complete. The FDA may not believe our accelerated approval strategy to move directly to a registration trial for ACTR used in combination with rituximab in r/r NHL upon completion of the current Phase I clinical trial is warranted and may require a Phase III clinical trial or trials prior to approval.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the number, design, or implementation of our clinical trials, including whether we have identified an appropriate surrogate marker or intermediate clinical endpoint to support an accelerated approval pathway;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe, pure and potent, or effective, for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates 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. Later discovery of previously unknown problems with our product candidates, 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 our product candidates, withdrawal of the product from the market or voluntary or mandatory product 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 license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we were able to obtain accelerated approval of ACTR087 or ACTR707 used in combination with an antibody, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other CAR-T therapies;
- the prevalence and severity of any side effects;

- the prevalence and severity of any side effects for other adoptive cell therapy and CAR-T products and public perception of other adoptive cell therapy and CAR-T products;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our ACTR platform differs in certain ways from the CAR-T approach, serious adverse events or deaths in other clinical trials involving CAR-T or other T cell products or with use of approved CAR-T products, even if not ultimately attributable to the relevant product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

In both domestic and foreign markets, successful sales of our product candidates, if approved, will depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, 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 approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, in 2010, the Affordable Care Act was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs and provided incentives to programs that increase the federal government's comparative effectiveness research.

Members of the United States Congress and the Trump Administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the Affordable Care Act. While Congress has not passed repeal legislation to date, the 2017 Tax Reform Act includes a provision repealing the individual insurance coverage mandate included in the Affordable Care Act, effective January 1, 2019. 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. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, the Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the Affordable Care Act for plans sold through such marketplaces. There may be further changes to the Affordable Care Act as a result of new legislation or further executive, administrative or judicial action.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the ATRA), which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the Affordable Care Act. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Regulatory requirements in the United States and abroad governing gene therapy products have changed frequently and may continue to change in the future, which could negatively impact our ability to complete clinical trials and commercialize our product candidates in a timely manner, if at all.

Regulatory requirements in the United States and abroad governing gene therapy products have changed frequently and may continue to change in the future. FDA established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee, among others, to advise this review. Prior to initiating a clinical study, because of our use of a viral vector for production of our ACTR T cells, our clinical protocols have been subject to review by the NIH's Recombinant DNA Advisory Committee (RAC). A Federal Register Notice in August 2018 proposed to remove this requirement for most gene therapy studies, which we interpret will include future studies that use ACTR T cell products. Adverse developments in clinical trials of genetically modified cell therapies conducted by other sponsors may cause FDA or other oversight bodies to change the requirements for clinical investigation and/or marketing authorization of any of our product candidates at any time.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others.

Under our collaboration agreement with Seattle Genetics for the development and commercialization of novel therapies for cancer, we depend on a license from Seattle Genetics for use of their proprietary antibodies. Additionally, aspects of the ACTR technology are subject to a license from St. Jude Children's Research Hospital (St. Jude's) and the National University of Singapore (NUS).

We are currently, and expect in the future to be, party to material license or collaboration agreements. These agreements typically impose numerous obligations, such as diligence and payment obligations. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. These licenses do and future licenses may include provisions that impose obligations and restrictions on us. For example, our license agreement with St. Jude's and NUS imposes some limitations on our ability to assign the license to a party other than an affiliate. This could delay or otherwise negatively impact a transaction that we may wish to enter into.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Currently, we have obtained one European patent, which is validated in Germany, France, and Great Britain, and one Japanese patent from our in-licensed patent portfolio. No other patents have issued from the patent applications that we own or in-license. We anticipate additional patent applications will be filed both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether any of our intellectual property will provide any competitive advantage;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate or defend litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products, such as ACTR-based product candidates, are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We have obtained issuances of composition of matter claims in one European patent from the licensed-in portfolio. We, however, cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered patentable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may induce or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held

unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Various post grant review proceedings, such as inter partes review and post grant review, are available for any interested third party to challenge the patentability of claims issued in patents to us. While these post grant review proceedings have been used less frequently to invalidate biotech patents, they have been successful regarding other technologies, and these relatively new procedures are still changing, and those changes might affect future results.

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when ACTR087 or another product candidate is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is “clear and convincing,” a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to certain intellectual property, through licenses from third parties and under patent applications that we own or will own, related to ACTR087, ACTR707, and BOXR constructs, and certain other product candidates. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights or are pursuing patent rights directed to certain ACTR constructs and BOXR constructs we may not be able to obtain intellectual property to broad ACTR constructs and BOXR constructs in certain jurisdictions.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific antibodies that will be used with our product candidates may be covered by the intellectual property rights of others.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings, including interference proceedings, provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, 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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our 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.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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. While an inadvertent 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. Noncompliance 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. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter parties* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, 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. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

We have less robust foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

Certain of our key patent families (covering the ACTR087 construct) have been filed in the United States, as well as in numerous jurisdictions outside the United States, and we plan to similarly pursue subgeneric claims prior to expiration of applicable deadlines (including a patent family covering the ACTR707 construct). However, we have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of the ACTR platform outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United

States or other jurisdictions. 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, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;

- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

Risks Related to Ownership of our Common Stock

An active trading market for our common stock may not be sustained.

Our common stock began trading on the Nasdaq Global Select Market on March 29, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares at attractive prices, at the times that they would like to sell them, or at all.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the commencement, enrollment, or results of the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;

- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed your purchase price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

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 for the foreseeable future. In addition, pursuant to our loan and security agreement with PWB, we are prohibited from paying cash dividends without PWB's prior written consent, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, and 5% stockholders beneficially owned over 60% of our voting stock as of September 30, 2018. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act) enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in this Quarterly Report on Form 10-Q and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and

stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Quarterly Report on Form 10-Q and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to "opt out" of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance, or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which requires, among other things, that we file with the Securities and Exchange Commission (the SEC), annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the date of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

The lock-up entered into during our IPO lapsed on September 24, 2018. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after other legal restrictions on resale entered into during our IPO lapse, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2018 Stock Option and Incentive Plan (2018 Plan) will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the Securities Act). If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of 13,646,028 shares of our common stock as of September 30, 2018, are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2018 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities, and costs associated with operating as a public company. To raise capital, 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, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock.

Pursuant to the 2018 Plan, our management is authorized to grant stock options to our employees, directors, and consultants. The number of shares initially reserved for issuance under the 2018 Plan is 2,547,558 plus the 1,030,234 shares of common stock remaining available for issuance under the 2015 Stock Incentive Plan (2015 Plan). Additionally, the shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by us under the 2018 Plan or the 2015 Plan will be added back to the shares of common stock available for issuance under the 2018 Plan. As of September 30, 2018, 2,820,460 shares remained available for future issuance under the 2018 Plan. The number of shares of our common stock reserved for issuance under the 2018 Plan shall be cumulatively increased on January 1, 2019 and each January 1 thereafter by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and 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 amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws or any action asserting a claim against us that is 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 certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with our IPO, we began the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Use of Proceeds from Initial Public Offering

On April 3, 2018, we completed the initial public offering of our common stock pursuant to which we issued and sold 5,770,000 shares of our common stock at a price to the public of $12.00 per share. In addition, on April 25, 2018, we issued and sold an additional 215,000 shares of common stock at the initial public offering price of $12.00 per share as a result of the partial exercise by the underwriters of their option to purchase additional shares of common stock.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-223414), which was declared effective by the SEC on March 28, 2018. Following the sale of all of the shares offered in the offering, the offering terminated. Morgan Stanley & Co. LLC and Cowen and Company, LLC acted as joint book-running managers and SunTrust Robinson Humphrey, Inc. and Wedbush PacGrow acted as lead co-managers of our IPO.

We received aggregate gross proceeds from our initial public offering of $71.8 million, or aggregate net proceeds of $63.9 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

We received proceeds of $5.0 million from our concurrent private placement of 416,666 shares of common stock with Seattle Genetics.

As of September 30, 2018, we estimate that we have used approximately $17.8 million of the net proceeds from our initial public offering for clinical development of our product candidates and research activities and for working capital and other general corporate purposes. We have invested the unused net proceeds from the offering in marketable securities and money market accounts. Our planned use of the net proceeds from the IPO and concurrent private placement as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on March 29, 2018 have been modified as a result of our decision to conclude enrollment in the ATTCK-20-2 study in the first half of 2019. We currently anticipate that the net proceeds will fund operating expenses and capital expenditures requirements through at least June 2020.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Label Linkbase Document.
101.PRE	XBRL Taxonomy Presentation Linkbase Document.

* Filed herewith

† This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 as amended (the “Exchange Act”), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

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.

UNUM THERAPEUTICS INC.

Date: November 13, 2018

By: /s/ Charles Wilson

Charles Wilson, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2018

By: /s/ Christiana Stamoulis

Christiana Stamoulis
President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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, Charles Wilson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Unum Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)):

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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

By: /s/ Charles Wilson
Charles Wilson, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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, Christiana Stamoulis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Unum Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)):

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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

By: /s/ Christiana Stamoulis
Christiana Stamoulis
President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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 Unum Therapeutics Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Charles Wilson, Ph.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2018

By: /s/ Charles Wilson
Charles Wilson, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Unum Therapeutics Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Christiana Stamoulis, President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2018

By: /s/ Christiana Stamoulis
Christiana Stamoulis
President and Chief Financial Officer
(Principal Financial Officer)